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Colorado Hospital Association

Health Care Regulatory Update

January 8, 2019

Denver, CO

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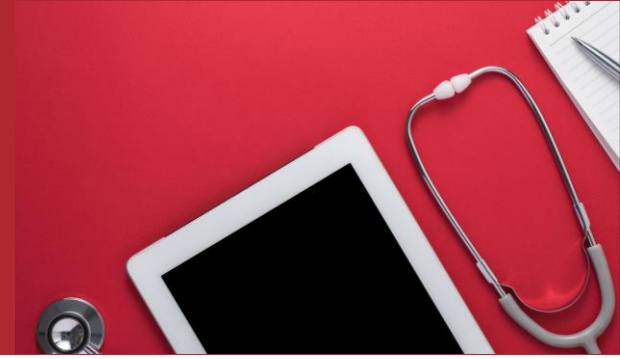
Danger Ahead: Fraud and Abuse – Year in Review

Jeff Fitzgerald, Shareholder

Overall F&A Liability Down, again



FRAUD STATISTICS - OVERVIEW

October 1, 1986 - September 30, 2018

Civil Division, U.S. Department of Justice

FY	NEW MATTERS°		SETTLEMENTS AND JUDGMENTS¹				
	NON QUI TAM	QUI TAM	NON QUI TAM	QUI TAM			TOTAL QUI TAM AND NON QUI TAM
			TOTAL	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL	
2016	149	707	1,896,930,624	2,925,411,797	108,298,069	3,033,709,866	4,930,640,490
2017	145	680	280,997,308	2,585,063,111	599,038,273	3,184,101,384	3,465,098,692
2018	122	645	767,115,453	1,994,733,622	118,671,636	2,113,405,258	2,880,520,711

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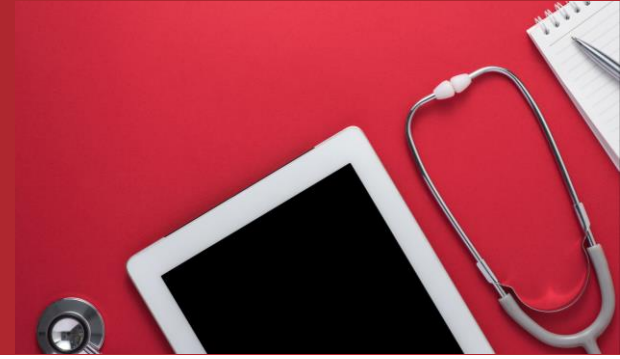

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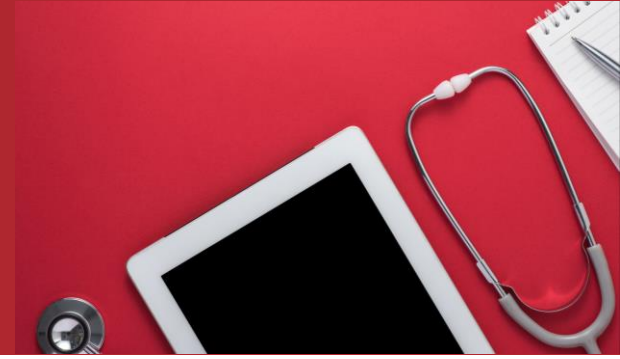

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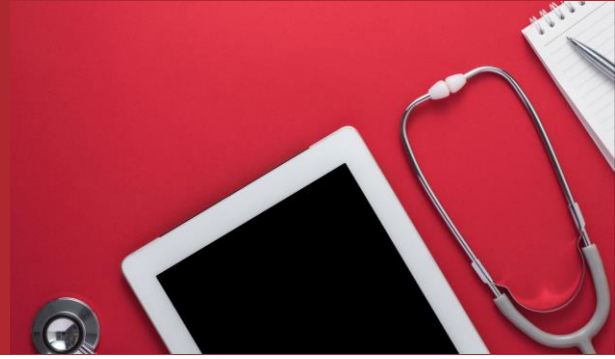
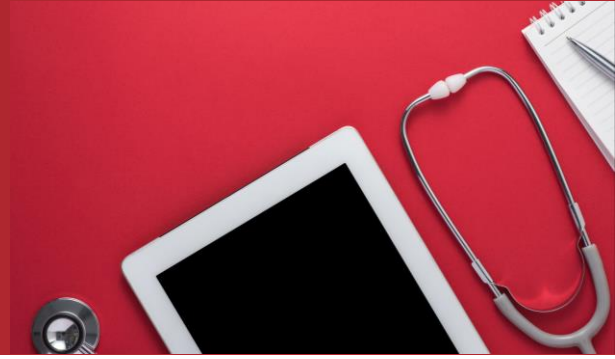
Settlement Trends



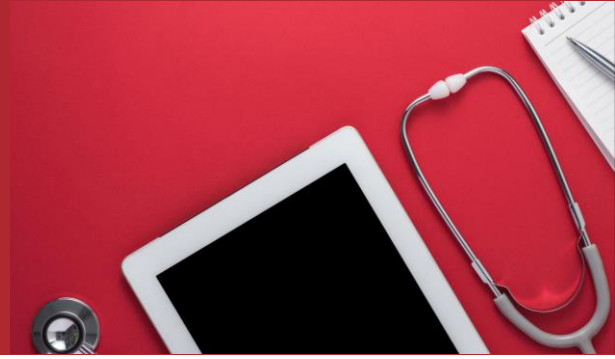
- Few “huge dollar” settlements
  - AmeriSource Bergen ($625M, FDA repackaging issues)
  - Health Management Associates ($260M, billing and AKS allegations)
  - HealthCare Partners ($270M, Medicare Advantage data)

Settlement Trends



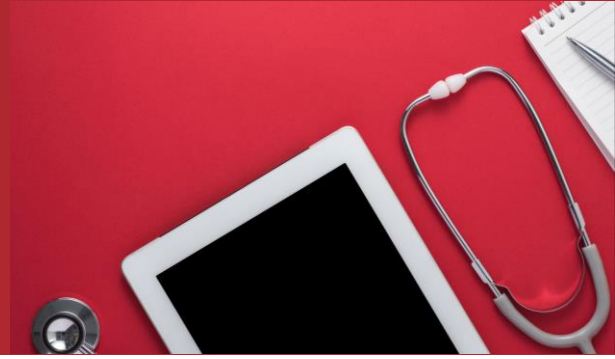
- Increase in volume of settlements with physicians
  - Kool Smiles ($23.9M, dental services, medical necessity)
  - Urology practice ($1M, non-FMV leases with other urologists)
  - Chiropractor ($1.45M, medical necessity & lack of supervision)
  - ENT practice ($2.79M, unlicensed staff & altered records)
  - Oncologist ($500K, imported chemo drugs)
  - Pediatric practice ($750K, unenrolled MDs & lack of supervision)

Settlement Trends



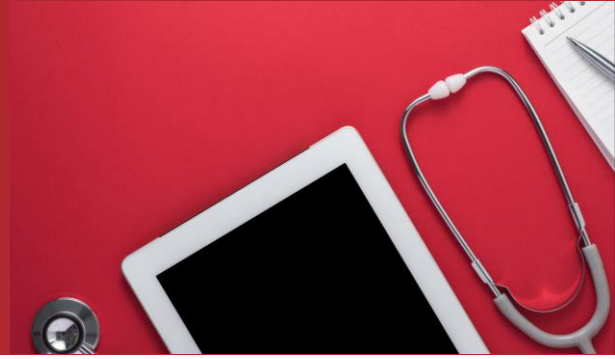
- Increase in volume of physician practice settlements
  - Orthopedic practice ($3.2M, free services to ASC for referrals & imported drugs)
  - Thoracic surgery practice ($1.5M, E&M upcoding & services not rendered as billed)
  - Urgent care ($6.6M, unenrolled MDs & upcoded E&Ms)
  - Solo practitioner ($1.53M, unnecessary diagnostic tests)
  - Spine and pain clinic ($1.5M, payments from urinalysis lab)
  - Dermatology ($4M, supervision & upcoding)

Settlement Trends



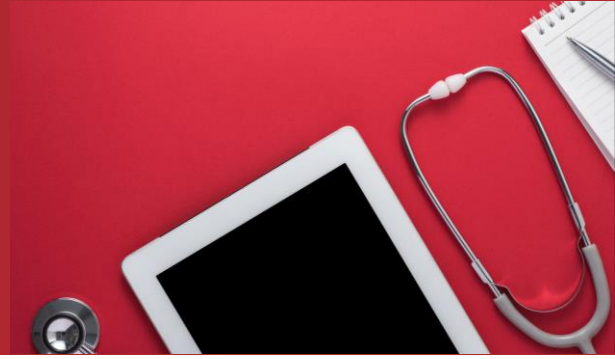
- Numerous hospice and LTC settlements, as expected
  - Spring Gate Rehab ($500K, worthless SNF services)
  - Caring Heart Rehab ($6M, unnecessary rehab services)
  - New Oaklawn ($5.1M, inflated RUGs scores & unnecessary rehab services)
  - Allegiance Health ($1.7M, unnecessary rehab services)
  - Signature HealthCARE ($30M, unnecessary rehab services)
  - Southern SNF Management ($10M, inflated RUGs scores & unnecessary rehab services)

Settlement Trends



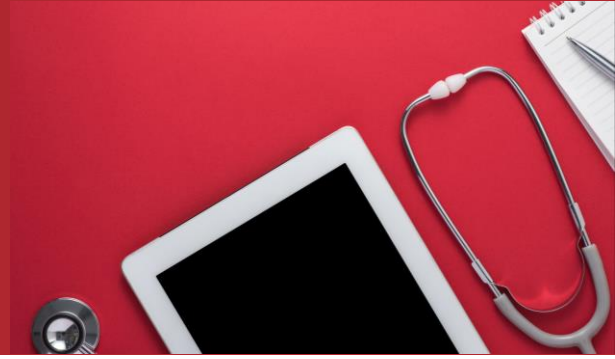
- Numerous hospice and LTC settlements, as expected
  - Post Acute Medical ($13M, inducements to physicians and reciprocal referral agreements)
  - Reliant Rehab ($6.1M, therapy provider paid inducements to SNFs, physicians and nurse practitioners)
  - Home Family Care ($6.42M, unqualified caregivers & billed for individuals with stolen identities)
  - Caris Healthcare ($8.5M, hospice medical necessity & retention of overpayments)
  - 365 Hospice ($1.24M, medical necessity & record alteration)

Settlement Trends

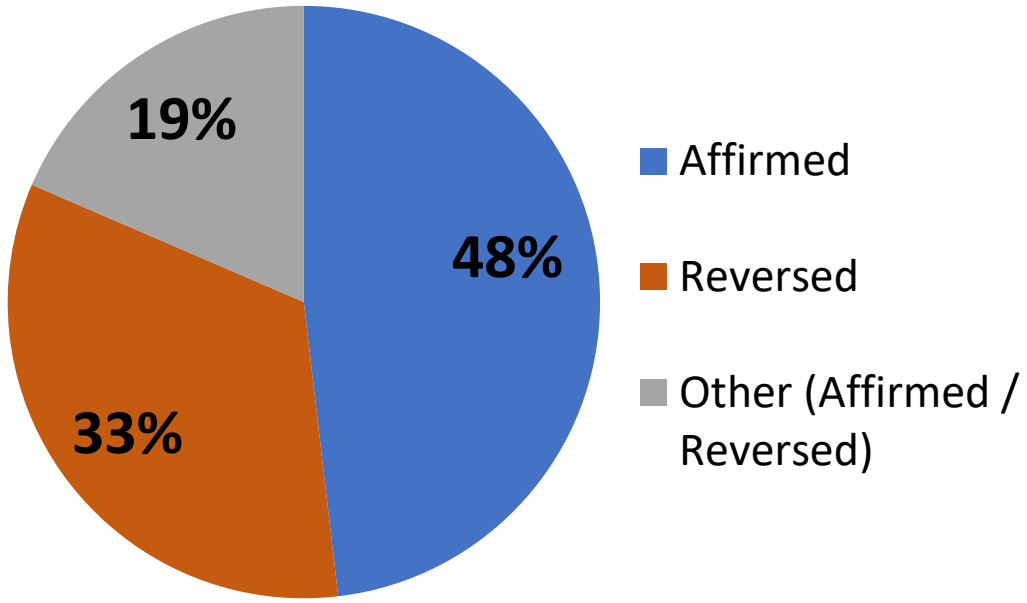


- Some hospital and health system settlements
  - UPMC Hamot ($20M, stark allegations including non-FMV and unnecessary admin. services with cardiology practice)
  - William Beaumont ($84.5M, non-FMV leases & provider-based CT)
  - Brattleboro Mem. ($1.6M, medical necessity of outpatient lab tests)
  - Kalispell Regional ($24M, non-FMV contacts with MDs)
  - Multiple hospitals and health systems for one-day, inpatient/outpatient claims totaling over $350M

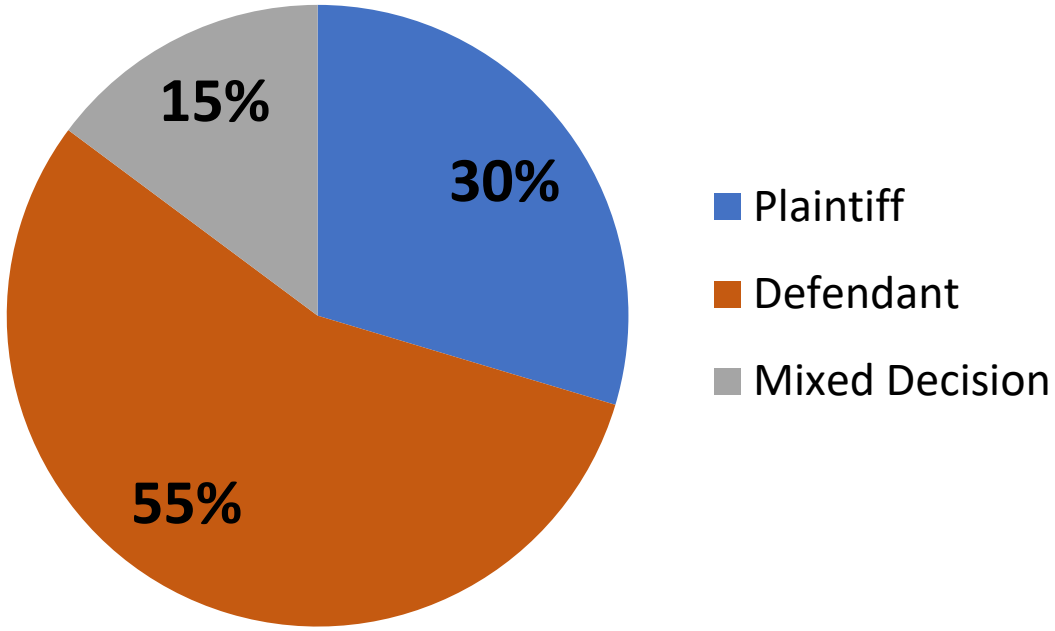
False Claims Act Litigation



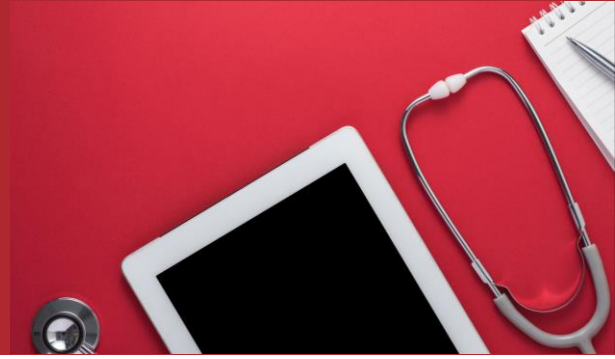
Appeals Court Ruling

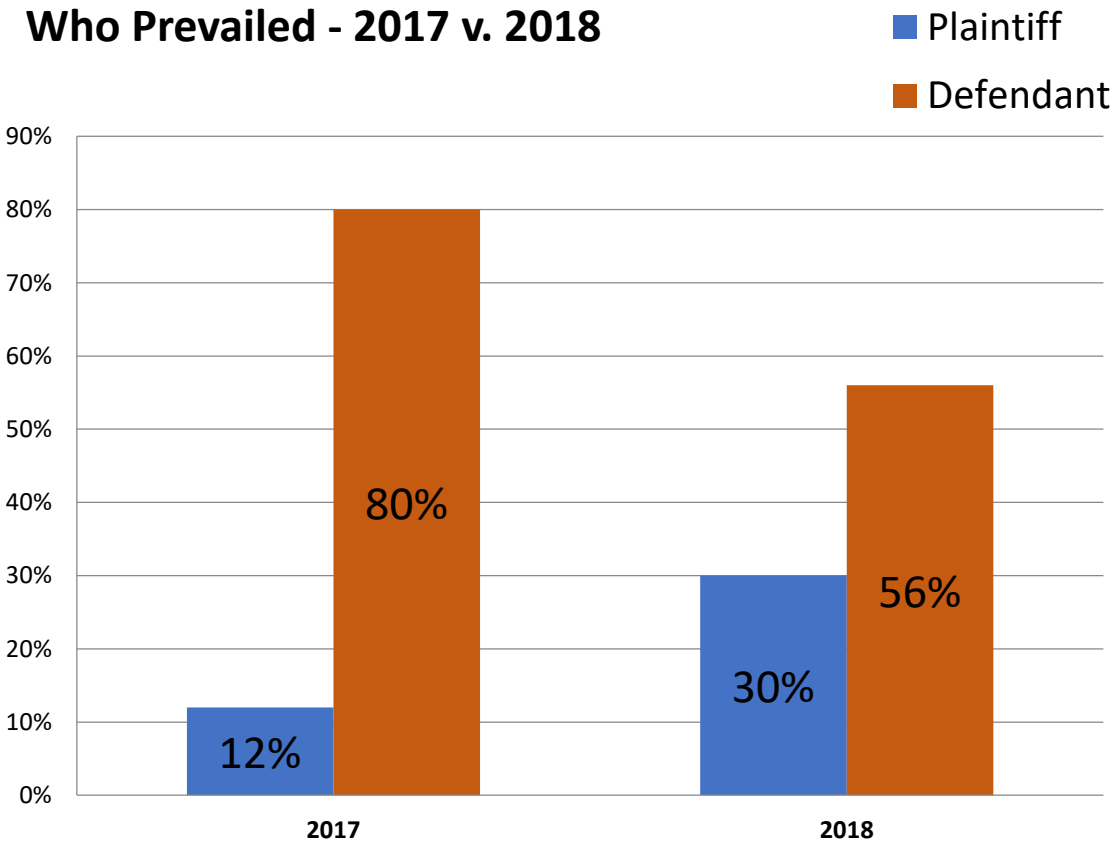


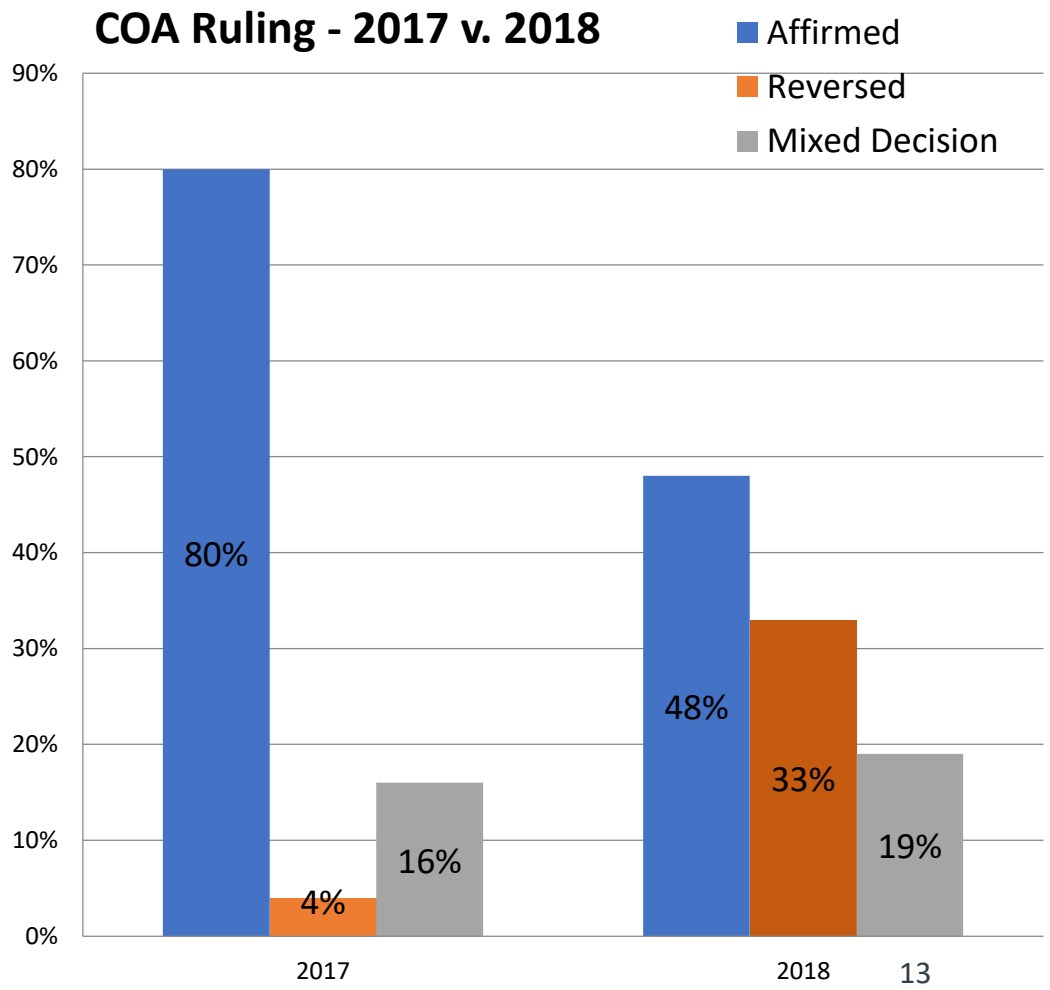
Who Prevailed?



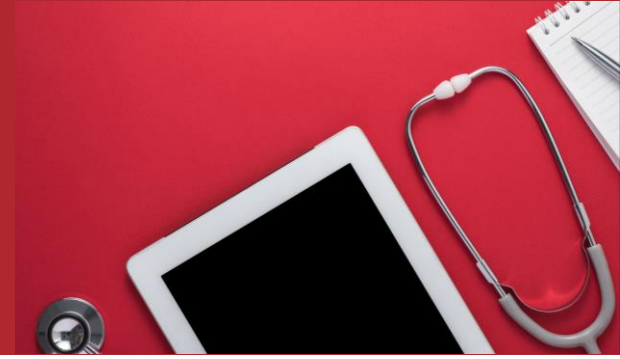
False Claims Act Litigation





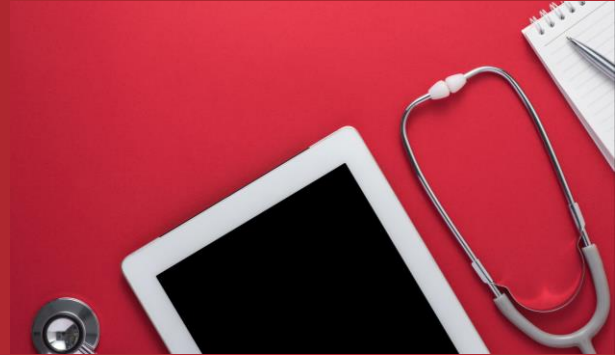


Noteworthy Court Decisions



- UnitedHealthcare Ins. Co. v. Azar, D.D.C., No. 16-157
  - United challenged CMS regulation interpreting the Medicare overpayment refund statute in context of Medicare Advantage
  - Court ruled that regulation created FCA liability for *negligence* (*i.e.*, lack of "reasonable diligence" to identify and repay) which contradicts FCA's *knowingly* requirement
  - Court invalidated the refund regulation for all of Part C

Noteworthy Court Decisions



- U.S. *ex rel*. Streck v. Allergan, Inc., 3rd Cir., No. 17-1014
  - Reasonable interpretation of statute prevents FCA liability
  - Here, drug manufacturer's interpretation of Medicaid Drug Rebate Program provisions was reasonable
- U.S. *ex rel*. Duffy v. Lawrence Memorial Hosp., D. Kan., No. 14-2256
  - Compliance with education requirements under the Deficit Reduction Act of 2005 not material to Medicare payment

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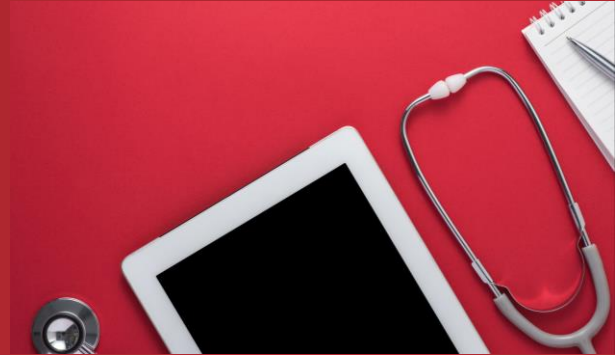
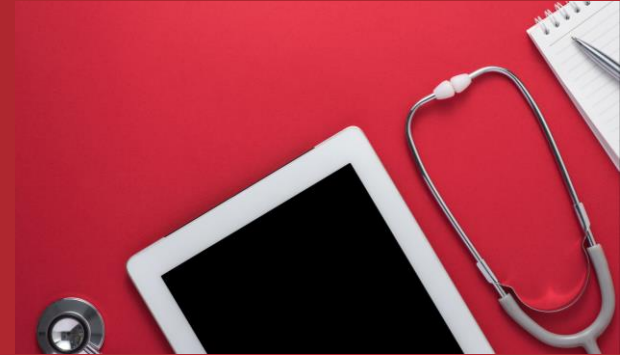


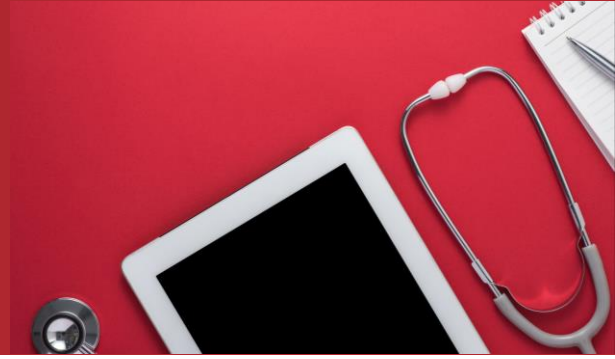
- U.S. *ex rel.* Poehling v. UnitedHealth Group, C.D.Cal., No. 2:16-cv-08697
  - Court dismissed substantial portions of complaint alleging that Medicare Advantage plan submitted false diagnosis information
  - United States did not file an amended complaint
- But, DOJ intervened in U.S. *ex rel.* Ormsby v. Sutter Health, N.D.Cal., No. 15-CV-01062

Other F&A Developments



- DOJ "Granson Memo" (Jan. 2018)
  - Directs DOJ lawyers to consider dismissing meritless FCA whistleblower cases
  - Factors to consider: meritless *qui tams*, parasitic or opportunistic *qui tams*, safeguarding classified information, addressing egregious procedural errors, interference with agency policies
  - Dec. 2018: DOJ dismisses 11 "cloned" *qui tams*, filed by LLC created merely to be a relator and claimed that patient education programs were kickbacks

Other F&A Developments



- DOJ "Brand Memo" (Jan. 2018)
  - Clarifies DOJ position that administrative agency guidance documents are not legal requirements
  - Directs DOJ lawyers avoid asserting FCA claims based upon informal agency documents

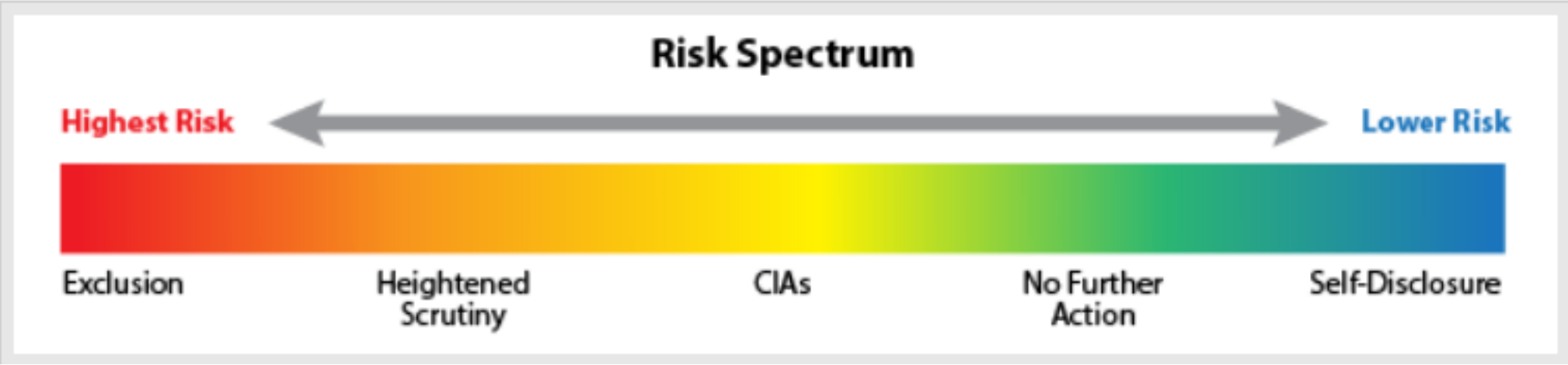
Guidance documents should not be used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or regulation.

*****

Likewise, Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases.

Other F&A Developments

- OIG announces that it will publish a Fraud Risk Indicator, to characterize entities what settle with OIG



https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp

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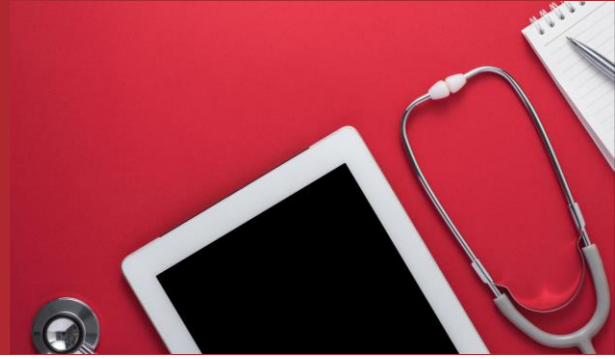


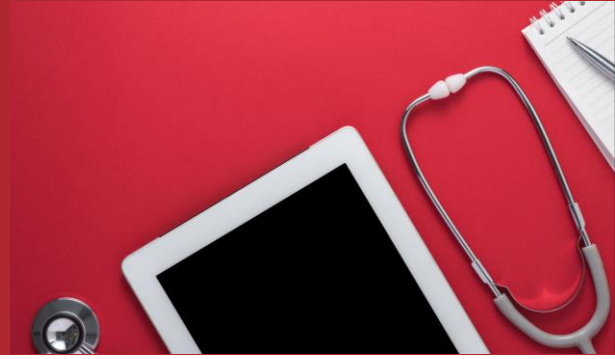
- OIG announces that it will publish a Fraud Risk Indicator, to characterize entities what settle with OIG

High Risk - Heightened Scrutiny −

Parties are in the High Risk category because they pose a significant risk to Federal healthcare programs and beneficiaries. This is because, although OIG determined that these parties needed additional oversight, they refused to enter CIAs sufficient to protect Federal healthcare programs. Parties in the High Risk category that reached settlements finalized on October 1, 2018 or later are listed here.

https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp

Other F&A Developments



- Section 8122 of the SUPPORT Act (Oct. 2018)
  - Created all-payer anti-kickback statute for referrals to "recovery homes, clinical treatment facilities, and laboratories"
  - Safe harbor for employment excludes commissions or compensation based upon referrals

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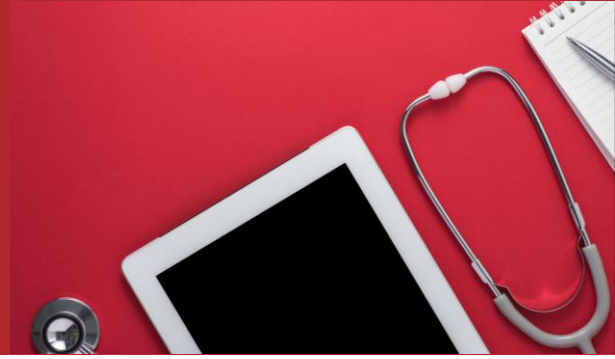
When Doctors Leave: Enforcement of Physician Non-Competes

Gillian Bidgood,
Shareholder

The Status Before 2018



- Employment Agreements & Equity Agreements with
  - Restricted Area
  - Non-Solicit
  - Liquidated Damages
- Between Hospitals & Physicians
- Between Hospitals & Groups
- Between Groups & Physicians

Non-Competes Generally

It shall be unlawful to use force, threats, or other means of intimidation to prevent any person from engaging in any lawful occupation at any place he sees fit.

C.R.S. § 8-2-113(1)

The Exceptions

(a) Any contract for the purchase and sale of a business or the assets of a business;

(b) Any contract for the protection of trade secrets;

(c) Any contractual provision providing for recovery of the expense of educating and training an employee who has served an employer for a period of less than two years; and

(d) Executive and management personnel and officers and employees who constitute professional staff to executive and management personnel.

C.R.S. § 8-2-113(2)

Physicians Generally

Any covenant not to compete provision of an employment, partnership, or corporate agreement between physicians that restricts the right of a physician to practice medicine, as defined in section 12-36-106, upon termination of the agreement, is void;

C.R.S. § 8-2-113(3)

Physician Exceptions

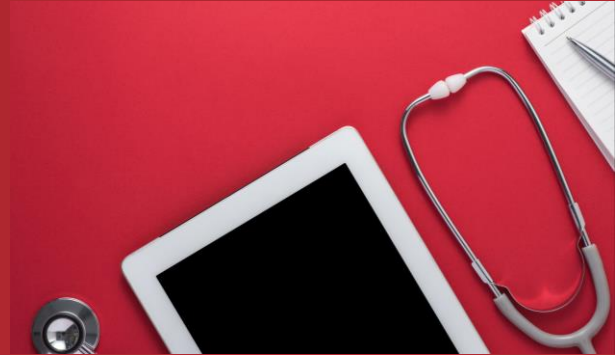
[E]xcept that all other provisions of the agreement enforceable at law, including provisions that require the payment of damages in an amount that is reasonably related to the injury suffered by reason of termination of the agreement, are enforceable. Provisions of a covenant not to compete that require the payment of damages upon termination of the agreement may include damages related to competition.

C.R.S. § 8-2-113(3)

In Sum…

- Agreement between physicians
- Can’t enforce a provision that restricts the right of a physician to practice medicine
- Can enforce provisions requiring payment of damages
- If amount is reasonably related to the injury suffered by reason of termination of the agreement
- Damages payable for breach of covenant not to compete may include damages related to competition

The Changes in 2018



- Statute
- Case Law

Rare Disorders

Notwithstanding subsection (3)(a) of this section, after termination of an agreement described in subsection (3)(a) of this section, a physician may disclose his or her continuing practice of medicine and new professional contact information to any patient with a rare disorder, as defined in accordance with criteria developed by the National Organization for Rare Disorders, Inc., or a successor organization, to whom the physician was providing consultation or treatment before termination of the agreement.

C.R.S. § 8-2-113(3)(b)

Liability Protection

Neither the physician nor the physician's employer, if any, is liable to any party to the prior agreement for damages alleged to have resulted from the disclosure or from the physician's treatment of the patient after termination of the prior agreement.

C.R.S. § 8-2-113(3)(b)

www.rarediseases.org

Home / For Patients and Families / Rare Disease Information

Rare Disease Information

NORD's Rare Disease Database provides brief introductions for patients and caregivers to specific rare diseases. Medical experts and representatives of patient organizations who would like to assist NORD in developing reports on topics not currently covered in this database may write to education@rarediseases.org.

Rare Disease Database

0-9 • A • B • C • D • E • F • G • H • I • J • K • L • M • N • O • P • Q • R • S • T • U • V • W • X • Y • Z

Aarskog Syndrome
Abetalipoproteinemia
Ablepharon-Macrostomia Syndrome
Acanthocheilonemiasis
Acanthosis Nigricans
Aceruloplasminemia
Achalasia
Achard Thiers Syndrome
Achondrogenesis
Achondroplasia
Acid Sphingomyelinase Deficiency
Acidemia Isovaleric
Acidemia, Methylmalonic
Acoustic Neuroma
Acquired Aplastic Anemia

1 2 3 ... 82 Next >

Search Rare Diseases

Enter a disease name or synonym to search NORD's database of reports.

In Sum…

- A physician may disclose his or her continuing practice of medicine and new professional contact information
- To any patient with a rare disorder
- In accordance with criteria developed by the National Organization for Rare Disorders, Inc., or a successor organization
- To whom the physician was providing consultation or treatment before termination of the agreement

Crocker v. Greater Colorado Anesthesia, P.C.

- Physician Employment Agreement with a Physician Group
- U.S. Anesthesia Partners
- 21.3% Reduction in Compensation
- 5 Year Vesting
- Offered Placeholder Agreement

Covenant

C. Competing Practice. For the purposes of this Agreement, "engages in a competing practice" or similar language shall mean that, during the term of his/her employment with the Corporation and within two (2) years following the effective date of the termination (for any reason) of Employee's employment with the Corporation (collectively the "Restrictive Period"), Employee participates, either directly or indirectly, as an employee, agent, contractor, shareholder, director, officer, partner, member, manager, owner or in any other capacity, in the practice of anesthesia at or within a fifteen (15) mile radius (known as the "Restricted Area") of any Health Care Facility, as defined herein. A Health Care Facility shall mean any hospital, ambulatory surgery center, clinic or any other health care facility at which the Corporation provides services during the period of Employee's employment, or at which the Corporation was providing services at the time of the termination of Employee's employment. The Board of Directors may waive the Restricted Area limit if it determines that the practice of anesthesia is at a Health Care Facility that Corporation believes is, not currently or in the future, in competition with Corporation's practice.

Formula

Description of Steps	Demonstrative Example Only – All Amts are Hypothetical For Demonstration Purposes Only
Step 1: The three-year average of gross revenues from Employee/Doctor's practice (if Employee/Doctor has been employed for less than three years, then the average gross revenues for all years Employee/Doctor has been employed by Corporation). This amount is calculated for any one year, by taking the average gross revenues per Shareholder Unit times the Employee Shareholder Units for that Year.	$540,000 (assuming an average of 10,000 units a year)
Minus Step 2: The three-year average direct cost of Corporation employing Employee. This is includes direct compensation paid to Employee and expenses paid directly on behalf of Doctor by Corporation.	($450,000)
Subtotal No. 1	$90,000
Multiply Subtotal No. 1 above by 2 (2 years' time of competition).	$180,000
Plus Step 3 The estimated internal and external administrative costs to terminate the departing and competing Employee/Doctor and to find and replace the Employee/Doctor, which Employee and Corporation agree are $30,000.	$30,000
Subtotal No. 2	$210,000
Step 4: Total Liquidated Damages for Competition under Paragraph 19 is equal to the lesser of Subtotal No. 2 or $250,000.	$210,000

In Sum…

- Exceptions for Rare Disorders
- Train People Hiring
- Separate Solicitation & Competition
- Documentation & Agreement Reflect Intent to Collect Damages Caused by Termination
- Base Liquidated Damage Amount on Actual Experience
- Record Actual Damages After Termination
- Evaluate Direct and Indirect Covenants with Physicians

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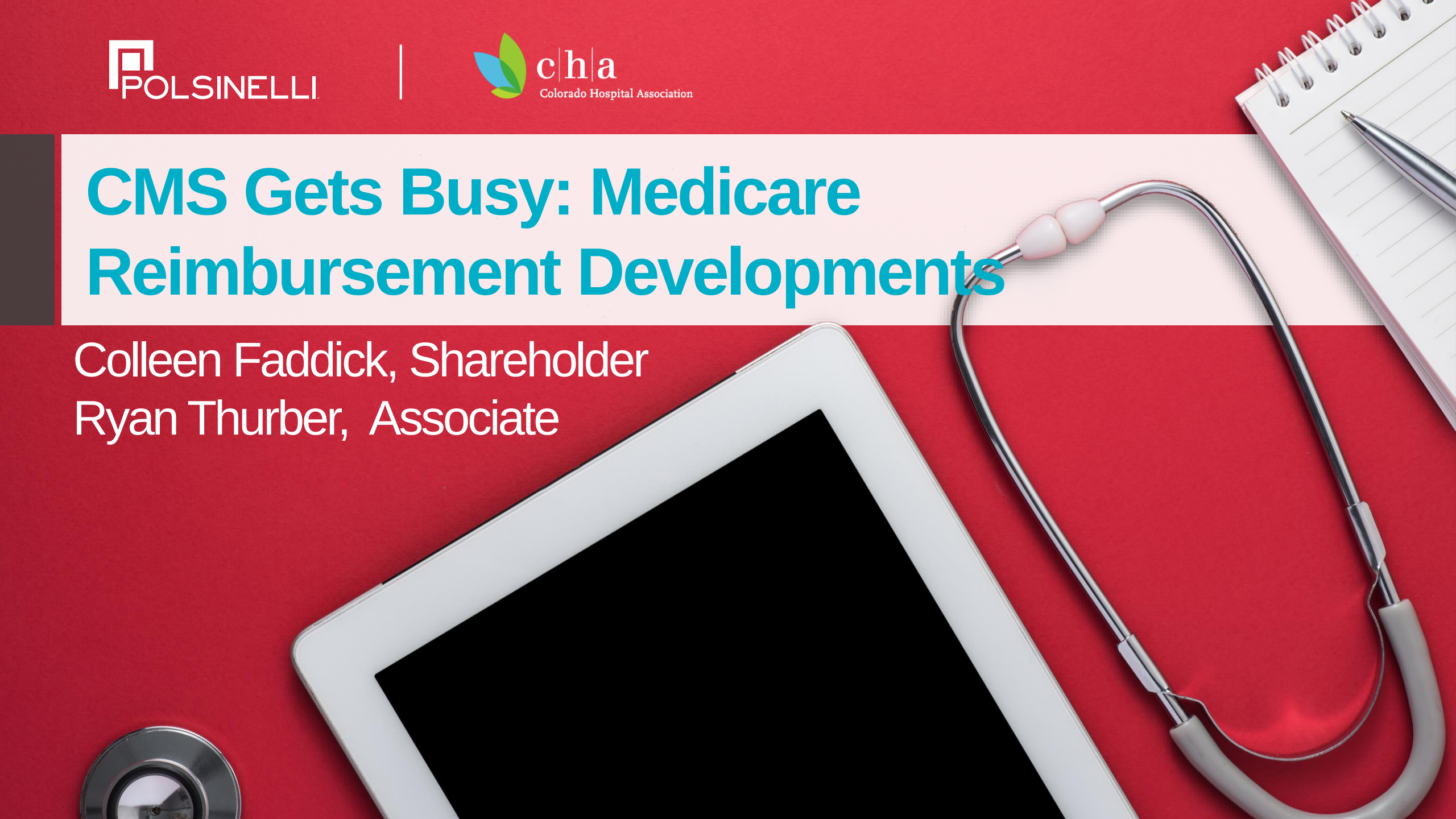
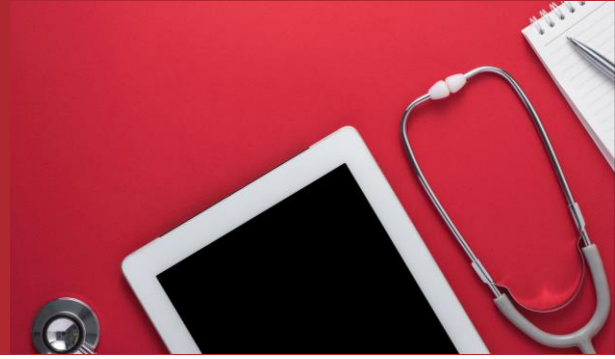
CMS Gets Busy: Medicare Reimbursement Developments

Colleen Faddick, Shareholder
Ryan Thurber, Associate



Agenda



- Provider-Based Payment Issues
- Provider-Based Enforcement
- Hospital OPPS Update
- 340B Update
- Provider Price Transparency Update
- Colorado Medicaid Update

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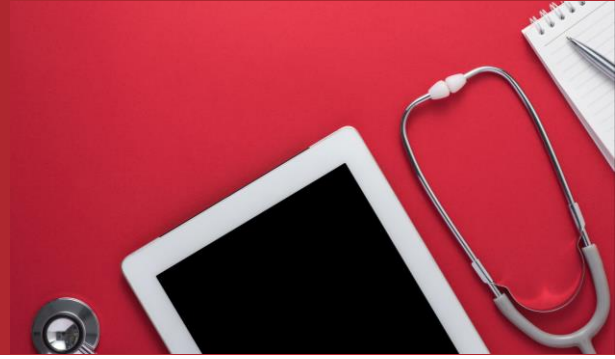
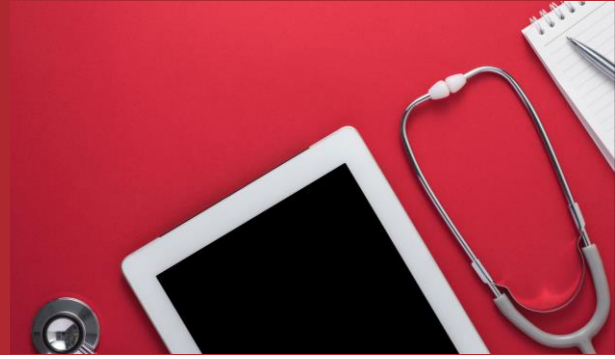
Provider –Based Payment Issues

Provider-Based Reimbursement



- Section 603 of the Bipartisan Budget Act of 2015 reduced reimbursement for certain off-campus provider-based departments
- 2019 OPPS Final Rule eliminates distinction between “excepted” and “non-excepted” provider-based departments for certain services
  - Excepted, off-campus outpatient departments now subject to payment cuts for clinic visit services (G0463)
  - Two year phase-in schedule (½ in CY 2019, ½ in CY 2020) to ultimate payment rate of 40% of OPPS
  - Cuts are not budget neutral – estimated payment reduction of $380M in CY 2019 alone
  - CMS intends to target additional services
- AHA (and others) have filed suit to block changes

Are you on- or off-campus?



Description	On Campus for PB Compliance Purposes?	On Campus for Section 603?	Payment Reduced by Section 603?	Payment Reduced by 2019 OPPS FR?
Outpatient clinic on main hospital campus (w/in 250 yards)	Yes	Yes	No	No
Outpatient clinic on campus of "remote location" of main provider	No	Yes	No	No
Excepted outpatient clinic not located on campus of main provider *or* remote location,	No	No	No	Yes (G0463)
Non-excepted outpatient clinic not located on campus of main provider or remote location	No	No	Yes	N/A

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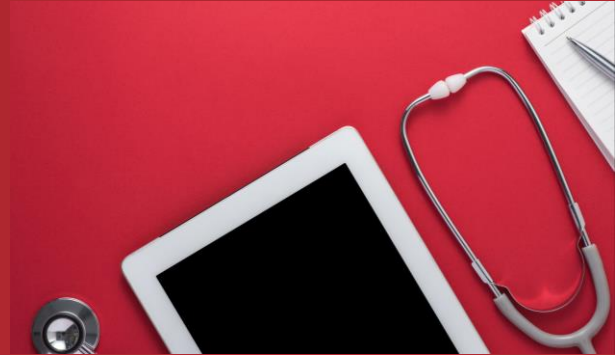
Provider – Based Enforcement

Provider-Based Enforcement



- Relief on the horizon?
  - November 27 – CMS (David Wright, Director – Quality, Safety, and Oversight) promises new provider-based guidance in first part of 2019
  - CMS signaled a shift in provider-based enforcement priorities
    - Recognition of rural provider challenges
    - Moving away from rigid application of space sharing/co-location rule
    - Focus on key issues impacting patient health/safety
    - More lenient view towards common areas
- In the meantime:
  - Consider contacting RO/CMS S&C with specific questions
  - New guidance expected to be more lenient than existing CMS position – but unclear how far CMS will go

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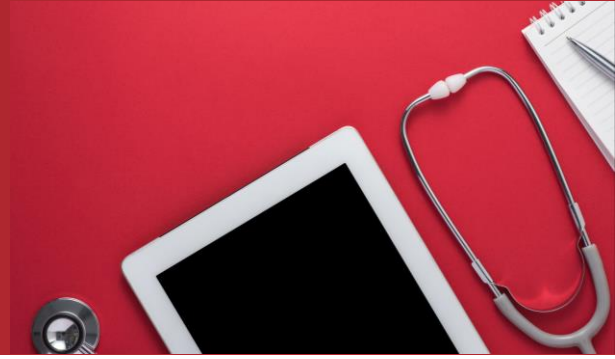
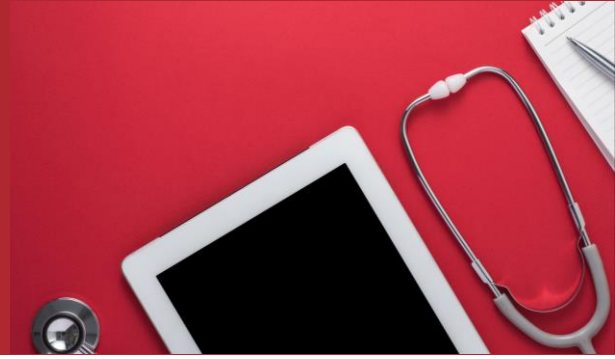
Hospital OPPS Update

Non-Site Neutral Updates



- General payment update of 1.35%
- Removed some quality reporting measures that do not align with current clinical guidelines, are topped out, are not strongly linked to better patient outcomes, or costs outweigh benefits
  - But not removing CAUTI/CLABSI
- Opioid crisis actions
  - Remove 3 recently-revised questions related to pain communication on the Hospital Consumer Assessment of Healthcare Providers and Systems survey (effective with 10/2019 discharges)
  - Unbundled non-opioid drugs from ASC payments that function as a supply when used in a covered surgical procedure furnished in an ASC

Non-Site Neutral Updates



- Collecting data on off-campus PB ED use
  - Effective Jan. 1, 2019, hospitals must append modifier “ER” to all services furnished in an off-campus, provider-based emergency department
  - Designed to monitor policies that CMS believes lead to growth in OPPS spending
  - CAHs exempt from this reporting
  - Look for manual guidance for implementation, but still effective now
- Payment for certain drugs
  - CMS will reduce payment from WAC+6% to WAC+3% for Part B drugs that do not report ASP, do not receive pass-through payment and are not acquired through 340B program

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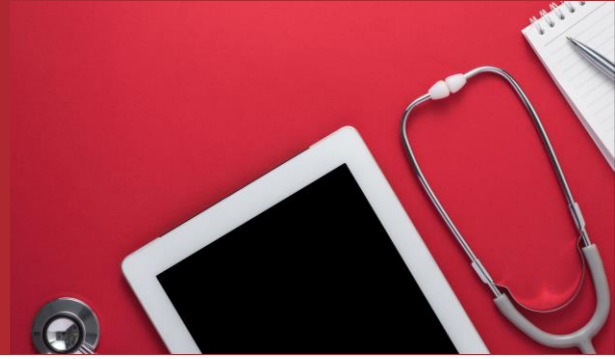
340B Update

340B Legislation Updates



- The 115th Congress (2017-2018) proposed 18 separate bills to amend the 340B Program
- House Energy & Commerce Committee held 3 hearings on the 340B Program and issued a report in January of 2018 outlining what it viewed as necessary reforms to the program
- Senate HELP committee held 3 hearings on 340B
- BUT, no legislative reforms passed

340B Policy Updates

- 2018 OPPS Final Rule
  - Effective 1/1/2018, changed Medicare Part B reimbursement for 340B-acquired drugs from ASP + 6% to ASP – 22.5%
  - 12/27/2018 a federal judge struck down the payment cuts to 340B drugs as beyond HHS's authority
  - Remedy has not been determined yet, and decision likely to be appealed
  - Does not automatically strike the identical payment methodology in 2019 OPPS Rule (would still require presenting 2019 claims for judicial review)
- 2019 OPPS Final Rule
  - Extended the 2018 cuts to 340B-aquired drug reimbursement to non-excepted off-campus provider based departments
  - Current lawsuit focusing on reductions to excepted site reimbursement, but suit on 340B reimbursement likely to be filed in wake of 2018 OPPS decision overturning the underlying 340B drug reimbursement methodology

340B Policy Updates

- 340B Ceiling Price and Civil Monetary Penalties Regulation
  - Implements CMPs for manufacturers who knowingly and intentionally charge a covered entity more than the 340B ceiling price – up to $5000 per instance of overcharging
  - Clarifies the calculation of 340B ceiling price and establishes the “penny pricing” policy of charging $.01 when the calculation equals zero
  - Original proposed rule released June 2015
  - After a series of delays to implementation, rule effective 1/1/2019
  - HHS’s 340B Pricing Reporting System is “forthcoming”

340B Audit & Enforcement Update

- HRSA Audit activity continued to increase through 2018
- Some changes to audit and corrective action process:
  - Newly stated “3-strikes” rule, where covered entities who are found to violate the same finding two or more times may be removed from the program (depending on severity)
  - HRSA Audit Corrective Action Plans must now include points addressing the Areas For Improvement (unless the only findings are AFIs, in which case no CAP is required).
  - Self-disclosures to HRSA now must include Corrective Action Plan

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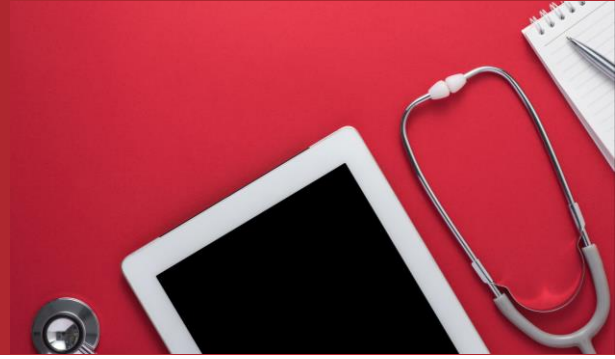
Price Transparency

Price Transparency



- Federal price transparency requirements are here (Eff. January 1, 2019)
  - All hospitals must post standard charges for all items and services furnished by the hospital, as reflected in the hospital's chargemaster
  - Choice of format – but must be "machine-readable" (e.g., XML/CSV, but not PDF)
  - All hospitals must comply – even if already participating in state-required transparency (like Colorado)
  - Considerations:
    - Format and ease of use
    - Other information to include
- More Colorado Legislation?
  - HB 19-1001 – Reports on Colorado uncompensated care

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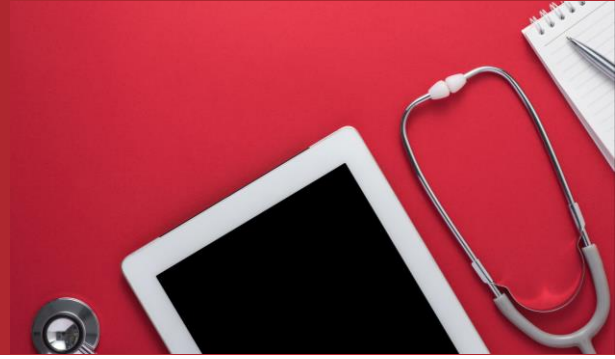
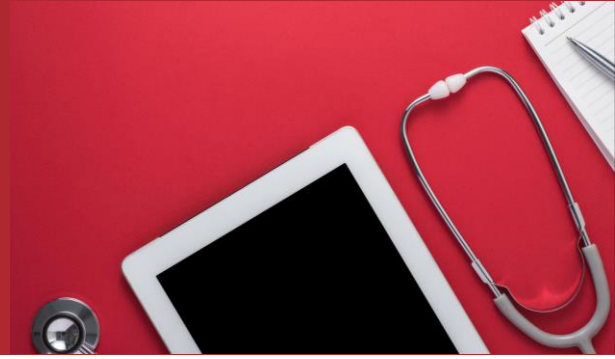
Medicaid Update

Medicaid Update - National



- National ACA lawsuit
  - N.D. Texas finds ACA unconstitutional
  - Stay permits law to remain in effect during appeal
  - No *immediate* threat to Colorado Medicaid expansion
- Continued state flexibility
  - Azar/Verma keep promise to allow states greater waiver flexibility
  - Work requirements
    - New Kentucky work requirements approved by CMS
    - Arkansas work requirements (almost 17,000 removed from coverage)
- Medicaid expansion efforts continue
  - New expansion efforts in Idaho, Nebraska, Utah
  - Additional action in Maine, Kansas
  - Other programs on the line: Montana

Medicaid Update - Colorado



- Governor Polis appoints Kim Bimestefer to continue leadership at HCPF
  - Expect continued emphasis on accountable care initiatives
  - Additional focus on other cost saving/efficiency efforts
- Regional Accountable Entities
- New Colorado legislation
  - Public option – high cost areas (SB19-004) and statewide (HB19-1004)
- Increased use of data/algorithm-driven repayment demands
- New source of guidance – HCPF Memo Series
  - Policy, Operational, and Informational memos
  - Not intended to supplant Provider Manuals/Bulletins

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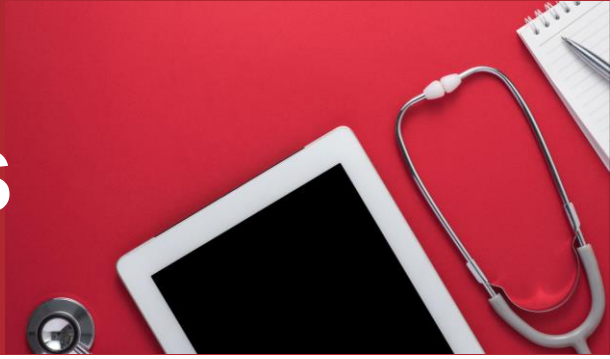
Data, Data, Data: Developments in Data Security and Privacy Laws

Liz Harding, Shareholder
Ryan Morgan, Associate

Data Security and Privacy Laws



- A few statistics to start with:
  - Estimated 12 billion records were stolen during 2018
  - Estimated to rise to 33 billion by 2023.
  - Expected that more than 50% of global data breaches in 2023 will occur in the US.
  - 229 data breaches affecting 6.1 individuals submitted to HHS' OCR breach portal in 2018.
  - Average cost per record lost or stolen = $148
  - Average total cost of a data breach = $3.86 million

Colorado Data Privacy – HB-1128

- Storage Rule: Must implement and maintain reasonable security procedures that are appropriate to the nature of the information and to the nature and size of the business
- Destruction Rule: Mandatory written policy for destruction or disposal of personal identifying information
  - Policy must require that information is destroyed when “no longer needed”
- Breach Rule: If an entity maintains personal information of a CO resident, must notify the resident and the CO Attorney General of any breach within 30 days.
  - Specific items to include in breach notification: info about the breach, credit reporting agency contact info, FTC contact information, suggestion to change password

Colorado Data Privacy – Contrast With HIPAA

HIPAA	CO HB 18-1128
Scope: Personal Health Information (PHI)	Scope: Personal Identifying Information
Security: Administrative, technical and physical safeguards	Security: Reasonable security procedures appropriate to the information and business
Risk Assessment: Optional	Risk Assessment: Mandatory
Breach: Acquisition, access, use or disclosure	Breach: Acquisition only
Notification Timeframe: 60 day limit	Notification Timeframe: 30 day limit
Penalties: Up to $55,910 per violation	Penalties: Up to $2,000 per violation, attorneys' fees for civil actions, treble damages for bad faith.
Destruction/Disposal: None	Destruction/Disposal: When no longer needed

Colorado Data Privacy – Achieving Compliance

- Update / Draft Policies
  - HIPAA policies – account for areas where CO law is more stringent (e.g.: application beyond PHI, risk assessment, breach notification timeframe and mechanics, Business Associate policies)
  - Security Policies – Are current processes appropriate to the nature of the information and to the nature and size of the business?
  - Record Retention Policies - Are records are really needed for full timeframe?
    - Include statement about need for records
    - Address CO-specific destruction procedures
- Update Business Associate Agreements
  - Account for shorter breach reporting timeframe
  - Consider adjusting insurance/indemnity requirements for new CO penalties

General Data Protection Regulation (GDPR)

- Applies to organizations which:
  - Are established in the EU (i.e have offices, servers or employees in the EU);
  - Offer goods and services to individuals in the EU (or to clients/customers which do so); OR
  - Monitor the behavior of individuals in the EU (as a core part of their business).
- Applies to “controllers” and “processors.”
  - Controller – decides how and why personal information is processed. Includes HIPAA covered entities.
  - Processor – processes personal information on behalf of a controller.

General Data Protection Regulation (GDPR)

- Key principals:
  - Lawful basis to process personal information
  - Transparency
  - Rights of individuals (access, correction, portability and erasure)
  - Contractual flow down of obligations from Controller to Processor
  - Security
  - Breach notification
- Fines can be substantial:
  - Greater of EURO20million (approx. $23million) or 4% of global revenue.
  - Portuguese hospital fined $455,000 for failing to properly secure access to patient personal information.

General Data Protection Regulation (GDPR)

- Does GDPR apply to my organization?
  - YES – if you have facilities physically located in the EU
  - YES – if you advertise services to individuals in the EU, use country specific website domains (.fr, .eu, .uk), offer payment in EUROs or GBP.
  - Yes – if you monitor the behavior of individuals in the EU (i.e monitoring of medical device information).
  - YES – if you perform services on behalf of an EU company which involve storing, accessing, anonymizing, deleting, or otherwise using personal information.

  - NO – if you just provide medical treatment for people from the EU whilst they are visiting the US
  - NO – if you are a US company and one of your employees visits the EU on vacation

California Consumer Privacy Act

- Applies to companies that collect personal information from California residents; and
  - Have annual gross revenues over $25million; OR
  - Derive 50% or more of their annual revenues from selling consumers' personal information; OR
  - Annually buy, receive for commercial purposes, sell or share personal information of more than 50,000 consumers, households or devices.
- Does not apply to medical information or PHI…..BUT
  - Applies to other information that "identifies, relates to, describes or is capable of being associated with….a particular consumer or household."
    - Education, finances, employment, internet use, household members and consumer activity.

California Consumer Privacy Act

- Key customer rights and company obligations:
  - the right for customers to opt out of the sale of personal information
  - right of customer access to certain information
  - obligation for company to include customer rights under CCPA in their privacy policy, and specify categories of personal information collected, disclosed or sold to third parties
  - obligation to delete certain customer data upon request and direct third party vendors to do the same
- Penalties:
  - Statutory damages of up to $7,500 per violation for intentional violations.
  - No need for individuals to show proof of hard resulting from a data breach.

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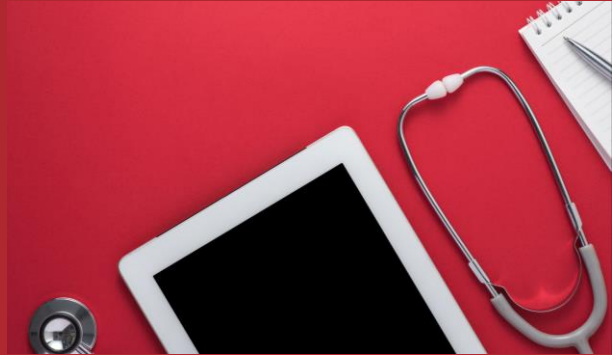
Behavioral Health Update

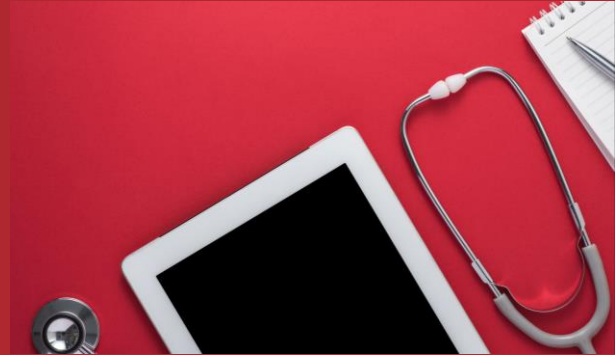
Bragg Hemme, Shareholder

Agenda



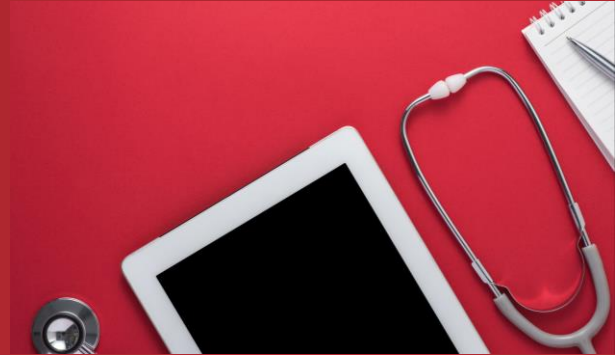
- Revenue and Reimbursement Update
- Mental Health Parity Update
- Emergency Mental Health Holds

Key Drivers



- Opioid crisis and an increase in the population in need of treatment
- Destigmatization of mental health and substance abuse treatment
- Growth in manage care-covered population
- Growth in coverage by government payers
- ACA / Obamacare: expanded insured population and BH / SUD as an essential health benefit
- Parity Law: equivalent coverage for BH as medical

Government Reimbursement - Medicare



Medicare

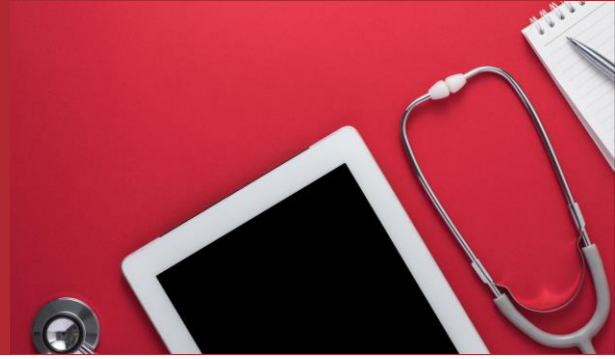
Behavioral Health Integration ("BHI")

- Physician Fee Schedule ("PFS") – provides billable codes for physicians and non-physician practitioners for BHI services in calendar month
  - Goal – integrating behavioral health with primary care
- 2018 – 4 CPT codes for services furnished using the Psychiatric Collaborative Care Model ("CoCM"); 1 CPT for services furnished under different models of care
  - CoCM – model of BHI that enhances primary care services by adding to key services: care management support and regular psychiatric inter-specialty consultation to primary care team
- RHC/FQHCs – 2 new codes effective Jan. 2018
  - General Care Management
  - CoCM

SUPPORT Act

- Expanded telehealth
- Expanded coverage of opioid treatment programs

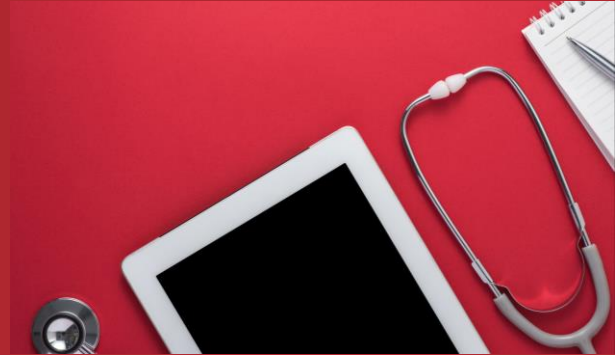
Government Reimbursement - Medicaid



Medicaid

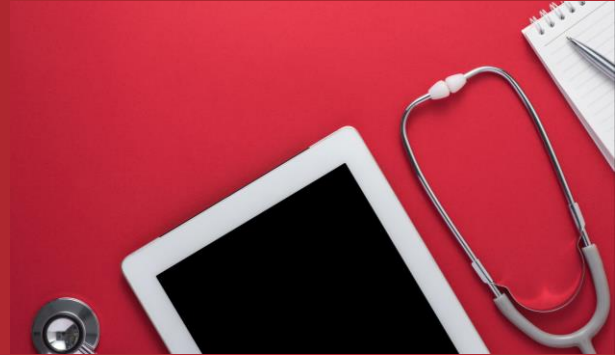
- CO Regional Organizations
  - Mental Health
  - Substance Abuse
- SUPPORT Act – Medicaid Provisions to Address Opioid Crisis
  - Medicaid Protection for at-risk and former foster youth
  - Demonstration project to increase substance abuse provider capacity
  - Medicaid drug review and utilization
  - Medicaid health homes
  - Expanded telehealth
  - Moms/babies
  - Assessing barriers to treatment
  - Additional flexibility for coverage of services by IMD
  - Studies of MAT utilization controls

Private Reimbursement Trends



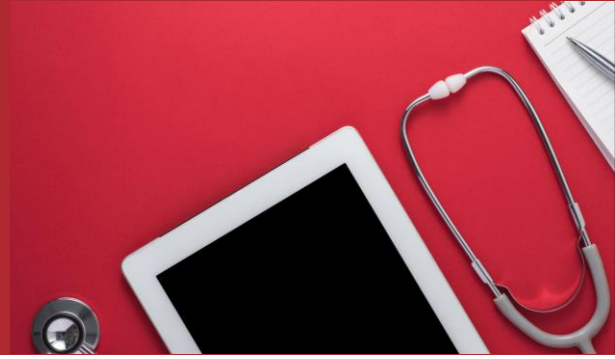
- In-network and Out-of-network audits up
- Payors spending more on substance abuse treatment due to increased coverage mandates
- Audit priority area
- BH is a “soft target” due to:
  - “diversity” of treatment models and payer standards
  - subjectivity of “medical necessity”
  - staff resistance to documentation and compliance norms
  - regulatory hot spots include: Labs, FL model, CPOM

Private Reimbursement Trends



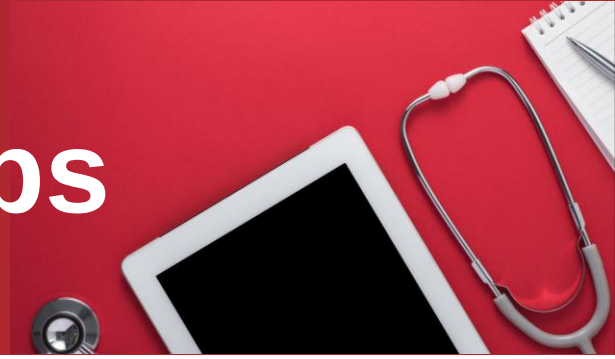
- Decreased Out-of-Network Reimbursement
  - Dramatically decreased rates (30-50% or more)
  - Increased denials and audits
  - Increased delays in payment
  - Increased pre-payment medical record requests
  - Decreased UCR amounts (e.g.: tying UCR to Medicaid or Medicare rates)
- Starting to get sufficient data to consider bundled/value-based models; mostly FFS
- Narrow networks

Parity



- Payors may not impose less favorable benefit limitations on behavioral health benefits than on medical/surgical benefits
  - Look out for higher patient copay/coinsurance, prior authorization requirements, etc.
- Plans forced to increase coverage for behavioral health services → opportunity for additional revenue

Parity – Common Payor Missteps



- Standards for participation, including rates and narrow networks
- Methods for determining UCR
- Restrictions based on geographic location, facility type, provider specialty
- Higher copays, separate deductibles
- Prior Authorization, Day Limits, and higher cost for prescription meds

Parity – Government Enforcement

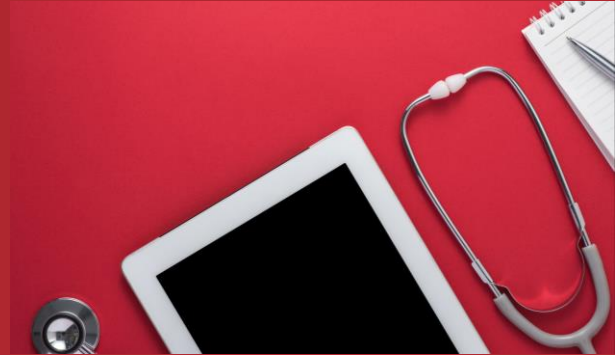
Federal:

- No strong, government enforcement mechanism
- Payors have been less than diligent at ensuring compliance
- Increased government enforcement
  - In 2017, 187 DOL investigations and 92 citations for MHPAEA noncompliance. Stated desire to increase enforcement
  - HHS Parity Portal assists consumers in determining if they have experienced a parity violation

State:

- Consequence of weak federal enforcement, but limited
- Some states enacted parity laws; often stricter than MPHAEA
  - Additional bases to demand or defend reimbursement
  - Protection for fully-insured and other products subject to state regulation (e.g. not ERISA, not Medicare Advantage)

Parity – Provider Enforcement



- Raise Parity as a defense to an audit / recoupment request
- Leverage for negotiation of INN contract, including rates
- Leverage to resolve other disputes
- Report to state Department of Insurance / DOL
- Litigation:
  - Success re: coverage of room/board for residential
  - Success re: autism / ABA Therapy
  - Success re: eating disorder
  - Mixed cases in last year over whether Wilderness Therapy must be covered

Mental Health Holds

SB 17-207 Mental Health Holds, CRS 27-65

- January 1, 2018, mobile response unit or telehealth must be able to respond to a behavioral health crisis (mental health or substance abuse) anywhere in the State of Colorado
- January 1, 2018, all crisis walk-in centers, acute treatment units and crisis stabilization units must be able to care for individuals under a 72-hour mental health hold
- May 1, 2018, an individual who appears to have a mental health disorder and as a result, appears to be an imminent danger to self or others or gravely disabled, may be taken to an “emergency medical services facility,” if a 72 hour facility is not available
- January 1, 2019, annual report required for each emergency medical services facility of persons treated under 27-65 (de-identified, aggregated)

Involuntary Transportation Holds

Involuntary Transportation Holds

- Separate from Emergency Custody and 72-Hour Holds
- If an Individual:
  - Appears to have a mental health disorder, and
  - Is in need of “immediate evaluation” to prevent physical or psychological harm to himself or herself of others
- Intervening Professional (e.g., physician, psychologist) may:
  - Upon probable cause
  - With such assistance as required
  - Transport the individual to an outpatient facility or other clinically appropriate facility designated or approved by the Office of Behavioral Health (“72 Hour Facility”)
  - If such a facility is not available, the individual may be taken to an “emergency services facility”
- CRS 27-65-105(1)(a)(1.5)

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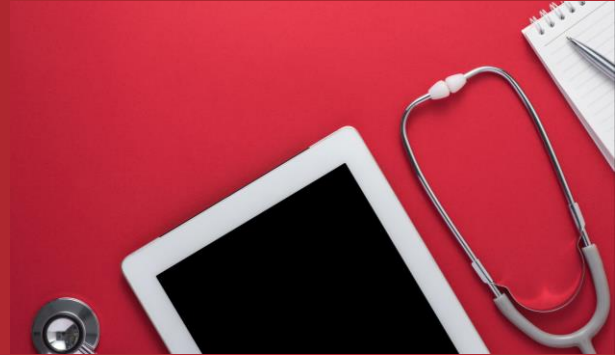
Value Based Care: Alive, Dying or Dead?

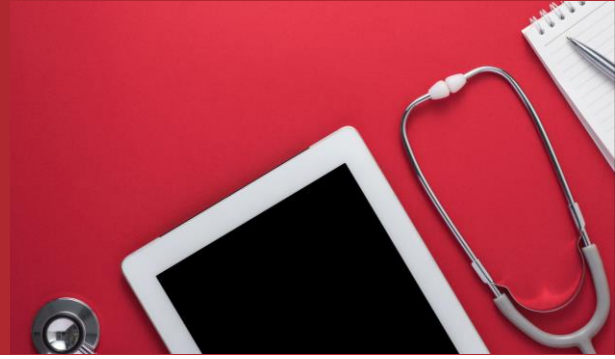
Bruce A. Johnson, Shareholder
Marissa R. Urban, Associate

Objectives



- Understand federal regulatory changes impacting the expansion or retraction of value based care
- Assess rule changes relating to the quality payment program, ACOs and others
  - Medicare Shared Savings Program final rule
  - Innovation Center Models
  - State Level Innovation
- Consider health provider strategic options in light of regulatory changes

Value-Based Care



- “Value-based” health care:
  - Health care delivery and payment models involving financial and other incentives to ensure patients receive appropriate, high-quality care to increase the overall “value” of that care
  - Care delivery and financial incentives linking fee-for-service payments to care quality and “value”
  - Examples:
    - Pay-for-performance
    - Episodes of care and population health
    - Shared savings and risk
    - Linkage to “quality”
    - Hospital Value-Based Payment Program
    - Physician Quality Payment Program/MACRA

Colorado Trends

- Recent articles on health care costs, hospital profits and other variables – Denver Post, Oct. 2018; Wall Street Journal, Dec. 28, 2018
- Urban vs. Rural differences in hospital/health system challenges
- Complexity of multiple public and private sector “value-based” initiatives
- Commercial and self-insured payor inconsistency and/or lack of opportunity on value-based initiatives
- Limited transparency to consumers related to quality and cost
- New Governor and shifting of Colorado legislature
- Federal policy shift and support of state innovation

Medicare Shared Savings Program

- Shared Savings Program (SSP) authorized by Affordable Care Act in 2010
- Authorized Medicare "Accountable Care Organizations" and CMS Innovation Center
- 2012 first performance year for SSP ACOs
- Jan. 2018 – 561 ACOs, serving 10.5M Medicare beneficiaries:
  - Track 1 – Shared savings upside only 460 ACOs
  - Track 1+ – Shared losses 55 ACOs
  - Track 2 – Shared losses 8 ACOs
  - Track 3 – Shared losses 38 ACOs
- CMS observations/perceptions:
  - Some Track 1 models increased costs to Medicare
  - Tracks 2 and 3 have shown savings to Medicare and are improving quality
  - "Low revenue" ACOs (typically physician practices and rural hospitals) outperform High revenue ACOs (typically involving hospitals with more than 100 beds)
  - Mixed historical results; need to migrate to risk

SSP Final Rule^
CMS Policy Objectives

- Accountability – Increase savings for Medicare Trust Funds
- Competition – Encourage physician-only and rural ACOs to provide pathways for physicians to remain independent and preserve beneficiary choice
- Engagement – Regulatory flexibility to permit ACO innovation on care coordination, quality and beneficiary engagement and incentives
- Integrity – Reduce opportunities for “gaming”
- Quality – Improve quality of care for patients through data sharing, interoperability, meaningful quality measures and combatting opioid addiction

^83 Fed. Reg. 67816 (Dec. 31, 2018)

Key Questions to Inform ACO Strategy

1. Should we stay or should we go?
2. Should we create or should we join?
3. ACO participants – keep, trim or expand?
4. Hospital/health system or physician (or other) owned?
5. What's my exit strategy?

Major Changes: SSP Final Rule

- 5 year participation agreement; July 1, 2019 or Jan. 1 start dates
- “Basic” and “Enhanced” Tracks
- Shared savings opportunity (linked to quality) and loss obligations
- Election/mandatory migration to higher level and risk
- Low Revenue, High Revenue, Initial, Renting and Experienced ACOs
- Beneficiary assignment methodology – annual choice
- Payment system waivers – Telehealth and 3 day SNF waivers
- Beneficiary incentives

Basic and Enhanced Tracks

	Basic Track Level A	Basic Track Level B	Basic Track Level C	Basic Track Level D	Basic Track Level E	Enhanced Track (fka Track 3)
Shared Savings 1st $ after MSR	≤ 40% based on quality; 10% benchmark cap	≤ 40% based on quality; 10% benchmark cap	≤ 50% based on quality; 10% benchmark cap	≤ 50% based on quality; 10% benchmark cap	≤ 50% based on quality; 10% benchmark cap	≤ 75% based on quality; 20% benchmark cap
Shared Losses 1st $ once MLR met/exceeded	N/A	N/A	30%; not to exceed 2% of ACO participant revenue; 1% benchmark cap	30%; not to exceed 4% of ACO participant revenue; 2% benchmark cap	30%; not to exceed 8% of ACO participant revenue; 4% benchmark cap	1 minus final sharing rate; minimum of 40%; maximum of 75%; 15% of benchmark cap
Duration; Migration to higher risk	1 year; Mandatory (but Low Revenue extension)	1 year; Mandatory (but Low Revenue extension)	1 year; Elective migration	1 year; Mandatory migration	1 year; Mandatory migration to Enhanced	5 years;
Payment System/ Beneficiary Incentive Waivers	No	No	Telehealth (2020) 3-day SNF (2019) Beneficiary Incent	Telehealth (2020) 3-day SNF (2019) Beneficiary Incent	Telehealth (2020) 3-day SNF (2019) Beneficiary Incent	Telehealth (2020) 3-day SNF (2019) Beneficiary Incent

Low Revenue vs. High Revenue ACOs

- Different rules/opportunities depending on:
  - ACO participant control over assigned beneficiaries (Low vs. High Revenues)
  - Experience with performance-based risk
- Low vs. High Revenue ACOs -- ACO participant TIN percentage of total Medicare Part A & B FFS expenditures for assigned beneficiaries:
  - Low Revenue – less than 35% of total (typically physician owned and rural)
  - High Revenue – 35% or more of total (typically involve hospitals)
- Experienced vs. Inexperienced with performance–based risk
  - Low Revenue Inexperienced -- 2 Basic agreement periods (10 years max)
  - High Revenue Inexperienced -- 1 Basic agreement period (5 years max)
  - High Revenue Experienced – Enhanced Track only
- Initial vs. Reentering ACOs

Benchmarks, Risk Adjustment, Beneficiaries and Pharmacy

- Benchmark rebase at beginning of 5 year agreement period
- Regional benchmarks for all agreement periods
  - Caps and limits on weighting of Regional benchmarks
- Risk Adjustment – use of CMS-Hierarchical Condition Category (HCC) scores to adjust benchmark each performance year (3% positive increase cap over 5 year agreement term)
- CMS corrective action plan and ability to terminate
- ACO annual choice of beneficiary assignment methodology
  - Prospective assignment
  - Preliminary prospective assignment with retrospective reconciliation
  - No Beneficiary “opt-in”
- Beneficiary incentive programs in at-risk models
- Beneficiary notification
- Pharmacy/Part D

Future Steps in Innovation, CMS Innovation Center (CMMI)

- Implements Quality Payment Program (i.e. Alternative Payment Models)
- Tests innovative care delivery models
  - Models often focus on high-cost conditions (i.e. oncology care model; comprehensive ESRD model) or general primary care management (comprehensive primary care plus model)
- Some models required by Congress and the ACA, others created by CMMI as allowed by Section 1115A waiver

Future Steps in Innovation, Controlling Drug Costs

- Part D Enhanced Medication Therapy Management (MTM) Model
  - Allows innovative MTM programs
  - Began in 2017, tested across 5 separate regions with a 5-year performance period.
  - Goal is to improve quality and reduce costs, optimize medication use, and improve care coordination and system links
  - 6 participating sponsors *(e.g.*, BCBS FL, CVS Health, UnitedHealthcare) with 1.7 million beneficiaries enrolled in participating plans
  - First performance year resulted in $325 million net reduction in anticipated spending

Future Steps in Innovation, Controlling Drug Costs

- Maternal Opioid Misuse Model
  - Care often fragmented for pregnant and postpartum Medicaid beneficiaries with opioid use disorder
  - Addresses access to comprehensive services during pregnancy and the postpartum period, fragmented systems of care, and maternity care/substance use provider shortages
  - CMS will solicit participation in early 2019 for 5-year model
  - Overlaps with proposed Integrated Care for Kids (InCK) model that addresses quality and cost concerns for Medicaid/CHIP population, including substance misuse

Future Steps in Innovation, Developments in IT

- Recent focus on information technology developments
  - Artificial Intelligence (AI) Health Outcomes Challenge
    - CMS acknowledges technology leaders using cutting-edge technology to redefine healthcare delivery
    - November 2018, CMS proposes cross-industry challenge/competition to identify how AI can be used in health care models
- Private sector participation in healthcare information technology
  - Amazon
    - Joint venture with JPMorgan Chase and Berkshire
    - Comprehend Medical (machine learning for clinical decision-making)
    - Pill Pack acquisition (competitor Nimble Pharmacy)
  - Google AI
    - Ophthalmology and digital pathology
    - Deep Mind data analytics (pharmaceuticals, patient deterioration)
  - Apple AI, more than just wearables

Future Steps in Innovation, Removing Regulatory Barriers

- Physician Self-Referral Law ("Stark" Law)
  - Prohibits physician referrals for designated health services ("DHS") to entities with which the physician has a financial relationship, unless an exception applies
- Anti-Kickback Statute
  - Prohibits offering, soliciting, providing, or receiving remuneration in exchange for referral of Federal health care program business
- Civil Monetary Penalties Law
  - Prohibits offering or providing remuneration to Federal health care program beneficiaries that is likely to influence beneficiary's choice of provider
  - Prohibits hospital from knowingly making (or physician from knowingly receiving) a payment to a physician to reduce or limit medically necessary services for Federal health care program beneficiaries
- Health Insurance Portability & Accountability Act
  - Restricts use of protected health information without patient consent, except in limited circumstances

Future Steps in Innovation, Removing Regulatory Barriers

- Recent Health and Human Services and CMS Requests for Information regarding removing barriers to value based care in various laws
- Industry players submitted comments
  - Fraud and abuse waivers for value-based arrangements similar to those used in the Medicare Shared Savings Program (MSSP)
  - Changes to FMV requirements and Advisory Opinion process
  - Creation of value-based exceptions
  - Ability to share technology/infrastructure
- Part of Agency's "regulatory sprint" to coordinated care
  - TBD, but the future suggests value

Implications – Alive, Dying or Dead?

- Where you stand depends on where you sit
  - 10 SSP ACOs in Colorado; 8 Track 1 (shared savings only); 1 Track 2, 1 Track 3
  - Mixed use of MSSP fraud and abuse waivers
- Perceptions in Colorado regarding health care costs and role of hospital/health systems in addressing
- Federal encouragement of state level innovation
- What might the future hold?
  - ACO Improvements Act – 116th Congress
  - CMMI Direct Provider Contracting models on horizon
  - Regulatory alignment and consistency at state level
  - Shared savings offerings in commercial plan design and TPA support
  - Provider incentives
  - Capital, innovation and infrastructure (i.e., Private Equity; super MSO)
  - Transparency and beneficiary incentives
- Value-Based Care – Not Dead Yet!

POLSINELLI

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Colorado Hospital Association

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