[Sutter Case Watch] A Huge Deal: Settlement Terms of Sutter Health Antitrust Case Will Promote Transparency and Competition in California Provider Markets

The high-profile antitrust case against Sutter Health settled on the eve of trial in October 2019, when the Northern California hospital giant reached a preliminary settlement agreement with the California Attorney General's office and class action plaintiffs after five years of litigation. The terms of the settlement were released late December, which include both monetary compensation for the private plaintiffs and injunctions against Sutter's conduct that will restore competition and promote transparency in the provider market.

In this post, we dissect the terms of the proposed settlement agreement and discuss how these terms may address and resolve Sutter's alleged market dominance and anticompetitive contracting practices that drive up healthcare prices.

Over Half A Billion Dollars in Monetary Damages to Appease Private Plaintiffs

As an initial matter, Sutter agreed to pay $575 million in damages to resolve private claims that the hospital system used its market power to force patients to pay inflated prices for healthcare services. This one-time all cash payment, which represents 60% of the nearly $1 billion damages that plaintiffs sought at trial, will be distributed to compensate self-funded employers and union trusts that brought the initial class action case, as well as cover administrative and legal fees.

Injunctions Against Anticompetitive Contract Terms to Appease the State AG

Far beyond the effect of monetary compensation is the injunctive terms of the settlement that promise to bring more far-reaching implications to California's provider market and potentially create ripple effects across the country.

In the consolidated lawsuit against Sutter, both the California AG and private parties United Food and Commercial Workers union (UFCW) and Employers Benefit Trust (UEBT) claimed Sutter engaged in anticompetitive behavior by using three specific types of contract provisions in its contracting practices, namely all-or-nothing, anti-incentive (anti-steering or anti-tiering), and price secrecy terms. (see The Source Blog for details of these claims). The settlement agreement enjoins Sutter from enforcing each of these anticompetitive provisions in all prior, existing, or future contracts with insurers:

- All-or-nothing contracts: Sutter cannot require insurers, employers and self-funded plans to include all of Sutter's facilities and products in their provider networks by leveraging must-have providers. Sutter cannot condition participation or hospital pricing on the inclusion of other Sutter providers that the health plan would otherwise exclude in a network. The settlement agreement would allow insurers to pick and choose hospitals within the system. Additionally, Sutter must cease bundling services and products to require the purchase of more services than necessary. Sutter is required to offer stand-alone pricing that must be lower than any bundled package price to offer insurers more choice.

- Anti-incentive provisions: Sutter is prohibited from using anti-steering and anti-tiering contract terms that impede payers' use of incentives, including differences in co-payments, co-insurance, and information as to quality and cost-effectiveness, to direct patients to cheaper and higher value health care providers. Sutter must allow the creation of narrow networks, tiered health plans, reference pricing, and value-based benefit design.

- Price secrecy or gag clauses: Sutter is prohibited from using gag clauses that prohibit insurers from disclosing prices for their healthcare services. Sutter is required to increase price transparency by allowing insurers and

employers to give their members access to pricing, quality, and cost information for purposes of comparison and making better health care decisions.

Beyond the requirement to cease anticompetitive contracting practices, the settlement agreement imposes additional restraints that target Sutter's conduct:

- Out-of-network charges: The settlement requires Sutter to limit charges for out-of-network services to remedy supracompetitive out-of-network prices that Sutter was allegedly able to demand as a result of its market dominance and anticompetitive practices. These caps are reinforced by limits on allowed annual increases in Sutter's billed charges for five years for out-of-network care that include trauma care, emergency room care, rural hospitals, and other more easily steered in-patient and out-patient hospital care. The limit on out-of-network charges will in turn prevent surprise billing.

- Market consolidation: The settlement agreement carves out exceptions to the injunctions against Sutter in cases of clinical integration and patient access consideration. Because clinical integration can be used as a way to mask market consolidation efforts, Sutter is required to set clear definitions for these terms to prevent it from abusing the exceptions to achieve anticompetitive purposes. Specifically, in order to claim that it has a clinically integrated system, Sutter must meet specific coordination of care standards, as mere geographic proximity and record sharing will not be enough to make this claim.

- Compliance monitor: An experienced, court-approved compliance monitor will oversee Sutter's contracts with insurers for ten years to ensure compliance with the specified parameters of the settlement terms. Sutter will pay all costs associated with the monitoring, which can be extended one time for an additional three years.

Winners, Losers, and Implications of the Settlement

What do these terms all mean for Sutter, insurers, consumers, and even beyond the California provider market? There was much anticipation that the Sutter case, had it gone to trial, would shed light on Sutter's business practices. The trial was scheduled to last at least three months, with 340 potential witness and 13,000 exhibits. As such, it was in Sutter's interest to settle outside of the courtroom so that much of its contracting practices would remain hidden. Also notable is that the settlement terms do not include findings of wrongdoing or that Sutter's contracting practice affected price and competition.

Nonetheless, there is much to celebrate, given the scope of the injunctions and their potential ripple effects across the country. As one of the largest actions against anticompetitive conduct in the health care marketplace in the nation, California AG Xavier Becerra called the "first-in-the-nation" settlement a "game-changer" that provides "unprecedented levels of injunctive relief to restore competition in the market."[1] The injunctions imposed against Sutter place significant restrictions on Sutter's use of market power to restrain competition and drive up healthcare prices in Northern California. The prohibition of anticompetitive contract terms and restraints on out-of-network charges and market consolidation work collectively to promote greater transparency and competition that would in turn lead to greater choice and lower costs for patients. Moreover, Health Access California, a health care consumer advocacy coalition, believes the settlement's aim at out-of-network charges gives support to federal and state efforts to enact surprise billing legislation.[2] Finally, as extra security, compliance monitoring of up to thirteen years promises to keep Sutter in line for the foreseeable future.

The American Hospital Association (AHA), however, suggests the real winner from the settlement is the commercial health insurance industry, as it would give insurers the ability to "cherry-pick the hospitals with which they contract,"[3] giving them better contracting terms and making contracting with dominant insurers more expensive. While AHA warns that insurers, instead of consumers, will reap most of the benefits, experts are optimistic that premiums may see gradual, albeit not significant, changes.[4] As Sutter is prohibited from inflating prices, insurers will be able to negotiate lower prices in the long term once competition is restored in the market.

Beyond the effects on healthcare market competition and prices in California, the Sutter settlement could have more significant implications for other large health systems across the country. As The Source Executive Editor Professor Jaime King pointed out in a post-settlement podcast, Sutter is a model for many other hospital systems around the country. In a recent quote for Kaiser Health News, she indicated that while a settlement does not set a legal precedent, the outcome of this case "is strong guidance that the kinds of behavior Sutter engaged in are not going to be allowed going forward."[5] This sends a clear message to those health system that could lead to changes in existing and future conduct in those systems. Furthermore, Professor King believes this settlement "really opens the door for attorneys general in other states to begin examining their own health systems for similar behaviors," which could pave the way for other state enforcement actions outside of California, to the benefit of healthcare consumers nationwide.

The settlement agreement is set for a preliminary approval hearing on February 25 by San Francisco Superior Court Judge Anne-Christine Massullo. Stay tuned as The Source Blog continues to bring the latest developments in this historic case.

---

[1] Press Release: *Attorney General Becerra: State, Unions, Employers, and Workers Reach Settlement to Address Alleged Anticompetitive Practices by Sutter Health that Increased Healthcare Costs for Californians*, Dec. 20, 2019.

[2] Don Thompson, *Health system pays $575 million to settle anti-trust lawsuit*, AP News, Dec. 20, 2019.

[3] Tara Bannow, *Sutter Health to pay $575 million antitrust settlement with up to 13 years of monitoring*, Modern Healthcare, Dec. 20, 2019.

[4] Jenny Gold, *California AG Details 'Historic' Settlement Agreement In Sutter Health Antitrust Case*, Kaiser Health News, Dec. 20, 2019.

[5] *Id.*

DOJ and FTC Release Draft Updated Guidelines for Vertical Mergers

On January 10, the Department of Justice (DOJ), along with the Federal Trade Commission (FTC), released a new draft guideline for vertical merger review. As opposed to horizontal mergers, vertical mergers generally combine entities that operate at different levels in the same supply chain. As vertical mergers become more commonplace in the healthcare industry, they are increasingly raising antitrust concerns as they often times don't trigger the same level of scrutiny as do horizontal mergers.

The much needed new guidelines specifically targeting vertical mergers serve to withdraw and update the DOJ non-horizontal merger guideline from 1984. The new guidelines adopt the principles and analytical frameworks used in the agencies' Horizontal Merger Guidelines, and adapt the antitrust review criteria and enforcement policy as specific to vertical mergers.

The draft guidelines are open for public comment for 30 days. Download the draft guidelines here and read the DOJ press release for more information.

California's 2020-2021 Budget Proposal Aims at Consolidation and

Drug Pricing

On January 10, California Governor Gavin Newsom released his 2020-2021 State Budget proposal. While the state budget process will not begin in earnest until after the Governor's May Revise, the state budget provides a glimpse of likely California health care reforms.

The Governor's January Budget Proposal proposes the following:

Proposal	Goals
Office of Health Care Affordability	• Increase price and quality transparency • Develop cost targets for health care industry • Address hospital cost trends by region, with focus on cost increases driven by delivery system consolidation • Establish standards for advance evidence-based and value-based payments
Medi-Cal Best Price	• Expand Department of Health Care Services (DHCS) authority to negotiate state supplemental rebates based on best prices offered by manufacturers internationally rather than other purchases within the United States

Golden State Drug Pricing Schedule	• Establish a single market for drug pricing by including: - Medi-Cal; - California Public Employees' Retirement System (CalPERS); - Covered California; - Private insurers; - Self-insured employers; and - Others • Drug manufacturers would bid to sell drugs at a uniform price in the California market • California would invoke a most-favored-nation clause (MFN) in the price bid, which would require manufacturers to offer California prices at or below what is offered in any other state, nation, or global purchaser
Generic Contracting Program	• Establish the state's own generic drug label via contracts with one or more generic drug manufacturers • Manufacture certain generic drugs on behalf of the state and participating entities
Center for Data Insights and Innovation	• Among other things, increase the state's ability to create evidence-based programs and maximize federal reimbursements • Allow policymakers to use linked data to inform policy and decision making • Increase collaboration between university-based researchers and state staff to translate data into knowledge
Medi-Cal Healthier California for All Initiative	• Reduce complexity in Medi-Cal. • Improve quality outcomes and change delivery system transformation via value-based initiatives, modernization of systems, and payment reforms

Universal Coverage for Medi-Cal	• Expand eligibility for full-scope Medi-Cal benefits to all persons aged 65 years and older, regardless of immigration status, no sooner than January 1, 2021. This is already expanded to children and young adults (under age 26)
Supplemental Payment Pool for Non-Hospital 340B Clinics	• Creation of a new supplemental payment pool to pay non-hospital clinics for 340B pharmacy services, starting January 1, 2021

These budget proposals aim to increase health access and lower healthcare costs (particularly prescription drug costs). How these proposals will end up in the final budget remains to be seen. Stay tuned!

The Source Roundup: January 2020 Edition

Happy New Year! We hope you had an exciting start to the new decade! In this edition of the Source Roundup, we cover articles and reports from December that discuss: (1) increase in US health care spending in 2018, (2) health system affiliation and how it affects patient access, (3) out-of-network provider charges between 2012 and 2017, and (4) how billing in-network could save millions.

U.S. Health Care Spending Increased 4.6 Percent to Reach $3.6 Trillion in 2018

In the Health Affairs article National Health Care Spending in 2018: Growth Driven By Accelerations In Medicare and Private Insurance Spending, Micah Hartman et al.

examine the increase in health care spending in the U.S. in 2018 as compared to the previous two years and the share of the economy devoted to health care spending, and discuss what influenced these two numbers. According to the authors, U.S. health spending in 2018 increased 4.6 percent to reach $3.6 trillion, which was a faster growth than the rate of 4.2 percent in 2017, but the same rate of growth as 2016. This growth is largely attributed to the increase of the net cost of health insurance. The Consolidated Appropriations Act, a health insurance tax, was imposed on all health care insurance providers as part of the funding for the Affordable Care Act in 2014. On the other hand, the share of the economy devoted to health care spending declined to 17.7 percent in 2018, a decrease of 0.4 percent from 2017, attributed to a growth in private health insurance and Medicare (which were both influenced by the reinstatement of the health insurance tax). Health care expenditures amounted to approximately $11,172 per person in 2018. Drug prices rose relatively slowly in 2018, which indicates that buyers are being smarter and perceptive while researching for generic alternatives and other ways to avoid high-priced medicines. The increase in spending is said to be fueled primarily by a tax on private and federal insurance providers as the IRS's estimate of the tax in 2018 was $14.3 billion. These numbers show that health care insurers are pushing a lot of the financial burden onto financially-struggling consumers, which are in turn contributing to a health care affordability crisis.

Health System Affiliation for Rural Hospitals May Be Detrimental to Patient Access

In Access, Quality, And Financial Performance Of Rural Hospitals Following Health System Affiliation, published by Health Affairs, Claire O'Hanlon et al. look at the effects of health system consolidation on rural hospitals. The study compared rural hospitals that affiliated with a health system between 2008-2017 with a propensity score — "a weighted set of nonaffilliating (sic) rural hospitals on twelve measures of structure, utilization, financial performance, and quality." According to the authors, affiliated hospitals experienced reductions in services including on-site diagnostic imaging technologies, the availability of primary care services and specialists like obstetrics, and outpatient nonemergency visits. The study also found that these

affiliated rural hospitals dealt with a significant increase in operating costs. Therefore, the authors believed that while being affiliated with health systems may be financially beneficial for rural hospitals, such consolidation may hurt patient access to care.

An Analysis of Provider Charges from 2012-2017

In a study done by the USC-Brookings Schaeffer Initiative for Health Policy, Loren Adler et al. analyze provider charges between the years 2012 and 2017. Provider charges are prices usually set by the medical provider and represent a list price for the services they provide. For most patients, the negotiated price between their insurance plan and medical provider is more important than the list price because that determines cost-sharing between the insurance provider and the patient. When a patient goes to an out-of-network provider, willingly or unwillingly, they are susceptible to large unsuspected, or surprise billing. The charges, usually from emergency and ancillary clinicians, are unilaterally set by the medical providers and are subject to minimal market constraint. The authors analyzed data on charges for providers treating Medicare patients between 2012 and 2017 and found that emergency and ancillary physicians, specialties that possess the ability to surprise bill patients, generally charged significantly higher amounts relative to Medicare rates than other specialties. Emergency medicine and anesthesiology specialties have had roughly forty percent growth in the five-year period as compared to other specialties (relative to Medicare costs). Furthermore, the ratio of mean charges to Medicare payment rates for these specialties varied significantly; rates ranged from four times Medicare rates to eleven times Medicare rates. The analysis showed that provider charges have increased throughout the five-year period relative to Medicare costs, but the steepest rises in costs come from emergency and ancillary medicine specialties.

Billing In-Network Could Save $40 Billion Annually

Similar to the USC-Brookings Schaeffer study, the Health Affairs article Out-Of-

Network Billing And Negotiated Payments For Hospital-Based Physicians also discusses out-of-network provider billing. Zack Cooper et al. examine the resulting financial risks and lack of a functional health care market from out-of-network charges. The study found that even at in-network hospitals, 11.3 percent of cases involving an assistant surgeon, 11.8 percent of anesthesiology care, 5.6 percent of claims for radiologists, and 12.3 percent of care involving a pathologist were billed out of network. The authors predicted that if the above specialists billed in-network, it would lower physician payments for privately insured patients by 13.4 percent and reduce health care spending for patients with employer-sponsored insurance by 3.4 percent. The total savings would equal approximately $40 billion annually. Out-of-network billing is prevalent at hospitals in concentrated and for-profit hospitals. Cooper et al. believe that patients need to be protected from financial harm and any policies that come out of this issue should introduce a competitive price for physician services or require providers to be transparent about how much a patient must pay if they are treated by an out-of-network physician.

That concludes this month's Roundup. If you find articles or reports that you think should be included in the monthly Roundup, please send them our way. Happy reading!

[Sutter Case Watch] BREAKING: Settlement Terms Released for Landmark Antitrust Case against

Sutter Health

Today, California Attorney General Xavier Becerra announced the settlement terms for the landmark antitrust case, *UFCW & Employers Benefit Trust v. Sutter Health*.

Sutter Health was alleged to engage in anticompetitive behavior by requiring "all or nothing" contracts, preventing insurance companies from providing tiered health plans, setting extremely high out-of-network rates, and restricting price transparency of provider cost information and rates. As Source Executive Editor Jaime King explains in a Tradeoffs episode, The Train Has Left the Station, "[t]his is a huge case. Sutter is a huge entity in Northern California in terms of health care, and it's really been a model for a lot of other systems around the country." The terms of this settlement may potentially reverberate among other large health systems and inspire other attorney generals to bring similar suits.

According to the Attorney General's press release, the settlement includes Sutter:

- Paying $575 million for compensation and legal fees
- Limiting out-of-network charges
- Increasing transparency to pricing, quality, and cost information
- Allowing patients access to lower-cost plans
- Stopping all-or-nothing contracting deals
- Ceasing anticompetitive bundling of services and products and instead offer a stand-alone price that must be lower than any bundled package
- Having a court-approved compliance monitor to ensure that Sutter is following the terms of the settlement for at least 10 years
- Clearly setting definitions on clinical integration and patient access consideration to prevent using clinical integration as a way to mask market consolidation

The press release by the Attorney General can be found here. The video of the press conference can be found here. The settlement filing can be found here.

The settlement still requires court approval with hearings slated to happen in February 2020. We will bring you more analysis in the new year!

Federal and State Price Transparency Efforts Face Legal Challenges from Industry Groups

Price transparency in healthcare is a hot topic that has captured the attention of many policymakers. While both federal and state governments have made efforts to promote price transparency in recent years, the path to achieving it is expected to be a bumpy one, as powerful industry groups that resist such change, including hospitals and pharmaceutical companies, are quick to seek legal challenges to block such efforts. In this edition of Litigation and Enforcement Highlights, we examine the latest lawsuits that challenge legislation to promote price transparency in healthcare and how they fared in courts.

Hospitals Sue Trump Administration over Disclosure of Negotiated Price

Late November, the Trump administration issued a new federal rule that would require hospitals to publicly disclose the actual discounted rates they negotiate with insurers for medical supplies and procedures. The Final Rule, set to take effect in 2021, targets the secretive nature of hospital pricing and seeks to promote consumer price shopping of healthcare services.[1] The hospitals, including the American Hospital Association (AHA), were quick to fight back, filing a lawsuit in the U.S. District Court for the District of Columbia just a week later to challenge the Final Rule.

In the complaint, plaintiffs argue that the administration does not have the legal authority to compel such disclosure of proprietary information. Specifically, while Section 2718(e) of the Public Health Services Act,[2] which the Centers for Medicare & Medicaid Services (CMS) cites as its legal authority to effectuate the rule, allows

CMS to require disclosure of "standard charges for items and services provided by the hospital," the section does not include payer-specific negotiated rates as part of the definition of standard charges.

Secondly, the hospitals contend that the Final Rule infringes upon their First Amendment rights, as "it mandates speech in a manner that fails to directly advance a substantial government interest." Plaintiffs argue that the rates negotiated between hospitals and insurers do not provide actual cost information to patients, which are out-of-pocket costs, and the new rule "will generate confusion about patients' financial obligations, not quell it." Additionally, the Final Rule places undue administrative inconvenience and burden on the hospitals. As the negotiated charges are confidential and proprietary to both hospitals and insurers, plaintiffs argue that disclosure of such information would prevent arms' length negotiation. The hospitals are also concerned that the complexity of compliance could crash hospitals' existing computer systems. As a result, such burden is not sufficiently justified by government interests under the First Amendment.

Federal Rule to Require Disclosure of Drug Prices in TV Ads Blocked in Court

Another recent federal attempt to promote price transparency, this time in the comparably opaque pharmaceutical industry, was met with similar legal roadblock. In May, the Trump administration via the Department of Health and Human Services (HHS) finalized a rule to require drug manufacturers to disclose list prices of their drugs in television ads. Set to go into effect on July 9, the rule would have required drugmakers to include the list price of their medications if they cost $35 or more for a month's supply.

In this case, drug manufacturers Merck, Eli Lilly, and Amgen launched arguments strikingly similar to the ones alleged in the hospital challenge, namely the government's lack of statutory authority and violation of the First Amendment, in the U.S. District Court for the District of Columbia, the same court in which the hospital lawsuit is filed. Similar to the hospital price disclosure lawsuit, the drug companies here argue that list prices do not reflect what most patients pay out of pocket, as it

does not take into account any discounts, rebates, and insurance payments. Accordingly, the plaintiffs contend that disclosing the list price of drugs would only confuse consumers instead of achieving the intended effect on consumer behavior. Given the lack of clear evidence that the rule would promote the intended goals, plaintiffs argue the government cannot justify the burden it places on free speech.

In the court's decision, Judge Mehta noted that the court did not question whether drugmakers should be required to disclose their prices or whether such policy could be effective in reigning in prescription drug costs. Additionally, the court also did not rule on the plaintiff's First Amendment argument. The court did, however, block the rule in favor of the plaintiffs the day before it was set to take effect based on HHS' lack of regulatory authority. Specifically, the court opinion states that the rule "is far afield of any other type of rulemaking authority HHS has previously exercised" under the Social Security Act, which the HHS cites its authority, and that "Congress… did not envision such an expansion of regulatory authority when it granted HHS the power to issue regulations."

This decision, while currently on appeal to the circuit court, could shed some light on how the same court may rule in the latest challenge against the hospital disclosure rule, particularly given their similarity in terms of legal arguments. While both cases challenge the government's statutory authority, the drug price rule is based on the Social Security Act. The hospital rate rule, on the other hand, rests on the Public Health Services Act. It remains to be seen whether the court would apply the same reasoning to limit the government's effort to extend its authority under a different statute.

Pharma Lawsuit Against California's SB 17 Allowed to Proceed

As federal policies to promote price transparency stumble on legal barriers, state efforts are not immune from resistance either. California's SB 17 has been under fire from the pharmaceutical industry since it was enacted in October 2017. The controversial state drug pricing transparency law requires drug makers to provide 60 days advanced notice and a reason for price hikes above a certain threshold.[3] The Source Blog previously reported that the U.S. District Court for the Eastern

District of California dismissed the initial lawsuit, PhRMA vs. Brown, on procedural grounds, but allowed Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical industry's main lobbying group and plaintiff in this case, to amend the complaint to satisfy procedural requirements.

Plaintiffs immediately refiled an amended complaint in September 2018, in the form of PhRMA v. David, alleging the California law violates the First Amendment and the Commerce Clause. Specifically, PhRMA claims that SB 17 improperly compels speech by forcing drugmakers to justify price changes and impermissibly regulates interstate commerce because it applies to wholesale acquisition costs that are national in nature. The complaint also raises due process concerns as it relates to potential retroactivity of the law.

Most recently, California federal judge Morrison C. England Jr., who tossed the initial lawsuit, gave the amended lawsuit the greenlight to move forward when he denied the state's motion to dismiss late this summer. The court opinion states that the plaintiff has adequately alleged that SB 17 may violate free speech and other constitutional rights.

As more federal and state policies target hospital and pharmaceutical prices and practices, the affected industry groups will no doubt vamp up their efforts to resist such changes in the form of additional litigation. With largely similar legal arguments cited as authority to block the intended policies, each case may set important legal precedents for other policy efforts to effectuate reform in healthcare price and competition. As the legal side of the equation may dictate the boundaries of healthcare reform, stay tuned as The Source Blog brings the latest developments and rulings from the courts.

---

[1]See The Secret of Health Care Prices: Why Transparency is in the Public Interestwritten by The Source for a detailed discussion of public interest in price

transparency of healthcare prices.

[2]42 U.S.C. § 300gg-18(e).

[3]See California's Drug Transparency Law: Navigating The Boundaries Of State Authority On Drug Pricingwritten by The Source for a detailed discussion of the legal and regulatory aspects of SB 17.

House Passes the Elijah Cummings Lower Drug Costs Now Act (H.R. 3)

On Thursday, December 12, 2019, the House passed H.R. 3, the Elijah Cummings Lower Drug Costs Now Act, with unanimous support of House Democrats, but only 2 Republican votes. While the primary provisions of the bill and the conclusions drawn in our original blog post remain unchanged, we highlight two changes made to the bill as described in our post before it was passed.

First, the original bill required drug manufacturers that increase the price of a drug faster than the rate of inflation (benchmarked to prices in 2016) to either reduce the cost of the drug or pay rebates to the government for any revenues above the inflationary price. The passed version of the bill extends these required rebates to drugs covered by private payers.

Second, the original bill required the Department of Health and Human Services (HHS) to negotiate prices for 25 drugs, but the passed bill sets the minimum number of drugs for which HHS should negotiate to 50 and allows the agency to negotiate prices for up to 250 drugs.

The bill now goes to the Senate, where experts doubt the likelihood of passing. The Senate Finance Committee also introduced more moderate legislation. Stay tuned as The Source continues to follow both state and federal legislation to address rising

drug costs.

Would House and Senate Bills to Lower Drugs Costs Achieve Savings or Affect Innovation?

**See 12/13/19 Update: House Passes the Elijah Cummings Lower Drug Costs Now Act (H.R. 3)*

Increasing the affordability of prescription drugs is of primary importance to Congress and to the nation. In this post, we review two of the federal bills receiving substantial press coverage – the Lower Drug Costs Now Act, introduced in the House by Speaker Pelosi and the Prescription Drug Pricing Reduction Act, introduced in the Senate by Senator Grassley. While the current bills may have a bumpy road to approval, we analyze the proposals in the bills to assess whether they are likely to reduce spending on prescription drugs or reduce investment in research and development.

The Lower Drug Costs Now Act of 2019

The House bill, the Lower Drug Costs Now Act of 2019 (H.R. 3), introduced by Speaker Nancy Pelosi, limits the annual out-of-pocket costs for Medicare Part D beneficiaries to $2,000 and requires the Secretary of Health and Human Services (HHS) to negotiate with drug manufacturers and sets a price ceiling, or "maximum fair price," for some single-source drugs.

Under this bill, HHS selects and publishes a list of drugs subject to the negotiation process. The original bill set the minimum number of negotiation-eligible drugs at 25, but the Energy and Commerce Committee increased that number to 35 during their review. The list is limited to single-source drugs that are among the 125 drugs with the greatest net expenditures and must include any insulin product approved by the Food and Drug Administration (FDA).[1] The bill states that the maximum fair price may not exceed 120% of the average international price (AIM).[2] In the case where an AIM cannot be calculated, for example when the drug is first released in the United States, the negotiated rate may not exceed 85% of the average manufacturer price (AMP) of the drug.[3] This price ceiling is the starting point for a negotiation between HHS and the manufacturer, although it is unclear what incentive a manufacturer has for agreeing to a price below that ceiling. This maximum price applies to all Medicare plans, and, perhaps more importantly, manufacturers must offer the maximum fair price to health plans in the commercial market, although private commercial plans may opt not to accept the negotiated price (e.g. if they think their pharmacy benefit manager can negotiate a lower price through formulary management).

If the manufacturer and HHS are unable to agree on a maximum fair price (i.e. if the manufacturer refuses to accept 120% of the AIM), then the manufacturer will be assessed an escalating mandatory rebate levied on the manufacturer's annual gross sales – starting at 65 percent and increasing by 10 percent every quarter the manufacturer is out of compliance, up to a maximum of 95 percent.[4] As a result, if a manufacturer cannot come to terms with the Secretary, it could lose all revenue for that drug. Furthermore, because this rebate is not deductible for income tax calculations, the manufacturer could actually lose money by selling a drug for which it cannot reach a pricing agreement with the Secretary.

The Prescription Drug Pricing Reduction Act of 2019

The Senate Bill, the Prescription Drug Pricing Reduction Act of 2019 (PDPRA, S. 2543), introduced by Senator Chuck Grassley, makes major revisions to payments for pharmaceuticals in the Medicare Part B and D programs.[5] In contrast to the

Lower Drug Costs Now Act**,**the PDPRA does not extend any of these changes to private plans. The reforms to the Medicare Part D program – the stand-alone prescription drug coverage – include capping out-of-pocket costs for beneficiaries at $3,100 annually and requiring manufacturers to pay an additional 20% rebate for drugs used by beneficiaries who have reached the out-of-pocket maximum. The reforms to the Medicare Part B program – the Medicare program that includes coverage for outpatient drugs administered by a physician – include refining the calculation of the Average Sales Price (ASP) to more accurately establish fair Medicare payment rates for physician-administered drugs.[6] Furthermore, the PDPRA mandates that manufacturers pay additional rebates to the government for any amount that occurs when an increase in the wholesale acquisition cost for a drug covered under Medicare Part B or D exceeds the rate of inflation.

Budget Implications of the Bills

The Congressional Budget Office (CBO) published a preliminary report of the effects of H.R. 3 on federal direct spending, estimating that the provisions of H.R. 3 would reduce Medicare spending by $345 billion between 2023 and 2029, with the largest savings coming from lower prices for drugs that are sold internationally.[7] The CBO anticipates that prices for drugs in other countries would rise in response to the link between prices in the U.S. and foreign markets. Preliminary calculations by the CBO anticipate reductions in revenues to drug manufacturers of $0.5 to $1 trillion over the next ten years.

The CBO also estimates that the PDPRA would decrease the federal deficit by $100 billion over the 2020-2029 period. Additionally, the CBO estimates modest savings to commercial prescription drug spending due to spillover effects from the Part D inflation rebate policy. In short, the CBO calculates savings to the government of H.R. 3 to be about three times that of the PDPRA and the savings in prescription drug spending to be about five to ten times greater for H.R. 3 than PDPRA.

What Do the Savings Mean for Drug Innovation?

Not surprisingly, the pharmaceutical industry vehemently opposes these bills and more than 100 CEOs of small drug companies signed a letter in opposition to H.R. 3. Perhaps the most vigorous opposition to these bills argues that the reduction in revenue for drug manufacturers will result in lower spending on research and development and fewer medications coming to market. Specifically, the Council of Economic Advisors issued a report on December 3, 2019, estimating that H.R. 3 could lead to about 10 fewer drugs entering the United States market annually. Although this estimate relies on the upper limit of the CBO's estimate and a highly criticized estimate of the cost of developing a new drug at $2 billion, we examine in more detail the idea that a reduction in drug manufacturer revenue may lead to a reduction in pharmaceutical development.

In 2019, large pharmaceutical manufacturers spent about 20% of revenues on research and development. Furthermore, a 2017 report from the Government Accountability Office estimated that from 2006 to 2015, pharmaceutical and biotechnology sales revenue increased from $534 billion to $775 billion, and most drug companies saw an increase in their annual profit margins. Nonetheless, spending on research and development only increased slightly from 2008 to 2014 – from $82 billion to $89 billion. These data demonstrate that increase or reduction in revenues is not necessarily correlated to investment in research. A report written by West Health Policy Center found that large pharmaceutical manufacturers are the most profitable of any industry group.[8] Furthermore, these large pharmaceutical manufacturers could have realized 11% fewer profits and still maintained their position as the most profitable industry.

Since large pharmaceutical companies have a large profit margin, a reduced profit margin will not necessarily correlate to a reduced investment in R&D as companies will continue to invest in innovative treatments if they believe new drugs will bring additional future profits and a large return on investment. A report from the American Enterprise Institute written by former FDA Commissioner Scott Gottlieb and Research Fellow Institute Benedic Ippolito analyzed how the provisions of the PDPRA may change investment in specific drug categories by affecting the expected return on investment. Gottlieb and Ippolito calculate which drugs are likely to face larger rebates under the PDPRA and, therefore, how the bill may incentivize manufacturers to alter research spending away from specific diseases. They found

that therapeutic classes with high net-priced drugs (e.g. cystic fibrosis, pulmonary arterial hypertension, and oncology) and disease areas where patients disproportionately receive low-income subsidies (e.g. hepatitis C, HIV, mental health and diabetes) were most likely to face additional rebates under the PDPRA. As a result, Gottlieb and Ippolito predict that investment for drugs on specialty tiers and in these disease areas "are likely to moderate" under the PDPRA.

It appears that lowering drug company revenues will not necessarily reduce investment in research and development, but rather encourage pharmaceutical companies to invest in therapeutic classes that are likely to have the largest return on investment. If new laws are passed to incentivize innovation, companies will likely invest in innovation. Many countries, including those used to calculate the AIM in H.R. 3, use an assessment of cost-effectiveness as part of the approval or coverage determinations.[9] As a result, tying price ceilings to those standards would, at least indirectly, incentivize investment in treatments that could command high prices for their effectiveness. It remains unclear, therefore, whether passing H.R. 3 or the PDPRA would substantially lower the number of drugs released in the United States market.

Conclusion

If passed, both H.R. 3 and the PDPRA will reduce expenditures by the federal government on prescription drugs. Furthermore, H.R. 3 will extend these savings to the private sector. While it is worth considering how the provisions of each bill will change incentives for investment in research and development by the pharmaceutical industry, it is far from certain that a reduction in pharmaceutical expenditures would lead to fewer new treatments. While both bills will reduce drug expenditures by the federal government, neither bill contains a cost-effectiveness analysis like that performed by many other countries. While H.R. 3 and PDPRA are commendable efforts by Congress, an ideal legislative solution to drug costs would ensure that cost-effectiveness is considered in both establishing an initial price and in any subsequent price increases.

---

[1]H.R. 3 § 1192 (e).

[2]The bill defines the AIM as "the average price (which shall be the net average price, if practicable, and volume-weighted, if practicable) for any dosage form and strength" for each drug sold in Australia, Canada, France, Germany, Japan, and The United Kingdom. (H.R. 3 § 1191 (c)(3)).

[3]H.R. 3 § 1194 (c)(2).

[4]H.R. 3 § 4192 (c).

[5]The bill also makes revisions to Medicaid prescription drug coverage and requires additional price transparency for services provided at physician offices (requires same reporting as ambulatory surgery clinics, ASCs) but those reforms are beyond the scope of this post.

[6] The bill requires manufacturer without a Medicaid drug rebate agreement to report ASP for those drug to Medicare, requires coupon amounts (only available to private plans) to be deducted from ASP, and narrows the definition of "bona fide service fees" to require more fees to be deducted from ASP price reported to HHS. All of these calculation changes will reduce the reported ASP and more accurately reflect the amount manufacturers receive for selling the drug. As a result, the Medicare payment rates for these drugs should be commensurately lower.

[7]Letter to the Honorable Frank Pallone Jr., Chairman Committee on Energy and Commerce*, Re: Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare*. October 11, 2019. Available from: https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf.

[8]The West Health Policy Center report says that the Return on Invested Capital (ROIC) is higher for large pharmaceutical manufacturers than any other industry group.

[9]See e.g.,

https://www.cadth.ca/sites/default/files/pdf/economic_guidelines_worked_example.pdf, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802685/ and https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness

---

Introducing the New Interactive Key Issue Page: Market Consolidation

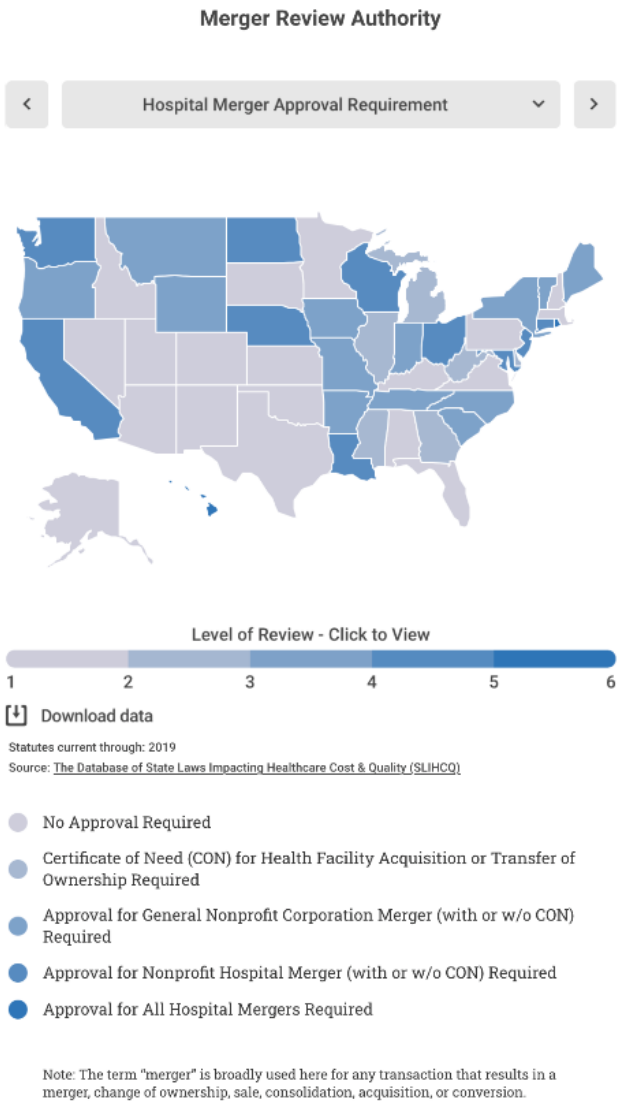
The Source on Healthcare Price and Competition is excited to announce that, in partnership with UC Berkeley's Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, we are unveiling a brand new interactive "Market Consolidation" key issue page that presents evidence-based information and analyses on the most effective strategies for states to address rapidly consolidating healthcare markets.

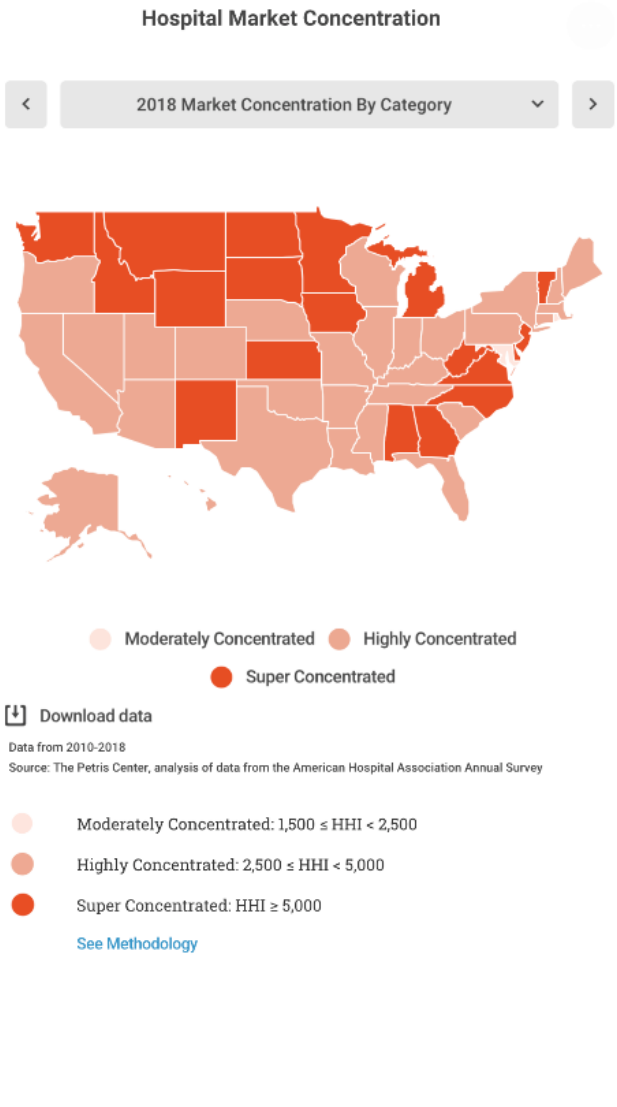
Recent evidence demonstrates that provider and insurer markets in the United States have been highly concentrated for years and have led to increased healthcare prices and insurance premiums without a commensurate increase in quality. Combining the legal expertise of The Source and the economic analysis and data modeling expertise of the Petris Center, this Arnold Ventures supported collaboration leverages the latest and most comprehensive data on state laws, healthcare markets, and healthcare prices and quality to analyze the variation in state laws and subsequent economic impacts in the last ten years (2008-2018).

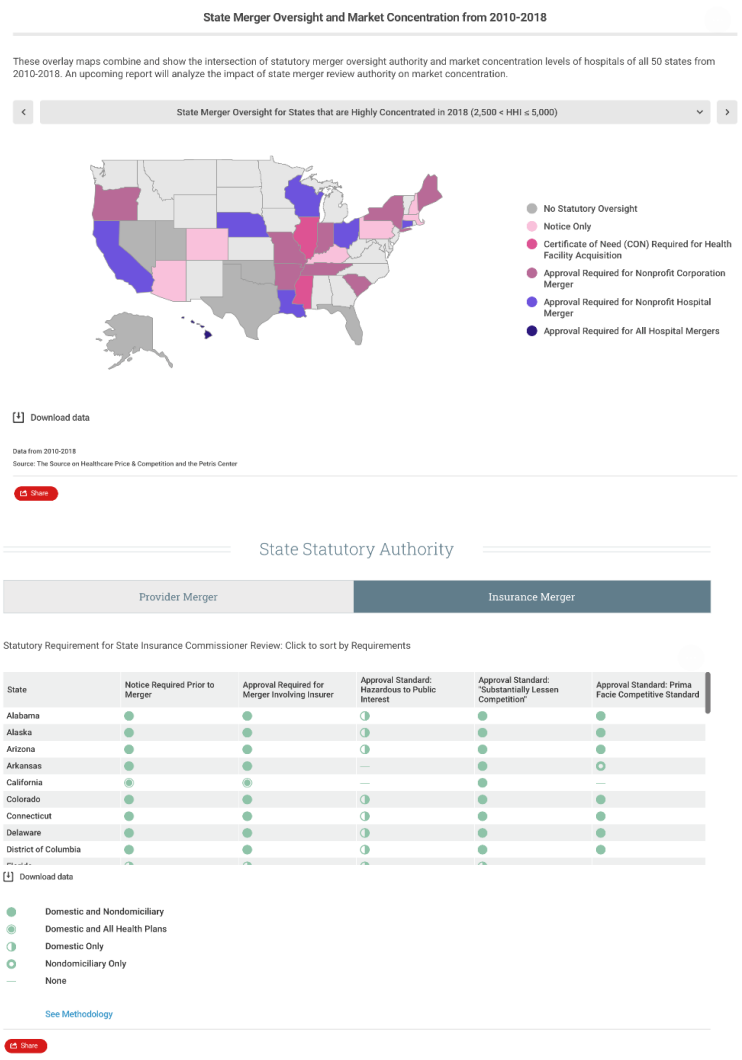
We present our findings in a series of user-friendly interactive features ranging from

trend maps and data charts to enforcement and policy timelines. The newly unveiled interactive features show, among other findings, that while 12 states and the District of Columbia have statutes specifically requiring approval for nonprofit hospital mergers and conversions, only 2 states require approval for all hospital mergers and 19 states do not require any approval at all. Additionally, the measure of provider market concentration by state reveals that all but two states' hospital market are "Highly Concentrated" or "Super Concentrated".

Find out more on the new page and stay tuned as we continue to roll out additional features and analyses in multiple phases throughout the next few months. We look forward to your comments and feedback here!







The Source Roundup: December 2019 Edition

Happy December! The holiday season is upon us and it is time to cozy up with a warm cup of tea to the latest health policy news. This edition of the Source Roundup looks at articles on 1) healthcare market consolidation and provider network access, 2) increases in insurance premium contributions and deductibles, and 3) lessons from healthcare system reforms abroad.

Healthcare Markets

Accountable care organizations (ACOs) have been lauded for providing higher quality medical care at lower costs. In a recent *Health Affairs* research article, Changes in Physician Consolidation with the Spread of Accountable Care Organizations, Genevieve P. Kanter, Daniel Polsky, and Rachel M. Werner analyze to what extent ACOs actually drive down healthcare costs. The authors reveal that ACOs may incentivize consolidation among physician groups. This is particularly concerning because consolidation can be associated with lower quality care and higher prices.

In another *Health Affairs* article, Simon F. Haeder, David Weimer, and Dana B. Mukamel report on the effect of provider networks on access to cardiologists, endocrinologists, obstetrician-gynecologists, and pediatricians for Affordable Care Act Marketplace plans in California. In A Consumer-Centric Approach To Network Adequacy: Access To Four Specialties In California's Marketplace, Haeder et al. applies geographic distances between consumers and providers and the availability of active providers to their approach and found that Marketplace plan networks are narrower than alternative commercial plans. These network designs ultimately create greater access issues for rural consumers compared to metropolitan consumers.

Healthcare Costs

Sarah R. Collins, David C. Radley, and Jesse C. Baumgartner investigate the cost of health insurance as compared to household incomes in the *Commonwealth Fund* study Trends in Employer Health Care Coverage, 2008–2018: Higher Costs for Workers and Their Families. Despite median wages rising over the past decades, employees are contributing a greater proportion of their income to their health plan premiums and deductibles. Average health insurance contributions exceeded ten percent of median incomes in forty-two states, and consumers remain vulnerable to high out-of-pocket costs due to the rise in deductibles. Lower-income families

experience even greater impact from these trends in employer health care coverage.

In addition to the rise in deductibles and premium contributions, Tim Xu finds that hospital sticker prices, or chargemaster rates, for emergency medicine and anesthesiology have increased faster than inflation in his *JAMA Internal Medicine* research letter, Markups on Emergency Medicine and Anesthesiology Services in the United States From 2012 to 2016. Uninsured patients or those who receive out-of-network care are billed at these higher rates and face legal repercussions if they do not pay up. Additionally, uninsured patients comprise a greater percentage of emergency departments visits and therefore more vulnerable to surprise medical bill practices.

Healthcare System Reform

As Americans continue to bear the brunt of out of control pharmaceutical costs, scholars and researchers are urging policymakers to look to other countries for price control models. In the *Commonwealth Fund* issue brief What Can the United States Learn from Pharmaceutical Spending Controls in France?, Marc A. Rodwin asserts that drug spending can be reduced in America if we implement similar French pharmaceutical price and spending control methods. These regulations include establishing maximum prices for new drugs that reflect the new drug's added value, capping price increases after a new drug enters the market, and requiring manufacturers to pay rebates when drug spending exceeds a national pharmaceutical spending limit. Contrary to popular industry criticism that pharmaceutical price control regulations will stifle innovation, Rodwin finds no significant impact on access to new drugs in France. As a result, Americans likewise could benefit from new drug control spending reforms that still inspire therapeutically useful new drug innovation.

Domestically, the popular Democratic presidential candidates' "Medicare for All" plan is not an unfamiliar healthcare reform proposal. In the *Manhattan Institute* report, Medicare for All? Lessons from Abroad for Comprehensive Health-Care Reform, Chris Pope describes how eight countries have successfully implemented four broad versions of "Medicare for All." Research reveals that a

citizen's ability to obtain expensive medical procedures increases in proportion with the ability to purchase private medical care insurance. Pope concludes that the most successful "Medicare for All" system will incorporate private insurance with public subsidies.

That concludes this month's Roundup. If you find articles or reports that you think should be included in the monthly Roundup, please send them our way. Happy reading!