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Healthcare Litigation in 2018

Disruption and Continuity

March 28, 2018

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Introduction

The Federal Health Policy Landscape

What Is the Trump Administration's Health Policy?

"Personnel is Policy"

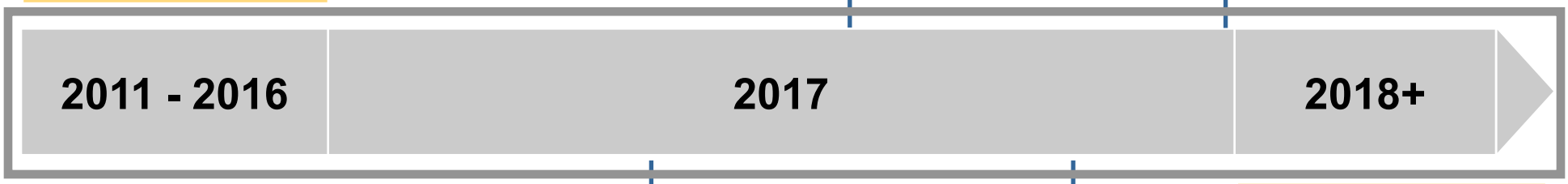
- Secretary of Health and Human Services Alex Azar
  - Confirmed January 2018
  - Emphasizing delivery system transformation to value-based payments
  - Regulatory relief
  - Price transparency
- CMS Administrator Seema Verma
  - Deprioritizing coverage expansion
  - Returning Medicaid to its welfare program roots
  - Flexibility on electronic health records meaningful use
  - Interoperability and consumer access to EHRs
- FDA Commissioner Scott Gottlieb
  - Interest in drug supply chain and pricing incentives
- Office for Civil Rights Director Roger Severino
  - Establishes new "conscience and religious freedom" division

ACA Repeal Efforts to Date

2011 – 2016:
70+ votes in Congress to repeal the ACA

July 2017:
Better Care Reconciliation Act (BCRA) failed in the Senate

December 2017:
Senate tax bill repeals the individual mandate



May 2017:
American Healthcare Act (AHCA) passed in the House of Representatives

September 2017:
Graham-Cassidy failed in the Senate

2018 and Beyond:
Medicaid and key ACA provisions remain at risk

Sources: https://www.washingtonpost.com/news/the-fix/wp/2014/03/21/the-house-has-voted-54-times-in-four-years-on-obamacare-heres-the-full-list/?utm_term=.07a777dd6e70; http://www.newsweek.com/gop-health-care-bill-repeal-and-replace-70-failed-attempts-643832

Recent Federal Actions to Undermine the Marketplace

Congress and the Executive Branch have both taken actions to undermine the Marketplace

EXECUTIVE BRANCH

- Eliminated CSR payments
- Proposed expansion of association health plans, limited-duration insurance, and health reimbursement arrangements
- Shortened open enrollment period
- Cut federal budget for advertising for Marketplace open enrollment period

CONGRESS

- Eliminated the individual mandate through the tax bill
- Sought to pass repeal and replace bills that would have instituted sweeping changes to the Marketplaces

Urban Institute projects that combined, the elimination of the individual mandate and other changes would lead to an additional 6.4 million people becoming uninsured between 2018 and 2019 than would have been expected otherwise, with short-term limited duration increasing number without minimum essential coverage by 2.6 million

Urban Institute, The Potential Impact of Short-Term Limited Duration Policies on Insurance Coverage, Premiums, and Federal Spending, Mar. 2018

Recent State Actions to Undermine the ACA

Idaho and Iowa have proposed selling plans with weakened consumer protections

IDAHO

- Governor Otter (R) issued an Executive Order citing the Tenth Amendment and directing the Idaho Department of Insurance (DOI) to approve lower cost benefit plans "even if not all PPACA requirements are met," provided the insurer filing the non-compliant plan also files an ACA-compliant plan
- The DOI Director implemented the Governor's order by issuing a bulletin specifying the type of non-compliant plans that would be approved.
- The bulletin authorizes product filings that are in direct conflict with the ACA, including using health status and 5:1 age bands to set premiums and limiting annual benefits to one million dollars
- HHS has concluded that this does not constitute substantial enforcement; Idaho disagrees

IOWA

- Two bills under consideration in the Iowa legislature seek to exempt certain types of health benefits plans from insurance regulation, saying that they "shall be deemed to not be insurance"

Urban Institute, The Potential Impact of Short-Term Limited Duration Policies on Insurance Coverage, Premiums, and Federal Spending, Feb. 2018, https://www.urban.org/sites/default/files/publication/96781/stld_draft_0226_finalized_0.pdf; IA H.F.2364 and S.F.2329; Gov. Otter, Executive Order No. 2018-02, https://gov.idaho.gov/mediacenter/execorders/eo2018/EO%202018-02.pdf; ID Dept. of Insurance, Bulletin No. 18-01, https://doi.idaho.gov/DisplayPDF?Id=4712.

Changes to Medicaid under repeal and replace proposals extended beyond just the ACA

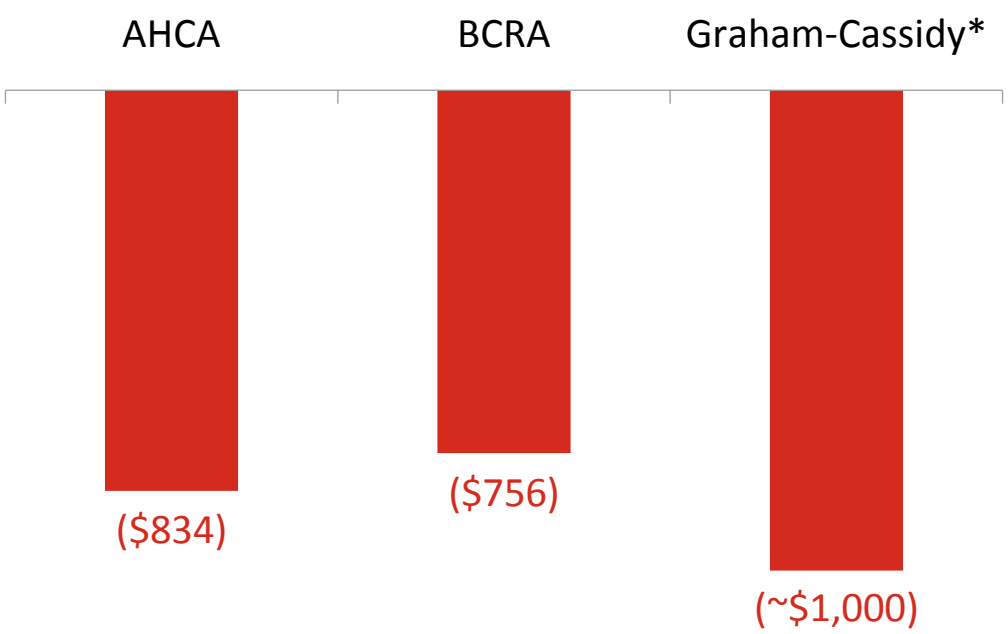
- Deep Medicaid cuts
- End the Medicaid expansion
  - Some proposals had a phase out of enhanced match
  - Graham-Cassidy eliminated not only the enhanced match but the ability of states to cover low income adults even at regular match
- Cap on virtually all federal Medicaid funding
  - Complicated formulas, but all used a per capita cap to build to an aggregate cap
  - State responsible for any spending above the cap
- Other Medicaid changes (e.g., DSH, retroactive eligibility)
- No new programmatic flexibility, except option to impose work requirements

Proposals impacting federal Medicaid funding are likely to re-emerge

Source: Cost Estimate, H.R. 1626 Better Care Reconciliation Act of 2017, Congressional Budget Office, retrieved from: https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/52941-hr1628bcra.pdf; Ohio Medicaid Group VIII Assessment, 2017, retrieved from: http://www.medicaid.ohio.gov/Portals/0/Resources/Reports/Annual/Group-VIII-Assessment.pdf.

AHCA, BCRA, and Graham-Cassidy all would have resulted in significant cuts in federal Medicaid funding

CBO Estimated Reductions in Federal Medicaid Spending, FY 2017-2026 (billions)



- AHCA and BCRA allowed marketplace subsidies to be available to expansion adults
- Graham-Cassidy provided block grant funding for various uses

Reductions in federal spending grow in the out years

Sources: https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr1628aspassed.pdf
https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/52941-hr1628bcra.pdf
https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/53126-health.pdf

Current State Medicaid Landscape

- States face intense Medicaid budget pressure and anticipate increased fiscal pressure as a result of federal legislative and/or administrative changes to Medicaid/CHIP
- States seek more flexibility to control costs and program features, including the ability to better manage total cost of care and reduce pharmaceutical expenditures
- The current administration is amenable to new Medicaid approaches and more state autonomy
- Heightened state and federal focus on: value-based approaches, private sector-like solutions (e.g., closed drug formularies), and more accountability for beneficiaries (e.g., work requirements)

"Today, we commit to ushering in a new era for the federal and state Medicaid partnership where states have more freedom to design programs that meet the spectrum of diverse needs of their Medicaid population…"

– Secretary Price and Administrator Verma

New “Coverage” Waivers Undo National Eligibility Standards

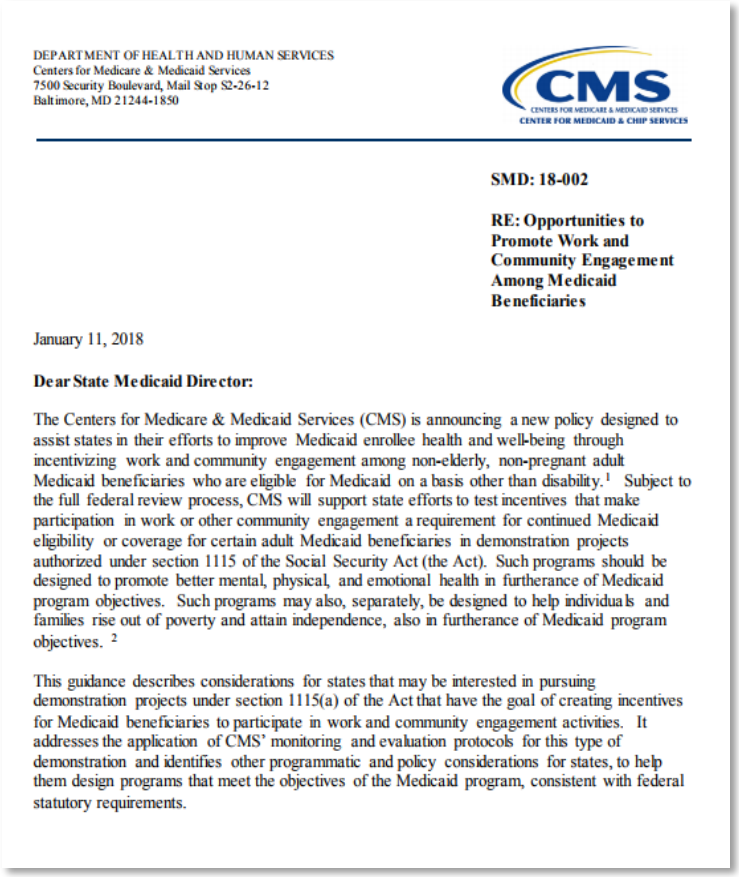
- **Under the law, eligibility is based on income (asset tests apply for elderly/disabled)**
- **States cannot impose additional, more restrictive eligibility requirements**
- **New waivers would allow such restrictions**

Past waivers expanded coverage, allowed for new delivery systems, and/or provided new funding for uncompensated care or delivery system change, for example:	**New “coverage” waivers would cut back eligibility for expansion group and also, in some cases, for traditional Medicaid populations through policies such as:**
Expanding coverage for adults	Work requirements
Implementing managed care	Lockouts
Establishing “DSRIP” programs	Drug testing
Uncompensated care pools	Time limits

Medicaid Work Requirements and Other Waivers

Trump Administration Open to Work Requirements

CMS released guidance in January stating that it would permit states to implement work and "community engagement" requirements



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

SMD: 18-002

RE: Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries

January 11, 2018

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) is announcing a new policy designed to assist states in their efforts to improve Medicaid enrollee health and well-being through incentivizing work and community engagement among non-elderly, non-pregnant adult Medicaid beneficiaries who are eligible for Medicaid on a basis other than disability.[1] Subject to the full federal review process, CMS will support state efforts to test incentives that make participation in work or other community engagement a requirement for continued Medicaid eligibility or coverage for certain adult Medicaid beneficiaries in demonstration projects authorized under section 1115 of the Social Security Act (the Act). Such programs should be designed to promote better mental, physical, and emotional health in furtherance of Medicaid program objectives. Such programs may also, separately, be designed to help individuals and families rise out of poverty and attain independence, also in furtherance of Medicaid program objectives. [2]

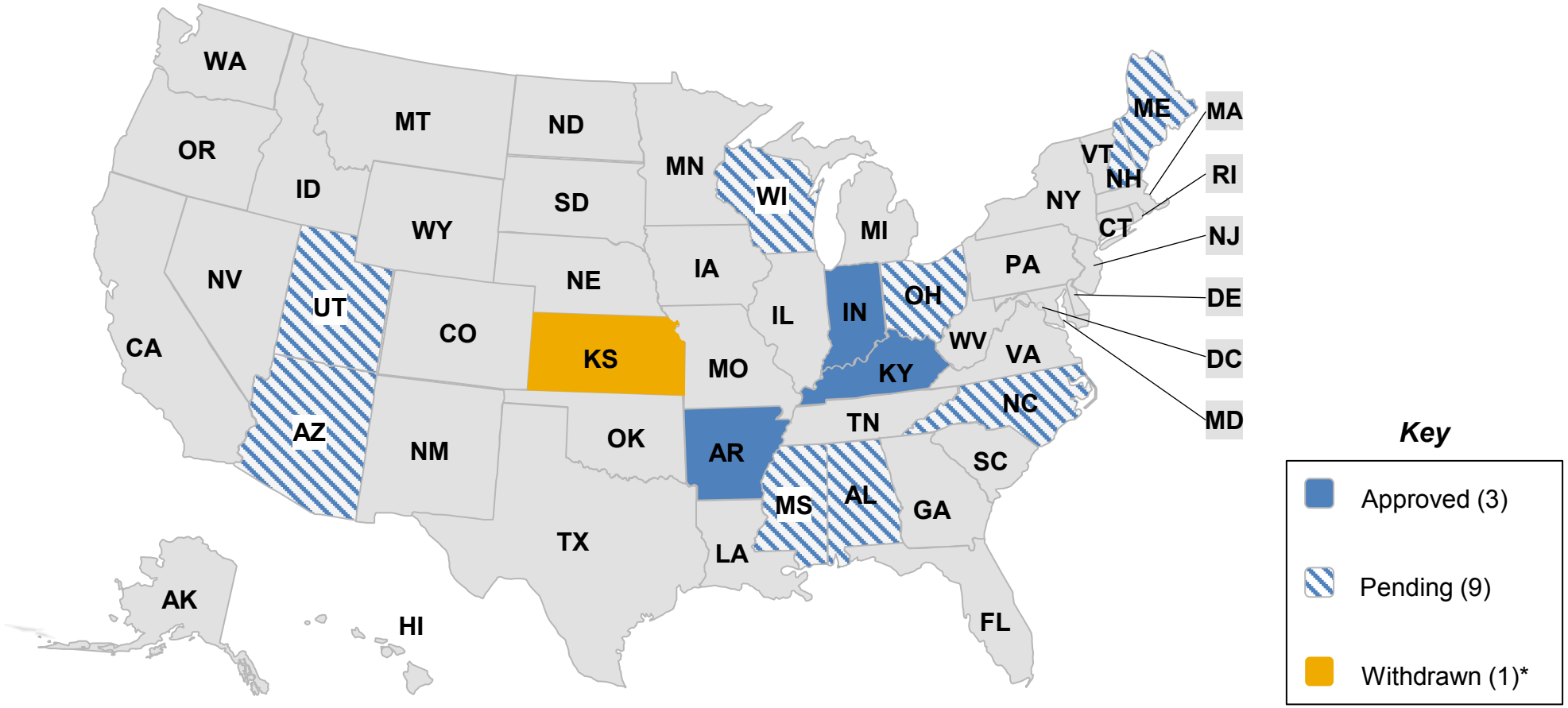
This guidance describes considerations for states that may be interested in pursuing demonstration projects under section 1115(a) of the Act that have the goal of creating incentives for Medicaid beneficiaries to participate in work and community engagement activities. It addresses the application of CMS' monitoring and evaluation protocols for this type of demonstration and identifies other programmatic and policy considerations for states, to help them design programs that meet the objectives of the Medicaid program, consistent with federal statutory requirements.

"…CMS will support state efforts to test incentives that make participation in work or other community engagement a requirement for continued Medicaid eligibility…"
[SMD 18-002]

Source: https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf

States Are Actively Pursuing Work Requirements

To-date, 13 states have requested authority to implement work or community-engagement requirements; CMS has approved three of these requests (AR, KY, and IN)



Source: Manatt analysis of Section 1115 waiver documents listed on Medicaid.gov

**Citing concerns about the cost of Medicaid in the state, Kansas Governor Sam Brownback (R) announced in January that the State will pull back plans to revamp its 1115 demonstration program, KanCare. Kansas is still expected to move forward with a plan to implement work requirements and other "budget neutral" adjustments to the current waiver.*

NHeLP Sues Over Kentucky Requirements

- Section 1115 demonstration waivers must "promote the objectives of the Medicaid program"
  - Must be "experimental, pilot, or demonstration project"
  - Substantive provision of Social Security Act must be waivable
  - Budget neutrality not a statutory requirement
- Proponents of work requirements argue they will reduce Medicaid enrollment and state and federal expenditures, and improve health
- NHeLP litigation (*Stewart v. Hargan*, No. 1:18cv152) challenges work requirements, premium requirements, and lock out periods for premium nonpayment
- CMS has moved to transfer the case from D.C. to Kentucky
- Briefing on summary judgment/preliminary injunction motions scheduled to be complete in late May (first briefs due March 30)

Approved and Pending Coverage Waivers

	Approved			Pending												
Features	**AR**	**IN**	**KY**	**AL**	**AZ**	**KS**	**MA**	**ME**	**MI**	**MS**	**NC**	**NH**	**NM**	**OH**	**UT**	**WI**
Premiums *(some states with lockout)*	✓	✓	✓		✓	✓	✓	✓	✓		✓		✓			✓
Cost Sharing	✓	✓	✓		✓		✓	✓	✓		✓	✓	✓		✓	✓
Work Requirements	✓	✓	✓	✓	✓	✓		✓		✓	✓	✓		✓	✓	✓
Healthy Behavior Incentives	✓	✓	✓		✓				✓				✓			✓
Non-Emergency Medical Transportation Waiver		✓	✓				✓									
Retroactive Coverage Waiver	✓	✓	✓				✓	✓				✓	✓		✓	
Prompt Enrollment Waiver		✓	✓										✓			
Drug Screening																✓
Limits on Enrollment Duration					✓										✓	✓
Partial Expansion							✓									
Health Savings-Like Accounts		✓	✓		✓	✓			✓							
Late Renewal Paperwork Penalty/Lockout		✓	✓													
1927 Waiver for Closed Formularies							✓									

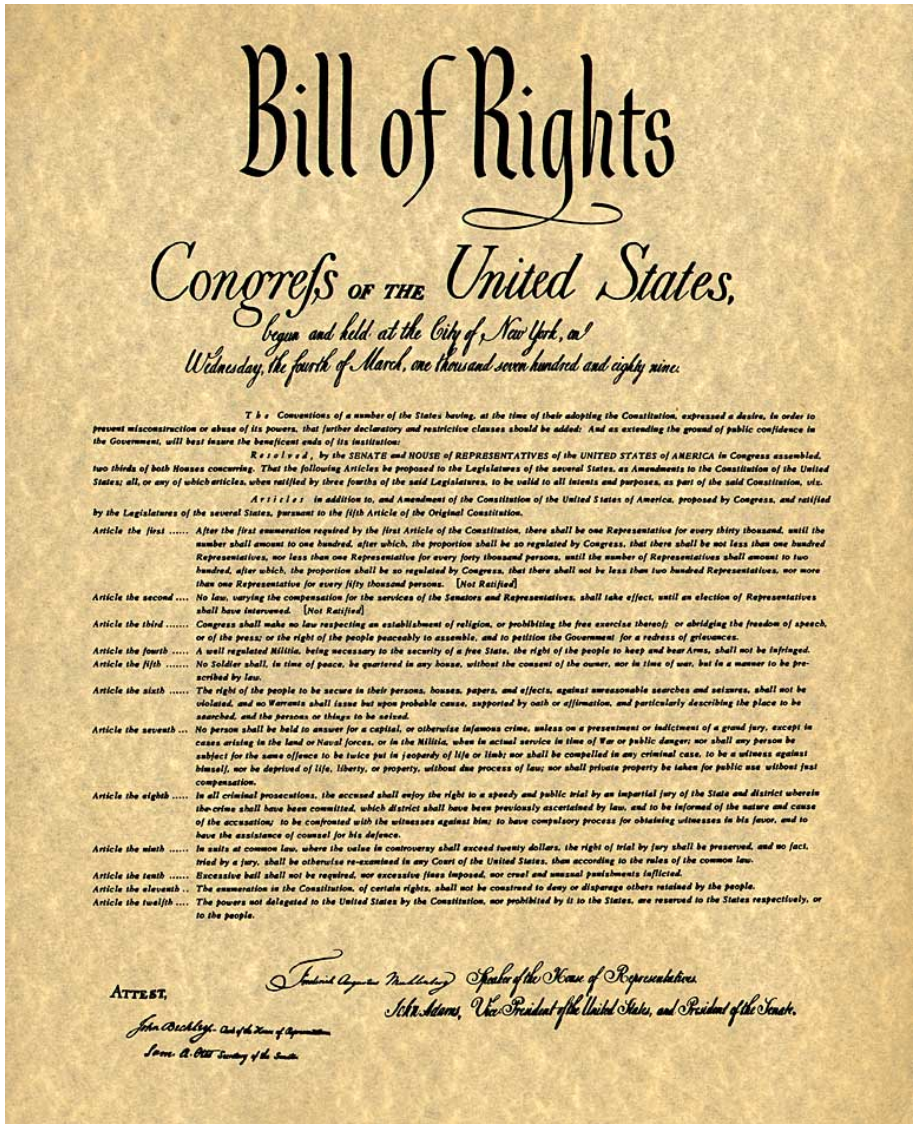
Conscience Rights and Civil Rights in Healthcare

DISCLAIMER – All Opinions are My Own

How Did We Get Here ?

Free Exercise

First Amendment



Bill of Rights

Congress of the United States,
begun and held at the City of New York, on
Wednesday, the fourth of March, one thousand seven hundred and eighty nine.

THE Conventions of a number of the States having, at the time of their adopting the Constitution, expressed a desire, in order to prevent misconstruction or abuse of its powers, that further declaratory and restrictive clauses should be added: And as extending the ground of public confidence in the Government, will best ensure the beneficent ends of its institution:

RESOLVED, by the SENATE and HOUSE of REPRESENTATIVES of the UNITED STATES of AMERICA in Congress assembled, two thirds of both Houses concurring, That the following Articles be proposed to the Legislatures of the several States, as Amendments to the Constitution of the United States; all, or any of which articles, when ratified by three fourths of the said Legislatures, to be valid to all intents and purposes, as part of the said Constitution, viz.

ARTICLES in addition to, and Amendment of the Constitution of the United States of America, proposed by Congress, and ratified by the Legislatures of the several States, pursuant to the fifth Article of the Original Constitution.

Article the first ..... After the first enumeration required by the first Article of the Constitution, there shall be one Representative for every thirty thousand, until the number shall amount to one hundred, after which, the proportion shall be so regulated by Congress, that there shall be not less than one hundred Representatives, nor less than one Representative for every forty thousand persons, until the number of Representatives shall amount to two hundred, after which, the proportion shall be so regulated by Congress, that there shall not be less than two hundred Representatives, nor more than one Representative for every fifty thousand persons. [Not Ratified]

Article the second .... No law, varying the compensation for the services of the Senators and Representatives, shall take effect, until an election of Representatives shall have intervened. [Not Ratified]

Article the third ..... Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Article the fourth ..... A well regulated Militia, being necessary to the security of a free State, the right of the people to keep and bear Arms, shall not be infringed.

Article the fifth ..... No Soldier shall, in time of peace, be quartered in any house, without the consent of the owner, nor in time of war, but in a manner to be prescribed by law.

Article the sixth ..... The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

Article the seventh ... No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a grand jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case, to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation.

Article the eighth ..... In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have compulsory process for obtaining witnesses in his favor, and to have the assistance of counsel for his defence.

Article the ninth ..... In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact, tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

Article the tenth ..... Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

Article the eleventh .. The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

Article the twelfth .... The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

Frederick Augustus Muhlenberg Speaker of the House of Representatives.
John Adams, Vice President of the United States, and President of the Senate.

ATTEST,
John Beckley, Clerk of the House of Representatives.
Sam. A. Otis Secretary of the Senate.

- Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . .

Relevant Federal Conscience Laws

- Church Amendment (1973)
  - Passed Senate 92-1
  - Exempted private hospitals receiving federal funds from any requirement to provide abortions or sterilizations
- Coats Snowe Amendment (1996)
  - Government may not discriminate against healthcare entities that refuse to provide or train for abortions
- Weldon Amendment
  - Adopted in connection with appropriations for Departments of Labor, HHS, and Education since 2004
  - None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual healthcare entity to discrimination on the basis that the healthcare entity does not provide, pay for, provide coverage of, or refer for abortions

Lawsuits Against Religious Hospitals – Part I

- *Doe v. Bellin Memorial Hosp.*, 479 F.2d 756 (7th Cir. 1973)
  - There is no constitutional objection to the decision by a purely private hospital that it will not permit its facilities to be used for the performance of abortions.
- *Taylor v. St. Vincent's Hosp.*, 523 F.2d 75 (9th Cir. 1975)
  - "If the hospital's refusal to perform sterilization infringes upon any constitutionally cognizable right to privacy, such infringement is outweighed by the need to protect the freedom of religion of denominational hospitals 'with religious or moral scruples against sterilizations and abortions.'"
- *Watkins v. Mercy Med. Ctr.*, 364 F. Supp. 799 (D. Idaho 1973), *aff'd*, 520 F.2d 894 (9th Cir. 1975)
  - Physician denied reappointment for refusal to agree to comply with ERDs
  - "Mercy Medical Center has the right to adhere to its own religious beliefs and not be forced to make its facilities available for services which it finds repugnant to those beliefs."
- *Allen v. Sisters of St. Joseph*, 361 F. Supp. 1212 (N.D. Tex. 1973)
  - "The interest that the public has in the establishment and operation of hospitals by religious organizations is paramount to any inconvenience that would result to the plaintiff in requiring her to either be moved or await a later date for her sterilization."

Supreme Court Free Exercise Cases

- *Sherbert v. Verner*, 374 U.S. 398 (1963)
  - Strict scrutiny – government must show a compelling interest and narrow tailoring where a law burdens the free exercise of religion
- *Employment Division v. Smith*, 494 U.S. 872 (1990)
  - Overrules *Sherbert*
  - "the right of free exercise does not relieve an individual of the obligation to comply with a 'valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)'"
  - "Any society adopting [a compelling interest standard] would be courting anarchy . . . A system in which each conscience is a law unto itself."
  - could have narrowly followed *Sherbert* to protect religious observance

- 42 U.S.C. §§ 2000bb, *et seq.* (1993)
- Bipartisan outrage with *Smith*
- Passed unanimously in House; 97-3 in Senate
- Reinstitute a *Sherbert*+ test
- A law of general applicability cannot burden free exercise rights unless it:
  - furthers a compelling government interest; and
  - is the least restrictive means

- *City of Bourne v. Flores*, 521 U.S. 507 (1997)
  - RFRA held unconstitutional as applied to state laws
  - Beyond Congressional power under the 14th Amendment
- 21 states have passed "State RFRA" laws to apply RFRA standard to state laws that burden free exercise rights

RFRA Expanded

- *Burwell v. Hobby Lobby*, 134 S Ct. 2751 (2014)
  - Recognizing religious beliefs of for-profit corporation
  - "An established body of law specifies the rights and obligations of the *people* (including shareholders, officers, and employees) who are associated with a corporation in one way or another. When rights, whether constitutional or statutory, are extended to corporations, the purpose is to protect the rights of these people."
- *Masterpiece Cakeshop v. Colorado Civil Rights Comm'n*, Docket No. 16-111, argued December 5, 2017
  - Like *Smith,* involves the standard to apply to a state law that burdens religious free exercise


KEEP
CALM
AND
LET'S TALK
ABOUT SEX

Federal Antidiscrimination Laws

- Affordable Care Act, 42 U.S.C. § 18116
  - "[A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance . . ."

What Does That Mean?

- Title IX, 20 U.S.C. § 1681
  - No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance, except that:
  - **. . . (3) . . .** this section shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization . . .

- Title IX cases follow Title VII cases
  - Prohibits adverse employment actions "because of an individual's . . . sex . . . ."

- But the ACA expressly did not incorporate Title VII

- *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1998)
  - "gender must be irrelevant to employment decisions"
  - "In saying that gender played a motivating part in an employment decision, we mean that, if we asked the employer at the moment of the decision what its reasons were and if we received a truthful response, one of those reasons would be that the applicant or employee was a woman. In the specific context of sex stereotyping, an employer who acts on the basis of a belief that a woman cannot be aggressive, or that she must not be, has acted on the basis of gender."

- *Simonton v. Runyon*, 232 F.3d 33, 35 (2d Cir. 2000) ("Congress's refusal to expand the reach of Title VII is strong evidence of congressional intent in the face of consistent judicial decisions refusing to interpret 'sex' to include sexual orientation")
- *Etsitty v. Utah Transit Authority*, 502 F.3d 1215, 1222 n.2 (10th Cir. 2007) ("If transsexuals are to receive legal protection apart from their status as male or female, . . . such protection must come from Congress and not the courts.")
- *Evans v. Georgia Regional Hospital*, 850 F.3d 1248 (11th Cir. 2017), *cert. denied* Dec. 11, 2017
  - Discharge for homosexuality is not prohibited by Title VII

- October 4, 2017 Attorney General Memorandum

- 21 states (plus D.C.) prohibit discrimination based upon sexual orientation
- 18 states (plus D.C.) prohibit discrimination based upon gender identity

- *Hively v. Ivy Tech*, 853 F.3d 339 (7th Cir. 2017) (en banc)
- *Zarda v. Altitude Express, Inc.*, 2018 WL 1040820 (2d Cir. Feb. 26, 2018)
  - Discrimination on the basis of sexual orientation is sex discrimination under Title VII
- *EEOC v. R.G. and G.R Harris Funeral Homes*, 2018 WL 1177669 (6th Cir. Mar. 7, 2018) (en banc)
  - "Discrimination on the basis of transgender status and transitioning violates Title VII"
  - Rejected employer's RFRA defense

Federal Regulations

2016 Final Rule Implementing Section 1557
July 18, 2016 – December 31, 2016

- Applied *Price Waterhouse* sex stereotyping theory for sexual orientation claims
- Specifically included gender identity
- Applied all of the exemptions applicable to discrimination claims under Title VI, Age Discrimination Act, and Rehabilitation Act . . .
- But not the exemptions in Title IX, which includes an exemption for religious organizations.
- Three years in the making; Enjoined 6 months later
  - *Franciscan Alliance., Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016)

2008 Final Rule Regarding Conscience Rights

- Announced December 2008; went into effect on the day of President Obama's inauguration
- Ensuring that HHS funds do not support coercive or discriminatory policies or practices in violation of federal law
  - Enforcement mechanism for Church Amendment, Coats-Snowe, and Weldon Amendment
  - Prohibits discrimination against doctors, nurses and health care aides who exercise their conscience rights to refuse to take part in morally objectionable procedures.
  - Included a written certification requirement, a formal complaint procedure, and appointed OCR as enforcement agency.

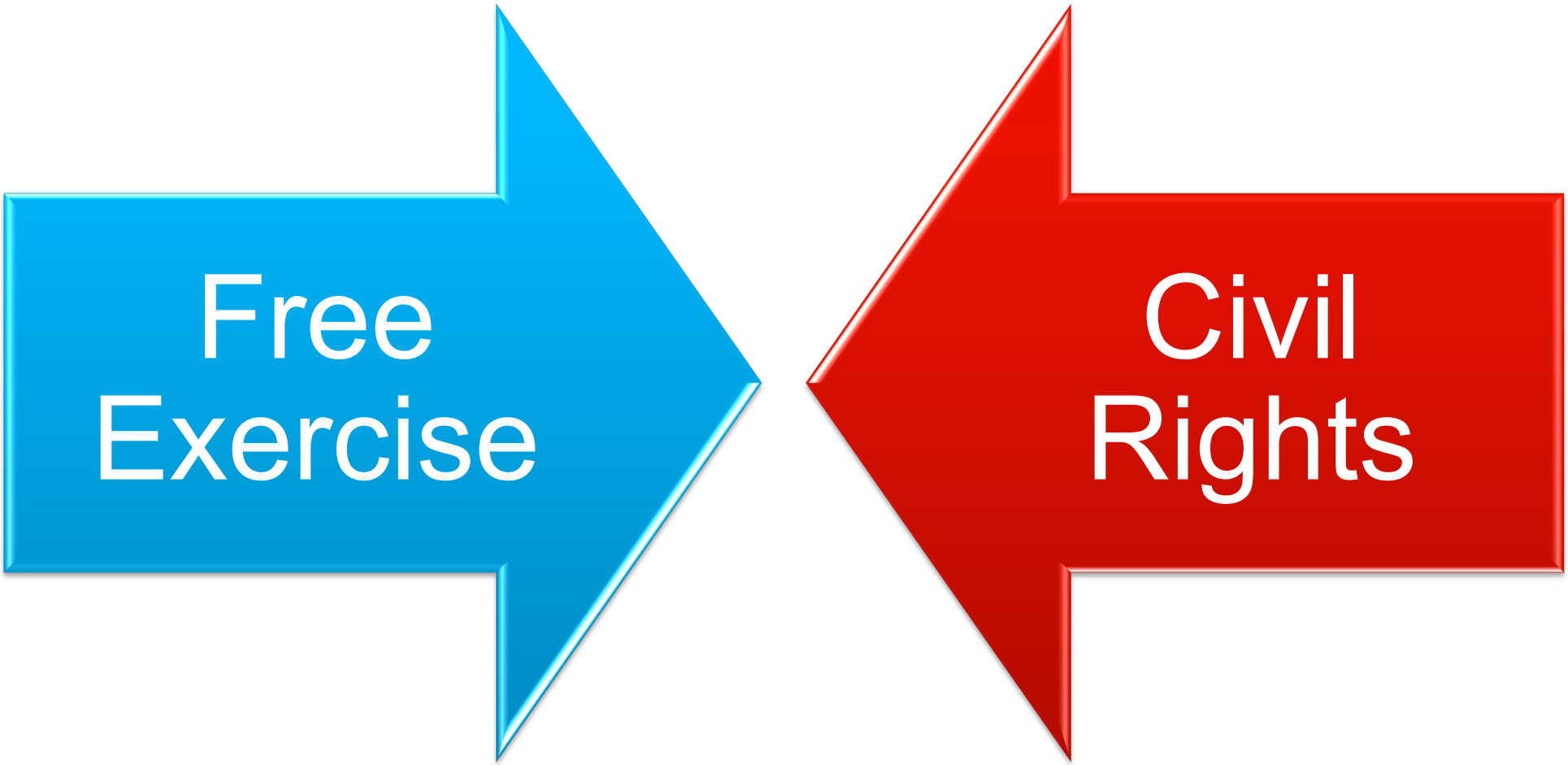
2011 Final Rule

- Obama Administration immediately announced intent to reconsider 2008 Final Rule
- Noted that the 2008 Final Rule was meant to clarify existing laws, but only caused "confusion" because it was "unclear and potentially overbroad in scope."
- Rescinded everything except the designation of OCR to receive complaints based on violations of Federal healthcare provider conscience protections statutes
- OCR received 10 complaints between 2011 and 2016

2018 Proposed Rule

- 34 complaints filed with OCR since Nov. 2016
- Return to 2008 because the 2011 Final Rule caused “confusion”
- Like the Final Rule on Section 1557, this Proposed Rule seeks to expand terms in the statutes by “clarifying” them
  - Broad definitions of “healthcare entity,” “entity,” “healthcare program,” and “referral”
- Protections
  - Provides a private right of action
  - Grants OCR authority to initiate compliance reviews and conduct investigations
  - Requires written certifications of compliance for any application for federal funding
  - Compliance and internal grievance procedures
  - Posted notices of conscience rights
- Would ultimately restrict information available to patients about procedures that are not available
- Title VII requires employers to accommodate religious practices that are not an undue hardship on employers; the proposed rule abandons this

WARNING: Highly Explosive



Lawsuits Against Religious Hospitals

- *Means v. U.S. Conference of Catholic Bishops*, 2015 WL 3970046 (W.D. Mich 2015), *aff'd* 836 F.3d 643 (6th Cir. 2016)
  - Plaintiff alleged negligent care based on ERDs
  - "The Court must defer to religious institutions in their articulation of church doctrine and policy."
  - "However, the Court's consideration of the legal duty of a physician to provide adequate medical care is not a matter of church doctrine. Plaintiff has a right to remedy in a secular court for medical malpractice without needing to resolve doctrinal matters."
- *ACLU v. Trinity Health Corp.*, 178 F.Supp.3d 614 (E.D. Mich. 2016)
  - Plaintiff alleged ERDs violate EMTALA
  - Dismissed for lack of standing

Patients

- *North Coast Women's Care v. Sup. Ct.*, 44 Cal.4th 1145 (2008)
  - Physicians' refusal to perform intrauterine insemination for lesbian patient violated Unruh Act.
  - To avoid liability, physicians must provide the IUI procedure to everyone or no one.
- *Chamorro v. Dignity Health*, No. 15-549626 (Calif. Super. Ct. Dec. 28, 2015)
  - Petitioners allege that adherence to ERDs violates California sterilization law
- *Masterpiece Cakeshop v. Colorado Civil Rights Comm'n*, Docket No. 16-111, argued December 5, 2017

Nurses

- *Cenzon-DeCarlo v. Mt. Sinai Hosp.*, 626 F.3d 696 (2d Cir. 2010)
  - nurse sued alleging she was compelled to participate in a late-term abortion
  - Court held there was no private right of action under the Church Amendment, but plaintiff could pursue state discrimination claims
- *Danquah v. Univ. of Med. and Dentistry of New Jersey*, No. 2:11-cv-6377 (D.N.J. Oct. 31, 2011)
  - nurses alleged they were required to participate in abortions
  - injunction against the hospital, hospital agreed to cease practice
- *Hellwage v. Tampa Family Health Centers*, 103 F. Supp. 3d 1303 (M.D. Fla 2015)
  - Nurse alleged she was denied interview based upon religious beliefs.
  - Court held no private remedy under Church Amendment, but plaintiff plead a Title VII claim.

Transgender Cases

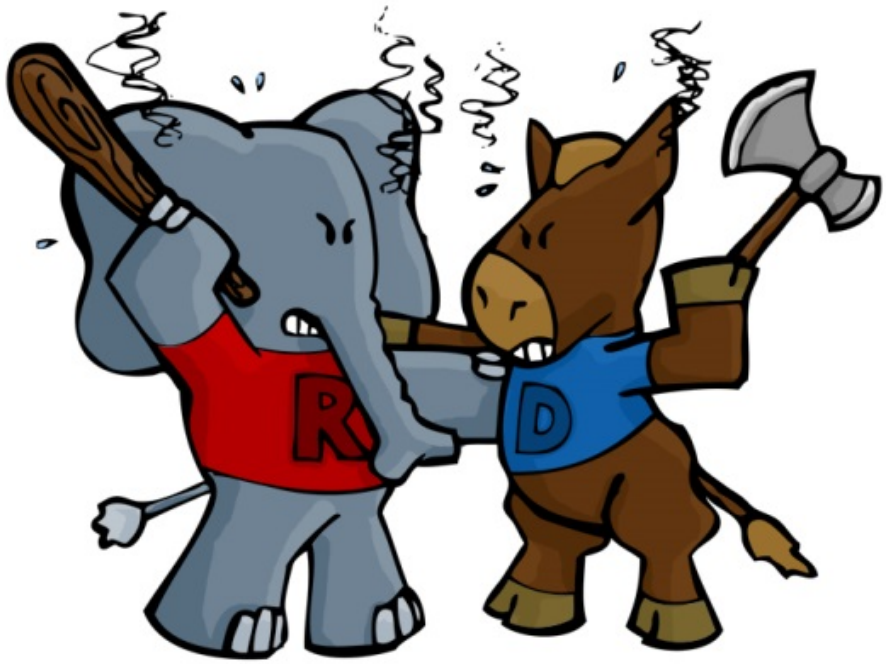
- *Tovar v. Essentia Health*, 857 F.3d 771 (8th Cir. 2017)
- *Enstad v. PeaceHealth*, No. 2:17-cv-01496-RSM (W.D. Wash.)
  - Employees sued religious hospitals whose self-funded health plans excluded gender transition surgery coverage.
- *Prescott v. Rady Children's Hospital-San Diego*, 265 F.Supp.3d 1090 (S.D. Cal. 2017)
  - ACA covers discrimination claims on the basis of transgender identity
- *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. Apr. 19, 2017)
  - Transgender plaintiff sued after Dignity Health cancelled his scheduled hysterectomy at a Catholic hospital and arranged procedure three days later at a non-Catholic hospital.
  - Judgment entered in favor of Dignity Health; Appeal filed.

Compelled Speech

- *Nat'l Inst. of Family and Life Advocates v. Harris*, 839 F.3d 823 (9th Cir. 2016), *cert. granted* (oral argument Mar. 20, 2018)
  - California's Reproductive Freedom, Accountability, Comprehensive Care, and Transparency Act requires: (1) licensed pregnancy-related clinics to post a notice regarding publicly available, full service family planning services; and (2) unlicensed clinics to post a notice that they are not licensed
  - Religiously affiliated, pro-life clinics sought to enjoin the FACT Act
  - 9th Circuit applied intermediate scrutiny and denied injunction
- *Evergreen Ass'n, Inc. v. City of New York*, 740 F.3d 233 (2d Cir. 2014)
- *Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v Mayor and City Council of Baltimore*, 879 F.3d 101 (4th Cir. 2018)
  - Clinics sued to enjoin city ordinances that required them to post disclaimers that the clinics do not make referrals for abortion or birth control services
  - Courts applied strict scrutiny and enjoined ordinances


WHY CAN'T WE JUST GET ALONG?

Competing Forces Leave No Daylight



- All sides feel attacked
- They're both right
  - Suits against religious providers demanding prohibited services
  - Religious providers do not want to provide those services, and they object to making referrals
- A reflection of our present national politics with no compromise on the horizon
- What about the patients?

- Do religious individuals and religious institutions share the same Free Exercise right?
- Are hospitals – and healthcare – unique?
- What is the definition of "sex?"
  - Depends where you live
- States can pass laws subject to lower levels of scrutiny than federal laws.
  - *Smith* and *Sherbert* were religious observance cases; *Masterpiece Cakeshop* is a for profit bakery open to the public
- Emergency care
- Mergers and Consolidation

- Rule-making follows the ideology of the administration
- Both parties have tried, thus far unsuccessfully, to use rule-making to expand the law
- Regulations take much longer to implement than to enjoin or replace

A Modest Proposal?

- Reduce anxiety, tension, and hostility
  - What has 50 years of culture war wrought?
  - We are all here to stay
- Recognize that hospitals – and healthcare – are unique
  - Clear First Amendment rights of religiously affiliated hospitals demonstrated by history and mission warrant protection
  - However, public policy demands that patients are entitled to access and information
- Expand *both* the protections and exemptions
  - End the rhetorical battle over “sex”
  - Conscience rights should include the ability to abstain from providing or performing abortions, sterilization, euthanasia, and gender transition procedures

False Claims Act: Healthcare Fraud Enforcement Trends

The Current State of Play: Healthcare Fraud Prosecutions Continue to Be a Priority for the Government

- Despite the uncertainty in the healthcare industry, one agenda that continues to remain nonpartisan is the government's focus on ferreting out healthcare fraud.
- The government's focus, along with the willingness of the relators' bar to pursue False Claims Act (FCA) cases when the government decides not to intervene, has placed every individual and entity participating in the healthcare industry in the crosshairs of those who seek to combat healthcare fraud.
- Healthcare fraud recoveries continued to reach staggering numbers in 2017.
  - US Department of Justice (DOJ) reported that it obtained more than $3.7 billion in settlement and judgments during the fiscal year ending September 30, 2017 from civil cases involving fraud and false claims against the government, $2.4 billion of which involved the healthcare industry (including drug companies, hospitals, pharmacies, laboratories, and physicians).
  - DOJ reported that relators filed 669 qui tam FCA lawsuits last year and 492 of those lawsuits related to healthcare fraud.
- False claims included those based on alleged off-label marketing, kickbacks, Stark, up-coding, double billing, and lack of medical necessity.

Key Fraud and Abuse Laws

- Criminal Healthcare Fraud Statutes

  False Claims: 18 U.S.C. § 287

  False Statements/Healthcare Programs: 18 U.S.C. §1035

  False Statements in Connection with a Claim: 42 U.S.C. § 1320a-7b(a)

  Kickbacks: 42 U.S.C. § 1320a-7b(b)

  Healthcare Fraud: 18 U.S.C. § 1347

  Misbranding: 21 U.S.C. § 331, 333

Other General Criminal Statutes Used in Healthcare Fraud Cases

Mail and Wire Fraud: 18 U.S.C. §§ 1341 and 1343; False Statements: 18 U.S.C. § 1001; and Obstruction of an "Official Proceeding": 18 U.S.C. § 1512(c)

Civil Healthcare Fraud Statutes

Stark Law: 42 U.S.C. § 1395nn

Civil Monetary Penalties (CMP): 42 U.S.C. § 1320a-7a

Civil False Claims Act: 31 U.S.C. § 3729

Key Fraud and Abuse Laws

Criminal Fraud and Abuse

- 18 U.S.C. § 287 (false claims)
  - Makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, *any claim upon or against the United States*, or *any department or agency thereof, knowing such claim to be false*, fictitious or fraudulent.
- 18 U.S.C. § 1035 (false statements in connection with a healthcare program)
  - In connection with the *delivery of or payment for any healthcare program benefits, items, or services, knowingly and willfully*
    - *falsifies, conceals or covers up* by any trick, scheme or device a material fact; or
    - makes any *materially false, fictitious or fraudulent statements or representations*; or
    - makes or uses any *materially false writing or document* knowing the same to contain any materially false, fictitious or fraudulent statement or entry.
- 42 U.S.C. § 1320a–7b(a)(1) (false statements in an application for benefits)
  - Knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a federal healthcare program . . .

Criminal Fraud and Abuse (continued)

- 18 U.S.C. § 1347 (healthcare fraud)
  - Knowingly and willfully executes or attempts to execute a scheme or artifice
    - to defraud any healthcare benefit program, or
    - to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by or under the custody or control of any health benefit program.

Key Fraud and Abuse Laws

Civil False Claim

- *Knowingly* presents or *causes to be presented a false claim for payment or approval*;
- *Knowingly* makes, uses or causes to be made or used a false record or statement *material to a false or fraudulent claim*;
- *Knowingly* makes, uses or causes to be made or used a false record to avoid or decrease an obligation to pay or transmit property to the government.
  - 31 U.S.C. § 3729(a)
- "Knowingly" includes "reckless disregard" or "deliberate indifference."
  - 31 U.S.C. § 3729(b)
- Potential penalties: Treble damages, penalties of not less than $10,957 and not more than $21,916, shareholder suits, a potential CIA . . . and the list goes on.

Enforcement Trends: Individual Accountability and Prosecution for Participation in Healthcare Fraud Activities

- On September 9, 2015, former Deputy Attorney General Sally Q. Yates issued a memorandum entitled "Individual Accountability for Corporate Wrongdoing" (known as the "Yates Memo"), which sets forth a framework for seeking accountability from individuals who perpetuate fraud, including corporative executives.
- Even though Ms. Yates has since departed the DOJ, individual accountability remains a point of emphasis.
- Examples:
  - In October 2016, Tenet Healthcare Corp. ("Tenet") and two of its subsidiaries agreed to pay over $513 million to resolve criminal charges and civil claims relating to a scheme to defraud the United States and to pay kickbacks in exchange for patient referrals. In February 2017, a former Tenet senior vice president of operations was indicted for his alleged role in the scheme.
  - The owner of Life Care Centers of America, Inc. paid $145 million to settle allegations that it caused skilled nursing facilities to submit false claims for rehabilitation therapy services that were not reasonable, necessary, or skilled.
  - In August 2017, a federal jury convicted a registered nurse who was the owner of two home health companies in Houston for her role in a $20 million Medicare fraud scheme.
  - On March 13, 2018, three Miami, Florida home health agency owners were charged in an indictment for their alleged participated in a health home fraud scheme involving a now-defunct home health agency in Miami.

Enforcement Trends: Investigations of Improper Financial Arrangements

- Although it has been a point of emphasis for years for the federal government, there have been several, noteworthy settlements relating to impermissible financial arrangements with referral courses.
  - In June 2017, the owners and operators of an acute care hospital in Los Angeles agreed to pay $42 million to settle allegations that they violated the FCA by engaging in financial arrangements with referring physicians in violation of the Anti-Kickback Statute and Stark Law.
  - In May 2017, two Southwest Missouri healthcare practitioners agreed to pay the federal government $34 million to settle allegations that they violated the FCA by submitting false claims to Medicare for chemotherapy services rendered to patients referred by oncologists whose compensation was based, in part, on a formula that improperly took into account the value of their referrals.
  - In September 2017, Galena Biopharma, Inc. agreed to pay $7.55 million for paying doctors kickbacks to prescribe a fentanyl-based drug.

Enforcement Trends: Efforts to Combat the Opioid Epidemic

- On November 17, 2017, Attorney General Jeff Sessions remarked that "we are facing the deadliest drug crisis in American history. Based on preliminary data, at least 64,000 Americans lost their lives to drug overdoses last year . . . . This crisis is driven primarily by opioids . . . ."
- Various government agencies are devoting substantial resources to addressing opioid abuse, including investigating and pursuing not only manufacturers but prescribers and healthcare providers who submit claims to federal healthcare programs for opioid prescriptions. These efforts include investigations under the FCA and administrative actions, in addition to criminal actions.
- With the Trump administration's public health emergency orders, it is expected that the government's enforcement activities will continue to grow.

Enforcement Trends: Efforts to Combat the Opioid Epidemic

- **Examples of government efforts:**
  - The DOJ and the US Department of Health and Human Services Office of Inspector General (OIG) have been engaged in the largest-ever healthcare fraud enforcement action by the Medicare Fraud Strike Force, involving more than 400 charged defendants across 41 federal districts. Of those subjects charged, over 120 defendants were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.
  - DOJ announced the formation of the Opioid Fraud and Abuse Detection Unit. In connection with the formation of this unit, DOJ assigned experienced prosecutors in 12 opioid "hot spots" across America to focus solely on prosecuting opioid-related healthcare fraud.
  - In October 2017, the DOJ announced the first-ever indictments of Chinese nationals and their North American-based traffickers and distributors for separate conspiracies to distribute fentanyl and other opioids in the United States.
  - On February 27, 2018, the DOJ Prescription Interdiction & Litigation (PIL) Task Force was created. Among other things, PIL is tasked with examining existing state and local government lawsuits against opioid manufacturers to determine what assistance, if any, federal law can provide in those lawsuits.

Enforcement Trends: Viability of FCA Cases Alleging Lack of Medical Necessity

- Courts have ruled that when a lack of medical necessity is claimed under the FCA, there must be more than just a difference of opinion between professionals about the appropriate mode of treatment.
  - *United States ex rel. Polukoff v. St. Mark's Hospital et al.*, No. 16-cv-00304, 2017 U.S. Dist. LEXIS 8167 (Jan. 19, 2017 D. Utah).
    - » Relator alleged that a physician performed medically unnecessary procedures, and that he and the hospitals where he performed the procedures violated the FCA by representing that procedures were medically reasonable and necessary.
    - » The court found that the relator's FCA claims failed as a matter of law because the realtor could not show that the defendants knowingly made an objectively false representation to the government. The court noted that "a mere difference of opinion between physicians is not enough to establish falsity" under the FCA.
    - » The *Polukoff* court joined *United States v. AseraCare, Inc.*, 176 F.Supp.3d 1282, 1283 (N.D. Ala. 2016) and several other courts in rejecting FCA claims premised on lack of medical necessity or other matters of scientific judgment.

False Claims Act Risks in a Managed Care Environment

The Ninth Circuit on Risk Adjustment FCA Cases

- *United States ex rel. Swoben v. United Healthcare Ins. Co*. (9th Cir. 2016)
  - One-sided retrospective chart reviews designed to identify only under-reporting and ignore over-reporting is actionable under FCA
  - Opinion amended in December 2016: allegations not specific enough against most defendants, but allegations sufficient against United and IPA that shared in percentage of MA payment
  - High RADV error score can be evidence that cannot in good faith certify to accuracy of data, but high RADV score alone is not enough to allege FCA violation
  - Blind coding during retrospective chart reviews not inherently suspect and may help ensure integrity, but need mechanism to reconcile with reported codes
    - Should not perform a "unidirectional comparison"
    - No holding regarding obligation if MA organization does not perform retrospective chart reviews
    - *"When, as alleged here, Medicare Advantage organizations design retrospective reviews of enrollees' medical records deliberately to avoid identifying erroneously submitted diagnosis codes that might otherwise have been identified with* ***reasonable diligence****, they can no longer certify, based on best knowledge, information and belief, the accuracy, completeness and truthfulness of the data submitted to CMS"*

What Does a False Claim Look Like in 2018 (the Effects of Escobar)?

- In a unanimous opinion written by Justice Thomas, on June 16, 2016, the Supreme Court resolved a circuit split and held in *Universal Health Services v. United States ex rel. Escobar*, a case alleging that, in submitting a claim for mental health services, the provider implicitly certified that the service provider employees administering the services were qualified as per required licensing and regulations:
  - The **implied false certification theory** *can* be a basis for liability under the False Claims Act when a defendant submitting a claim makes specific representations about the goods or services provided, but **fails to disclose noncompliance** with **material** statutory, regulatory or contractual requirements that make those representations misleading with respect to those goods or services.
  - Liability under the FCA for failing to disclose violations of regulatory requirements does not turn upon whether those requirements were expressly designated as conditions of payment. In other words, to determine whether the relator has stated a false claim material to the government's decision to pay, it is not determinative if the regulation violated is a condition of payment or a condition of participation.

What Does a False Claim Look Like in 2018 (the Effects of Escobar)?

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  - Evidence that a false statement or omission of a fact *could* have affected the government's decision to pay is not sufficient to establish materiality for purposes of surviving a summary judgment motion; relator must establish that the government's decision was likely to have been affected or was, in fact, affected by the false statement or the statement rendered false by the omission.
  - A decision by the government to continue to pay following receipt of knowledge of falsity may negate an allegation of materiality, *but it is not determinative*.
- The decision ultimately rejected
  - the First Circuit view that all regulatory violations not disclosed can form the basis of an FCA case, and
  - the view that a regulation must be a condition of payment to form the basis of a claim.

What Does a False Claim Look Like in 2018: The Risk Adjustment/Medicare Advantage Cases

- *U.S. ex rel. Swoben v. Scan Health Plan et al.*, CV 09-5013-JFW (JEMx) (C.D. Cal. Oct. 5, 2017)
  - U.S. alleged MA plan received inflated risk adjustment payments based on inaccurate patient health data
  - DOJ withdraws complaint following court ruling that U.S. failed to plead materiality; focus on attestations of validity
- *U.S. ex rel. Poehling v. UnitedHealth Group, Inc. et al.*, CV 2:16-08697 WMF (SSx) (C.D. Cal. February 2018)
  - Attestation of validity of providers' codes is not material
  - But Relator/DOJ survived MTD and *Escobar* by alleging United Health submitted invalid diagnostic data related to the health status of patients enrolled in MA plans and hence received inflated risk adjustment payments

Factors That May Affect "Knowledge" Assessment

- When does reliance on diagnosis data supplied by providers constitute deliberate ignorance or reckless disregard?
  - Is the provider owned or controlled by the insurer?
  - Is the provider paid under a percentage of premium risk-sharing arrangement where the insurer has incentivized the provider to increase premiums?
  - To what extent does the insurer audit medical records?
    - What type of data mining is used to target audits?
    - Is the sample size adequate?
    - What findings trigger broader audit?
    - Is only down-coding adjusted or is over-coding corrected as well?
    - If an outside auditor is used, how are they compensated?

Potential "Reverse False Claims" Liability

- FCA extended to cover cases where a person "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government ..."
- The ACA creates an "obligation" to return an identified overpayment.
- The failure to carry out this obligation can trigger reverse false claims liability under the FCA

What type of information triggers the obligation to conduct a post-payment audit?

What Does a False Claim Look Like in 2018: "The Overpayment"

- ACA § 6402(d)(1) governs payments from Medicare or Medicaid.
  - If a person has received an overpayment, the person shall:
    - report and return the overpayment to the Secretary, the State, an intermediary, a carrier or a contractor, as appropriate, at the correct address; and
    - notify the Secretary, the State, intermediary, carrier or contractor to whom the overpayment was returned in writing, including the reason for the overpayment.
- ACA § 6402(d)(3) ties the overpayment to the FCA
  - Any overpayment retained by a person after the deadline [of *60 days from the date overpayment was identified*] for reporting and returning the overpayment is an obligation for purposes of [False Claims Act].
- Intent at the time claim was submitted is *irrelevant*.
- Liability may exist even where company is *unaware* of overpayment, if company shows "reckless disregard" or "deliberate ignorance" of the mistake.

What Does a False Claim Look Like in 2018: "The Overpayment"

- *U.S. ex rel. Kane v. Continuum Health Partners*, No. 11 Civ. 2325, 2015 WL 4619686 (S.D.N.Y. Aug. 3, 2015)
  - Court ruled that the 60-day clock starts running when a provider becomes aware of a "potential" overpayment.
    - At the end of 60 days, the payment has been "withheld" and gives rise to FCA liability.
  - Creates a strong incentive for whistleblowers to file on day 61 because of the First-to-File Rule.
  - Potential defense: If the provider is conducting a good faith investigation, the repayment arguably isn't being "improperly" withheld.

Reporting and Returning MA Overpayments Regulation

- MA organization must report and return an overpayment within sixty days of being "identified" (42 C.F.R.§422.326 (published in 79 Fed. Reg. 29958 (May 23, 2014))
- For MA plans, an "overpayment" exists when MAO has received CMS payments to which it is not entitled after January 31 of the year following the payment year
- Overpayment "identified" when MAO has determined – or should have determined through *reasonable diligence* – overpayment has occurred
- Must correct data within sixty days of identification, though actual recovery may take longer due to CMS payment processing rules
- United Healthcare is challenging this regulation in federal court in D.C.
  - Principal concern is failure to take into account coding intensity difference between MA and FFS
  - Also views "reasonable diligence" standard as much more searching standard than required by FCA

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Thank You

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