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TWENTY-EIGHTH ANNUAL
CORPORATE COUNSEL SYMPOSIUM
TUESDAY, OCTOBER 31, 2017

Behind the Headlines: What's Really Happening in Health Care?

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Program Materials are available on www.dorsey.com at https://www.dorsey.com/NewsResources/Events/Event/2017/10/Corporate-Counsel-Symposium-2017-Materials

1. PowerPoint Presentation

2. Dorsey Health Law Blog: *New Medicare Proposals that Reduce Payment to Hospitals for 340B Drugs in 2018*, Nicole Burgmeier and Alissa Smith (July 18, 2017) https://dorseyhealthlaw.com/new-medicare-proposals-that-reduce-payment-to-hospitals-for-340b-drugs-in-2018/

For more information on **health law** matters, see Dorsey's *Health Law Blog* at https://dorseyhealthlaw.com/.

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Behind the Headlines: What's Really Happening in Health Care?

Charlie Johnson, ***Managing Counsel, Prime Therapeutics LLC***

Ross D'Emanuele, Melinda Maher and John Marti,
Dorsey & Whitney LLP

Tuesday, October 31, 2017

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Topics

- **Affordable Care Act: Executive Order, CSRs, and "Synthetic Repeal"**
- **Health Care Fraud Enforcement**
- **Drug Pricing**
- **Opioid Crisis**

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2016 Health Insurance Enrollees (From Kaiser Family Foundation)

• Employer coverage:	155,965,800	48.9%
• Medicaid:	62,384,500	19.6%
• Medicare:	43,308,400	13.6%
• Uninsured:	28,965,900	9.1%
• Non group:	21,816,500	6.8%
• Other public:	6,422,300	2.0%
•	_____	
• Total:	318,863,400	

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Affordable Care Act: "Synthetic Repeal"

Without successful legislation to repeal and replace, the Trump Administration is trying a "Synthetic Repeal" by:

- **Ending ACA Cost Sharing Reduction (CSR) Payments**
- **Enacting regulations to soften and reduce the ACA contraceptive coverage mandates**
- **Making Association Health Plans more feasible**
- **Making Short Term Limited Duration Insurance Policies more feasible**
- **Making Health Reimbursement Arrangements (HRAs) more feasible**

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Cost Sharing Reduction Payments

- Cost sharing reduction payments enable certain low-income individuals to get help with deductibles or copayments
  - Premium tax credits are available to eligible individuals with incomes between 100%-400% federal poverty line for insurance purchased through exchanges
  - Cost-sharing reduction payments are available to eligible individuals with income between 100%-250% federal poverty line, reducing deductibles, copays and coinsurance
- ACA requires insurers to credit the cost sharing reductions to qualified individuals and then insurers would then be reimbursed for CSR payments from the federal government
- The Republican members of the House of Representatives sued in 2014 claiming that the CSR payments were not appropriately funded

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How Will States and Carriers Handle the End of CSR Payments?

- 18 states and the District of Columbia are suing the Trump Administration
- Carriers, overseen by state regulators, considered it as part of 2018 premium setting:
  - 8 states appear to have assumed CSR payments would continue throughout 2018.
  - 7 states are spreading the CSR load evenly across all individual market plans, both on and off the exchange.
  - 29 states appear to be "Silver Loading"...that is, loading the cost onto Silver plans only, both on and off exchange.
  - 11 states appear to be placing the CSR load on the Silver Exchange Plans only, which allows the premium subsidies to go up.
  - These add up to more than 50 because some states have a mixed strategy, with different carriers choosing different paths.

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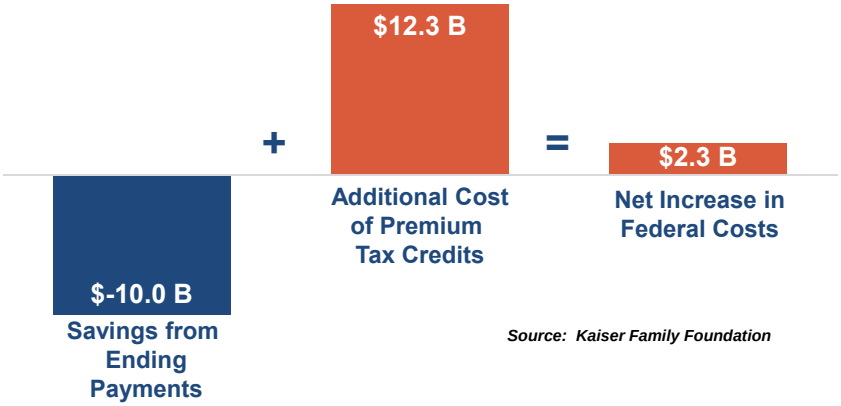
Impact of Stopping ACA Cost Sharing Reduction Payments in 2018



Source: Kaiser Family Foundation

Contraceptive Changes

- On October 6, 2017 the Department of Health and Human Services and the Department of Labor issued interim final rules.
- The rules allow nonprofits and for-profit employers with an objection to contraceptive coverage based on religious beliefs to qualify for an exemption and drop contraceptive coverage from their plans.
- The regulations also exempt all with moral objections to contraception except publicly traded employers.

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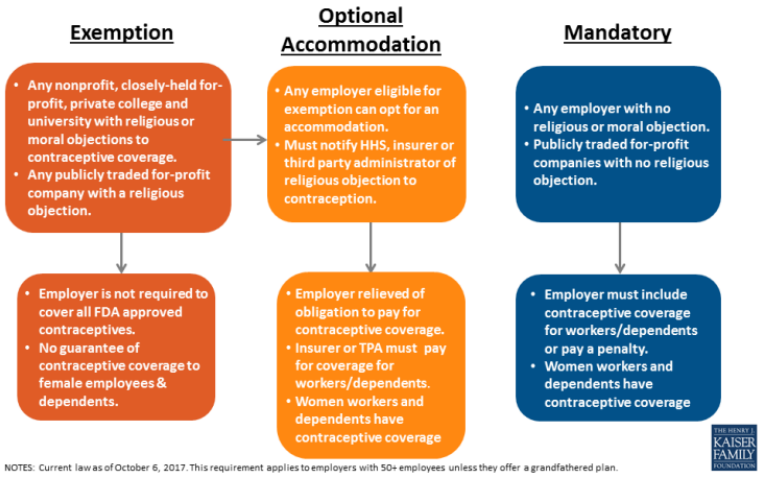
Figure 1

Employers Objecting to Contraceptive Coverage: Exemptions and Accommodations Under the Trump Administration Regulations



NOTES: Current law as of October 6, 2017. This requirement applies to employers with 50+ employees unless they offer a grandfathered plan.

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Association Health Plans (AHPs)

- **Loosening restrictions on AHPs make it easier for unrelated employers or individuals to group together to purchase insurance or to self insure**
- **What will this do?**
  - **Negative view: (i) siphon off healthy individuals into the AHPs, leaving the sicker individuals on the Exchanges – thereby further damaging the Exchanges (ii) impinge upon states' regulation of insurance**
  - **Positive view: More choice; more flexibility. Putting smaller employers and individuals on the same footing as large employers who self fund across state lines.**
  - **Another view: may not have much impact, particularly in the near term, due to non-legal constraints such as provider networks.**

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Short Term Limited Duration Insurance (STLDI)

- This type of insurance is issued to individuals (not groups) and traditionally has been designed for gaps in more robust insurance coverage (e.g. individuals between jobs)
- Was exempted from much of ACA (e.g. lifetime or annual caps and pre-existing condition exclusions may still apply)
- Trump administration looking to expand STLDI reach (e.g. longer time period than 3 months permitted)
- Positive view: allows more flexibility in the marketplace, particularly for younger and healthier individuals
- Negative view: siphons off the young and healthy from the Exchanges and larger insurance pool; takes away ACA protections for unsuspecting purchasers

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Health Reimbursement Arrangements (HRAs)

- Employers may contribute money into HRAs on a tax favored basis to be used by employees for health care
- ACA reduced the ability of employers to use HRAs for active employees unless they were also paired with major medical plans
- The Trump administration appears to want to increase HRA use (not clear as to exact ways yet)
- Positive view: more flexibility in the marketplace; it makes sense, particularly for smaller employers, to be able to use HRAs to allow employees to purchase insurance on the Exchanges or open market; “defined contribution” health plans are attractive to employers
- Negative view: Could result on less healthy on the Exchanges; could increase cost to the federal government

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What is next for the ACA?

Alexander (R-TN) – Murray (D-WA) bill to continue cost sharing reduction payments for 2 years while giving states more flexibility to offer wider variety of health insurance plans

- **President Trump liked it, then did not like it**
- **Speaker Ryan opposes it (as of 10/23)**
- **White House (as of 10/23) says that it wants the following to be added to the bill:**
  - **Lift individual mandate penalty for 2017 and employer mandate penalty for 3 years**
  - **Expand STLDI and AHPs**
  - **More flexibility for the states**

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What is next for the ACA?

- **A "real" (not synthetic) repeal and replace not likely in the near term: tax reform will now take precedence (using the reconciliation process in the Senate, which requires 51 votes rather than 60 votes to avoid a filibuster)**
- **But look for something about health care in the tax bill ….?**
- **Why? Current exclusion from tax for health care was $659 billion from 2010-1014. Compare this to the mortgage exclusion ($484 Billion), Capital Gains exclusion ($303 billion), Defined Benefit Plans exclusion ($303 billion) and Defined Contribution exclusion ($212 billion) for the same time period**

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State Drug Pricing Laws

- **California SB17**
  - Manufacturer of any prescription drug with a Wholesale Acquisition Cost (WAC) > $40 per course of therapy must notify each CA purchaser (60 days prior) if they increase WAC more than 16%. See Cal. Health & Safety Code § 127677(a).
  - Must also provide quarterly report to OSHPD that include:
    - Factors increasing the drug's WAC and describing how these factors explain the increase;
    - Schedule of WAC increases for previous 5 years if the drug was manufactured by the company; and
    - If the drug was acquired by the manufacturer within the previous five (5) years, information about the WAC price at time of acquisition, sales volume, purchase price, etc. See Cal. Health & Safety Code § 127679(a).
  - Manufacturers must notify OSHDP within 3 days after the release of any new prescription drug at a WAC that exceeds the Medicare Part D specialty drug threshold (currently $670) See Cal. Health & Safety Code § 127681(a).
  - Manufacturer report to OSHDP regarding such new prescription drug:
    - Marketing and pricing plans for new drug launch (U.S. and international);
    - Estimated patient volume;
    - If drug has FDA breakthrough therapy designation or priority review; and
    - Acquisition date and price if drug not developed by the manufacturer. See Cal. Health & Safety Code § 127681(b).
  - New reporting for CA health plans.
- **Maryland**
  - A manufacturer or wholesaler distributor may not engage in price gouging in the sale of an essential off-patent or generic drug. Md. Code Ann., Health §§ 2-801 - 2-803.
  - "Price gouging" means an unconscionable increase in price, defined as an increase that is excessive and not justified by production cost or expansion of access, and results in consumers having no meaningful choice to purchase at the excessive price.
  - Attorney General can demand a manufacturer or wholesale distributor of an essential off-patent or generic drug to justify a price increase.
  - A MD circuit court, upon AG request, may enjoin violation, restore to consumer and payors money resulting from price gouging, make drug available to state purchasers at price prior to violation, and impose of civil penalty.
- **Nationwide, over 230 bills addressing pharmaceutical access and pricing introduced in 2017 in state legislatures.**

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Medicare 340B Drug Price Proposal

- **CMS stated that its current reimbursement rates, "…allow[s] these providers to generate significant profits when they administer Part B drugs." Specifically, CMS proposes to reduce its reimbursement to hospitals for certain 340B covered drugs from the average sales price (ASP) plus 6 percent (which is the current reimbursement for prescription drugs paid by Medicare) to ASP minus 22.5 percent.**
- **Dorsey Health Law Blog Article on Proposal: dorseyhealthlaw.com**

State Laws on "Clawbacks"

- **CT Public Act No. 17-241**
  - **No health carrier or PBM shall require an individual to pay for a covered prescription drug at the point of sale in an amount greater than the lesser of: (1) the applicable copayment; (2) the amount the carrier or PBM pays the pharmacy; or (3) the amount of the drug if the individual purchased it without using their health insurance.**
- **5 other states have laws combatting the same practice.**

Opioid Crisis

- **What would declaring a national public health emergency do?**
  - **Access to the disaster relief fund possible**
  - **HHS Secretary declaration of a public health emergency would allow emergency use authorization for medication and waiver of state licensure for deployment of medical personnel**
  - **Medicaid waivers to facilitate federal funding for services currently not funded (e.g., certain inpatient addiction facilities)**

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Opioid Crisis

- **Payer/PBM Strategies:**
  - **HIPAA permitted data analysis to identify potential abuse.**
  - **Targeted patient education efforts in partnership with pharmacies and prescribers.**
  - **Utilization management from benefit designs that favor less addictive alternatives.**
  - **Benefit designs that limit the number of pills dispensed or who can prescribe.**
  - **Fraud, waste and abuse monitoring to identify and act against problematic prescribers or pharmacies.**
  - **Ensuring the availability of Naloxone or other life-saving treatments.**

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Opioid Crisis

- **State Prescription Drug Monitoring Programs (PDMP)**
  - **Some states (e.g., AZ, CA, ME) require a prescriber to consult the PDMP database before prescribing, and on an ongoing basis for so long as prescribing is part of treatment.**
  - **MN Stat. § 152.216 does not mandate that prescribers consult the database.**
- **Chicago Drug Rep Licensing**
  - **Beginning July 1, 2017, pharmaceutical representatives who market or promote pharmaceuticals within the City of Chicago for more than 15 days per year must obtain a license. Reps must complete online education at the time of initial application and then at least 5 hours per year of approved continuing education thereafter. Reps must also disclose information on the marketing or promotion of Schedule II controlled substances on the Chicago Department of Public Health website.**

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Thank you.