

THE STATE OF
HEALTHCARE
IF THE DEMOCRATS
SWEEP IN
NOVEMBER



THE STATE OF HEALTHCARE IF THE DEMOCRATS SWEEP IN NOVEMBER

DOUGLAS HERVEY, JD/MBA

In a prior whitepaper entitled "Medicare for All vs. Medicare for More," we highlighted some of the potential iterations of universal coverage that Democratic presidential candidates supported in their policy positions. This article will follow up with that analysis by providing a high-level overview of likely healthcare priority focus areas in a hypothetical Biden presidency and a Democratic-led Congress. This article will also discuss various regulatory and legislative mechanisms for change, along with healthcare-related bipartisan dynamics. The Biden campaign team and Congress are understandably heavily focused on the COVID-19 public health emergency. The pandemic is impacting each of the categories discussed below, and they will be important to track as the nation gradually moves into a new-normal in the months and years to come.

SIX HEALTHCARE PRIORITY FOCUS AREAS

If Joe Biden gets elected and Democrats hold the House and retake the Senate, the following six areas would potentially be central to their healthcare reform agenda: 1) strengthening the Affordable Care Act (ACA)'s individual marketplace; (2) enhancing Medicaid support and incentivizing expansion; (3) scaling back 1332 waivers, including association and short-term plans; (4) ending surprise medical billing; (5) engaging in drug price reform; and (6) moving toward value-based care. This article deemphasizes reforms such as lowering the Medicare age limit and implementing a new Medicare-like public-option given their estimated costs. They are likely to be near-term political non-starters given their political opposition.



Figure 1. Priority Areas to Watch if Democrats Sweep in November

Although each of these six topics could merit an entire policy brief, this article will provide a panorama of the topics rather than exhaustive coverage of any one. Cicero Group does not endorse platforms or policies; nor does it endorse the positions we covered in our last whitepaper. Rather, Cicero Group highlights perspectives across the political spectrum to further educate and engage readers in key areas that could impact their families, businesses, and communities.

1. Strengthen the ACA's individual marketplace

The Trump administration has withheld support all along for the ACA individual marketplace. Despite COVID-19, the administration has so far refused requests to create a nationwide enrollment opportunity. In recent years, the administration also pulled several levers that adversely impacted the individual market, including eliminating cost-sharing subsidies, reducing advertising dollars, and removing the individual mandate.

A Biden White House and Democratic Congress would look to reverse these trends by enhancing subsidies, protecting network adequacy, and guarding against rate hikes. On June 22, 2020, Democrats in the U.S. House of Representatives introduced the Patient Protection and Affordable Care Enhancement Act (HR 1425). HR 1425 provides a helpful view into how the Biden team might look to strengthen the ACA. First, they would enhance premium subsidies for ACA exchange plans. Those without access to Medicaid would more easily access premium-free ACA coverage. Currently, plan subsidies are based on the cost of a middle-coverage "silver" plan with a 70% actuarial value, where consumers are responsible for 30% of covered benefit costs. Biden would like the subsidies to be based on a more expensive "gold" plan with an 80% actuarial value, increasing the size of premium tax credits and reducing deductibles and co-pays for subsidized beneficiaries.

Biden and Democrats would like to decrease a beneficiary's percentage of income exposed to premium payments. They would like to lower the share that income subsidized households pay for their coverage, capping it at 8.5%. Currently, people below 400% of the federal poverty level are capped at 9.8%, and those higher than that threshold do not have a ceiling. That, together with Biden's proposal to remove the current cap limiting subsidies to those making 400% of the federal poverty level or below, would set a ceiling at 8.5% that Americans would have to pay of their annual income toward premiums. Second, Biden and Democrats will work to protect and strengthen network adequacy standards for exchange plans. The ACA required marketplace health plans to have a sufficient number of in-network hospitals and physicians, including specialists, within service areas. The Trump administration weakened federal oversight in 2018 with its market stabilization rule. Consequently, there has been heightened concern that patients are receiving more expensive care, travelling longer distances, waiting longer for appointments, or in some cases foregoing care altogether.

Third, a Biden administration would likely protect consumers from rate hikes using the threat of civil monetary penalties and rate review requirements. HR 1425 would support the ACA's rate review standards by allowing HHS or states, where possible, to deny or modify excessive, unjustified, or unfairly discriminatory rates—or require rebates to be issued to consumers.

It will be easier for Biden and Democrats to pass individual marketplace changes given payers and providers largely support them. As for paying for proposed ACA reforms, there is a chance Democrats would finance individual marketplace reforms through drug pricing legislation.

2. Enhance Medicaid support and incentivize expansion

Section 1115 Medicaid demonstration waivers allow states the flexibility to experiment with new methods in Medicaid that deviate from those the federal government mandates. Perhaps the most controversial area of 1115 waivers involves work requirements. The Trump administration has reversed actions of previous Democratic and Republican administrations by supporting states in making work requirements a precondition for eligibility. As of July 2020, the Trump administration has approved multiple states that have created work requirement conditions, but courts have struck down several of the programs. Litigation challenges to waivers in states such as Kentucky and Arkansas are ongoing.* Biden and the Democrats would surely work to scale back and end work requirement waivers.*

As for the ACA's Medicaid expansion, Republicans have sought to limit state approval since its inception, and they came closest to accomplishing their goal when the House passed the American Health Care Act (AHCA) in 2017. Republicans would like to remove the enhanced federal matching rate for the Medicaid expansion population to pre-expansion levels. They would also support replacing the current

open-ended federal match with a fixed-block grant. Given the political challenges of enacting federal block grant legislation, the Trump administration has been exploring 1115 waivers as a potential way for states to do it on their own. For example, Tennessee has submitted its own block grant proposal through an 1115 waiver but is waiting on federal approval.xii Utah could follow.xiii

The Biden team and a Democratic Congress would work to incentivize Medicaid expansion—potentially providing state funding with 100% federal funding for the first three years. They could also try to reduce administrative matching funds for non-expansion states. Under plans currently being discussed, states would need to provide 12 months of continuous coverage for Medicaid and Children's Health Insurance Program beneficiaries. Medicaid programs would also need to offer postpartum eligibility for a year as opposed to the current 60-day mandate.xiv

Under Biden's plan, individuals who would have been eligible for coverage under a Medicaid expansion but live in states that chose not to expand would be eligible for a premium-free version of the public option.** Expansion states could embrace the new option, but it is unclear if they would switch because they would still be required to pay a share of costs.**

Finally, the Biden team would roll back any proposed changes to the upper payment limits introduced in the Medicaid fiscal accountability rule (MFAR). MFAR requires that states which want to add or renew supplemental payments would have to report considerably more information and go through an intensive review process. *vii In addition, states would need to have their payments re-approved by the CMS every three years and would have to quantify their yearly audits of disproportionate-share hospital payments.*viii Even if there is consensus that more accountability is needed, MFAR has and will face continued pushback from Democrats, especially given COVID-19 and concerns around key stakeholders' abilities to effectively respond to the epidemic.*ix

3. Scale back 1332 waivers, including association and short-term health plans

Section 1332 allows states to waive certain ACA requirements, subject to approval from HHS and the Treasury. These innovation waivers enable states to consider different coverage methods within the individual and small-group markets that conform to ACA goals. As a funding mechanism, the federal government can share the money it would have spent on premium tax credits, cost sharing reductions, and small employer credits.** The Trump administration has already relaxed Section 1332 guardrails by enhancing access to association and short-term plans. A Biden White House would likely reverse 2018 guidance on 1332 waivers and restore Obama-era requirements.**

Association Health Plans (AHPs) enable small business, such as dairy farmers, car dealers, and accountants, to pool resources to buy health insurance on the premise that more enrollees would offer a more attractive and less costly healthcare benefit for employees. AHPs have been around for decades, but the ACA heightened oversight of AHPs, subjecting them with little exception to individual and small-group market rules requiring essential health plans.

Through the Department of Labor (DOL), the Trump administration significantly expanded AHP's scope and reach. In 2018, the DOL increased the number of circumstances where aggregated small groups could be labeled as large groups. Recent court decisions have found that the health plans violate federal law, and the Biden team would likely return AHP oversight to Obama-term levels.**

The Trump administration has also loosened restrictions on short-term health plans, and a final rule released in July of 2018 reversed an Obama administration mandate that short-term plans be limited to 90 days. As a result, short-term plans are legal for up to 12 months and can also be renewed for up to three years.

Democrats have expressed concerns that individuals with ACA plans will see higher premiums.***
Although legal challenges followed the short-term plan rule, courts have upheld the plans to date. A Biden election would likely restrict short-term plan availability.***

4. End surprise medical billing

Republicans and Democrats have supported reforms to protect patients with surprise medical bills from out-of-network treatment.** Biden specifically supports barring providers from billing patients out-of-network rates when the patient has no control over the provider attending him or her.** Common balance billing scenarios involve emergency surgeries and ambulance transport. But Biden has been unclear how he would end surprise billing—whether it be through a benchmark or arbitration.

The White House issued statements in December 2019 to support legislation to lower healthcare costs through a ban on balance billing proposed by Senate Health Committee Chair Lamar Alexander (R-Tenn), House Energy & Commerce Chair Frank Pallone (D-N.J.) and Energy and Commerce Ranking Member Greg Walden (R-Ore).**

Despite the months of painstakingly thorough negotiations among different committees, Senate and House leadership never brought a bill to the floor. Reports indicate that Senate Minority Leader Chuck Schumer (D-N.Y.) called Senator Patty Murray (D-W.A.), ranking member of the Senate Help Committee, to postpone the deal. Lawmakers extended funding for several Medicaid and Medicare programs until late May 2020. As a result, a surprise billing rider for the health extenders legislative deal was the best hope for activity on this front in 2020. **XVIII

Then came COVID-19. HHS stipulations essentially banned all hospitals taking federal funds from balance billing COVID-19 patients. On its surface, it appeared the ban would only apply to COVID-19 patients, but the finer print indicated that HHS "broadly views every patient as a possible case of COVID-19." While further legislation this year is unlikely, there is clearly an appetite among the current Congress and the Biden team to get something done.***

5. Engage in drug price reform

Both the Trump and Biden teams have been active on several fronts to engage in drug price reform.*** It is no secret that rising drug prices are inflating premiums and layering increasing debt on millions of families across the nation.

The Trump administration has pushed for reform in areas including drug importation and international reference-based pricing. President Trump has often been willing—at least in rhetoric—to go against the policy positions of more conservative Senate Republicans. This is particularly true on capping drug prices.** However, Trump has refused Democrat calls to allow the HHS secretary to negotiate on the highest-priced drugs as well as those with little competition.***

While a Biden administration may focus on insurance market reforms, they will need to find ways to pay for them. Drug pricing legislation could create the needed savings to enact other healthcare reforms. It will be a high priority topic in the campaign this fall and in years to come. Joe Biden's platform supports Medicare Part D negotiations, a ceiling price on some drugs when launched, and the removal of tax deductions for direct-to-consumer ads.**xxiv

Several of these proposals—including any launch price restriction—would face stiff drug lobby and Senate Republican resistance. Given the partisan opposition many drug-pricing legislative issues face, the Biden team would likely work through regulatory channels where possible. For example, it could tap CMMI to test new drug pricing programs for government payers, such as an international pricing index or pricenegotiating powers.**

Medicare Part D reforms will be a focus area with at least the minimum equivalent to bi-partisan packages Sens. Charles Grassley and Ron Wyden supported.** Priority focus areas would include determining whether drug manufacturers should reimburse Medicare if prices rise faster than inflation or a certain predetermined percentage.** Reform packages would also likely include drug price hike limits and out-of-pocket caps for patients.

Nothing significant in the drug pricing space will likely pass this election year—especially given the COVID-19 public health emergency—but campaigning on the issue now and addressing rising drug prices post-2020 is almost certain regardless of who wins the Presidential race. While COVID-19 provided the drug industry with near-term cover, the sector will still face long-term political headwinds.**xxxviii

6. Promote value-based care

Value-based care reform efforts have avoided the partisan rhetoric so often on display in other healthcare topics. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) formalized many innovative value-based payment reforms and received over 90% support from Congress.**** While there is less bipartisan consensus on whether models should be mandatory in nature, there is widespread agreement that the current fee-for-service system fosters the wrong kinds of incentives.**I

COVID-19 and deficit spending bills only heighten the need to address costs by changing the ways government pays for Medicare. The Biden team will almost certainly emphasize the need to tie payments to quality as opposed to the number of tests ordered or days spent in a hospital.

Updates to the Stark Law and Anti-Kickback Statute as well as interoperability reforms will also facilitate rather than restrict provider willingness to coordinate care, share data, and adopt risk-bearing contracts. In October 2019, CMS proposed a rule that would allow specialty groups to share patient records with primary care providers and hospitals. A Biden administration would have the difficult task of advancing value-based care without creating even greater incentives for providers to restrict care, cherrypick low-risk patients, dump patients, and/or manipulate or falsify outcomes data.*

While a hypothetical Biden administration would likely wait for COVID-19's dust to settle, it will almost certainly push for more mandatory downside risk and bundled payment models down the road. The Obama administration implemented joint replacement and oncology care models, and the Biden team will likely continue to support further reforms within these and additional specialty areas. **III Expect value-based care acceleration to occur as refinements are made to the Primary Care First and Direct Contracting models.**

MECHANISMS FOR CHANGE

This article outlined several hypothetical healthcare reforms in a post-2020 election scenario, but how could these changes occur? If Biden is elected, he may drive healthcare changes via legislative and regulatory mechanisms. While changing some policy and legislative domains would require federal legislation, Biden could change other areas through administrative rulemaking or executive orders. In some circumstances, a new administration could pursue joint legislative and regulatory paths. Figure 2 below highlights where different policy priorities might fall in the legislative and regulatory landscape.

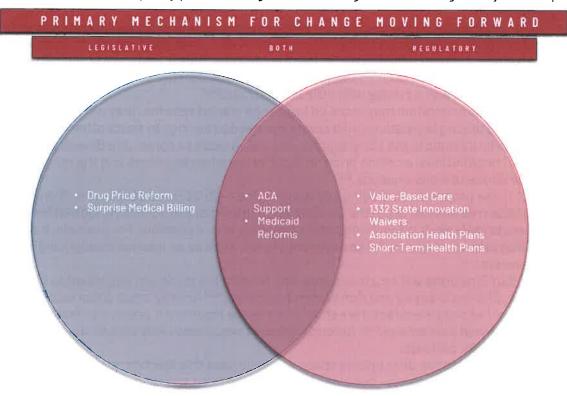
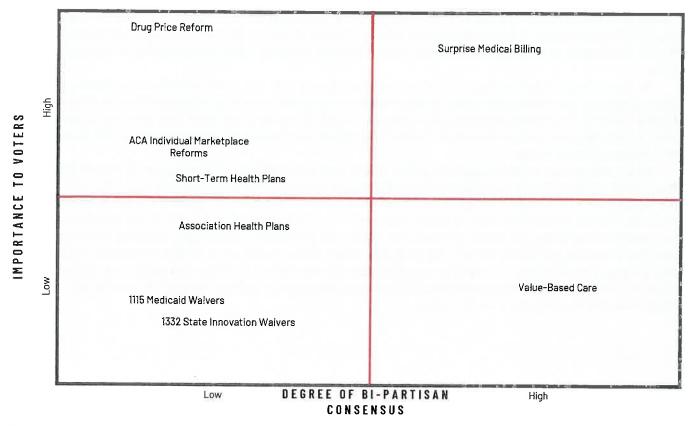


Figure 2. Policy Priorities in Legislative and Regulatory Landscape

Several political conditions would need to be met for Biden's proposed healthcare policies to be put in place. To pass legislation to enact partisan policies, the Democrats would have to hold the House and retake the Senate in 2020 and Joe Biden would need to be elected. Even then, Senate support and filibuster avoidance could affect whether a bill could proceed via reconciliation and a 50-vote majority. Some domains face more bi-partisan political support than others. Consequently, laws and rules that have general collective political support have a better chance of moving forward despite any one focused interest group's opposition. Figure 3 below highlights some of these dynamics.

Figure 3. Degree of Bi-Partisan Consensus



Further, court rulings could decide if Trump administrative rules and/or legislation allegedly runs afoul of existing legislative, regulatory, and/or constitutional provisions. Figure 4 below underscores areas in which the courts are hearing litigation challenges to administration policies.

RELEVANT LITIGATION AREAS INCLUDE:



Figure 4. Litigation Regarding Challenges to Current Administration Policies

CONCLUSION

In conclusion, the six-item priority list outlined above clearly does not cover all of Biden's and the Democrats' healthcare focus areas. Price transparency, telemedicine, site neutrality, provider licensing rules, PBM rebate cuts, and interoperability will all be areas to watch. Further, COVID-19 will significantly impact the healthcare horizon for the next several years in material ways that are difficult to predict at this point.

On top of the political battles and industries' interactions with the Administrative rule-making process, Federal district and appellate courts will continue to weigh in on several of these matters (as shown in Figure 4 above). The Supreme Court could also play a wild card role since it will hear arguments on the ACA prior to the election. Overturning all or some of the ACA would materially impact the Biden administration's priorities and focus areas.

While one cannot predict future specifics, this article has analyzed past trends to illuminate likely focus areas moving forward. Some areas are significant to voters and consequently may influence public platforms. But, even if an issue is not top-of-mind for consumers, it may still matter immensely to focused interest groups with a lot at stake and with a lot of leverage. While COVID-19 has clearly shaken the healthcare agenda, the issues listed above will not be going away. Some have become even more relevant given the pandemic. Others will gradually return to the forefront as COVID-19 headlines subside. Regardless, it is important to map the impact of possible scenarios, to defensibly stress test projections, minimize risk, and maximize the potential to create a sustainable business model that serves the healthcare community well into the future.

ENDNOTES

- Cicero Group. Medicare for all vs. Medicare for more," (October 21, 2019). https://cicerogroup.com/wp-content/uploads/2019/10/Cicero-Group-Medicare-for-All-vs-Medicare-for-More.pdf
- Politico. "Trump rejects Obamacare special enrollment period amid pandemic," (March 31, 2020). https://www.politico.com/news/2020/03/31/ trump-obamacare-coronavirus-157788
- Modern Healthcare. "Dem ACA improvement plan hikes subsidies, incentivizes Medicaid Expansion," (June 22, 2020). https://www.modernhealthcare. $\underline{com/politics-policy/dem-aca-improvement-plan-hikes-subsidies-incentivizes-medicaid-expansion}$
- H.R. 1425 "State Health Care Premium Reduction Act [Patient Protection and Affordable Care Enhancement Act], (June 24, 2020). https://rules. i٧ house.gov/bill/116/hr-1425
- Joe Biden's campaign website. "Health Care," (July 6, 2020). https://joebiden.com/healthcare/
- vi
- νii Modern Healthcare. "Dem ACA Improvement plan hikes subsidies, incentivizes Medicaid expansion," (June 22, 2020). https://www.modernhealthcare. com/politics-policy/dem-aca-improvement-plan-hikes-subsidies-incentivizes-medicaid-expansion
- Pew. "Trump administration: Let states decide if health plans have enough doctors," (February 6, 2018). https://www.pewtrusts.org/en/reviii search-and-analysis/blogs/stateline/2018/02/06/trump-administration-let-states-decide-if-health-plans-have-enough-doctors
- iχ
- Kaiser Family Foundation. "Section 1115 Medicaid demonstration waivers: The current landscape of approved and pending waivers," (February 12,
- 2019). https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/
- House Committee on Energy & Commerce. "House Democrats oppose unlawful Medicaid work requirements," (February 14, 2018). https://energycom-<u>e.gov/newsroom/press-releases/house-democrats-oppose-unlawful-medicaid-work-requirements</u>
- Fierce Healthcare. "A group of Republicans has unveiled its healthcare plan. Here is what's new and what isn't," (October 22, 2019). https://www.fiercehealthcare.com/payer/a-group-republicans-have-a-new-healthcare-plan-here-what-new-and-what-isn-t
- xiii
- χίν Modern Healthcare. "Dem ACA improvement plan hikes subsidies, incentivizes Medicaid expansion," (June 22, 2020). https://www.modernhealthcare. com/politics-policy/dem-aca-improvement-plan-hikes-subsidies-incentivizes-medicaid-expansion
- Health Affairs. "House Democrats introduce new coverage bill, "June 24, 2020). https://www.healthaffairs.org/do/10.1377/hblog20200624.197845/ χv full/
- χví Modern Healthcare. "5 questions about Joe Biden's healthcare plan," March 4, 2020). https://www.modernhealthcare.com/politics-policy/5-questions tions-about-joe-bidens-healthcare-plan
- Kaiser Family Fund. "What you need to know about the Medicaid Fiscal Accountability Rule (MFAR)," (January 27, 2020). https://www.kff.org/medicaid/ xvii issue-brief what-you-need-to-know-about-the-medicaid-fiscal-accountability-rule-mfar/
- xviii
- xix Modern Healthcare. "CMS should toss proposed MFAR rule, experts say," (April 28, 2020). https://www.modernhealthcare.com/payment/cms-shouldtoss-proposed-mfar-rule-experts-say
- Health Affairs. "Feds dramatically relax Section 1332 Waiver guardrails," (October 23, 2018). https://www.healthaffairs.org/do/10.1377/ ХX
- Modern Healthcare. "Dem ACA improvement plan hikes subsidies, incentivizes Medicaid expansion," (June 22, 2020). https://www.modernhealthcare. com/politics-policy/dem-aca-improvement-plan-hikes-subsidies-incentivizes-medicaid-expansion
- xxii The Commonwealth Fund. "The past and future of association health plans," (May 14, 2019). https://www.commonwealthfund.org/blog/2019/past-future-asso
- xxiii Kaiser Health News. "Trump administration loosens restrictions on short-term health plans," (August 1, 2018). https://khn.org/news/trump-administration-loosens-restrictions-on-short-term-health-plans/
- Health Affairs. "Court upholds rule on short-term plans," (July 20, 2019). https://www.healthaffairs.org/do/10.1377/hblog20190720.616648/full/
- House Committee on Energy & Commerce. "Bipartisan House and Senate committee leaders announce agreement on legislation to lower health care XXV costs," (December 8, 2019). https://energycommerce.house.gov/newsroom/press-releases/bipartisan-house-and-senate-committee-leaders-announce-agreement-on
- xxvi Joe Biden's Campaign Website. "Health Care," (July 6, 2020). https://joebiden.com/healthcare/
- Associated Press. "White House backs emerging deal on consumer health costs," (December 9, 2019). https://apnews.com/3dac32daee5fa5c474cfiivxx 2c0ecc064c5
- xxviii Modern Healthcare. "How Congress' surprise billing compromise fell short," (December 23, 2019). https://www.modernhealthcare.com/politics-policy/ how-congr ess-surprise-billing-compromise-fell-short
- HHS.gov. "CARES Act provider relief fund," (March 27, 2020). https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html xxix
- NPR. "Congress considers bipartisan compromise legislation on surprise medical bills," (December 17, 2019). https://www.npr.org/sections/health-XXX shots/2019/12/17/788624397/congress-considers-bipartisan-compromise-legislation-on-surprise-medical-bills
- STAT News. "Donald Trump says Medicare should negotiate drug prices," (January 26, 2016). https://www.statnews.com/2016/01/26/trump-negotixxxi ate-drug-prices/
- xxxii The Hill. "Pelosi aide hopeful White House will support drug-pricing bill despite criticism," (November 13, 2019). https://thehill.com/policy/healthcare/470310-pelosi-aide-thinks-white-house-will-still-support-drug-pricing-bill-despite
- The Hill. "Trump draws ire after retreat on drug prices pledge," (November 24, 2019). https://thehill.com/policy/healthcare/471735-trump-draws-ireafter-retre at-on-drug-prices-pledge
- Fierce Pharma. "FiercePharmaPolitics-How would a Biden White House handle drug prices? Depends on congressional races, analysts say," (Jun 29, xxxiv $\textbf{2020)}. \ \underline{\textbf{https://www.fiercepharma.com/pharma/fiercepharmapolitics-how-would-a-biden-white-house-handle-drug-prices-depends-congressional and the field of the field o$
- XXXV
- Fierce Pharma. "FiercePharmaPolitics-How would a Biden White House handle drug prices? Depends on congressional races, analysts say," (Jun 29, xxxvi
- s://www.fiercepharma.com/pharma/fiercepharmapolitics-how-would-a-biden-white-house-handle-drug-prices-depends-congressional 2020). http
- Health Affairs. "Prescription Drug Legislation in Congress: An Update," (December 12, 2019). https://www.healthaffairs.org/do/10.1377/ ivxxx hblog20191211,802562/full/
- xxxviii
- XXXIX Care Allies. "Medicare Access and CHIP Reauthorization Act (MACRA)," (2016). https://www.careallies.com/static/docs/careallies-macra-fact-sheet. pdf
- Modern Healthcare. "Congress will try to score drug pricing, surprise billing wins in 2020," (January 4, 2020). https://www.modernhealthcare.com/ politics-policy/congress-will-try-score-drug-pricing-surprise-billing-wins-2020
- U.S. Department of Health and Human Services. "HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordixli nated Care. (October 9, 2019). https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html
- Forbes. "What could value-based healthcare look like next?" (March 14, 2020). https://www.forbes.com/sites/jasonarora/2020/03/14/what-will-valuebased-healthcare-look-like-under-the-next-president/#690cf130522e
- Modern Healthcare. "Congress will try to score drug pricing, surprise billing wins in 2020," (January 4, 2020). https://www.modernhealthcare.com/ politics-policy/congress-will-try-score-drug-pricing-surprise-billing-wins-2020

WHITE PAPER / STRATEGY & TRANSFORMATION

THE STATE OF HEALTHCARE IF PRESIDENT TRUMP GETS REELECTED

A high-level overview of twelve relevant healthcare topics the Trump administration is impacting and how policies could play out among them in a hypothetical second term.

CICETS
INDIGNORM DELECTION OF STREET,

THE STATE OF HEALTHCARE IF PRESIDENT TRUMP GETS REELECTED

DOUGLAS HERVEY, JD/MBA

In a prior whitepaper entitled "The State of Healthcare if the Democrats Sweep in November," we highlighted some of the potential policy priorities Democrats would support in a hypothetical election sweep. This article will provide a high-level overview of twelve relevant healthcare topics the Trump administration is impacting and how policies could play out among them in a hypothetical second term. This article will also discuss various regulatory and legislative mechanisms for change, along with healthcare-related bipartisan dynamics. The Trump administration and campaign teams are understandably heavily focused on the COVID-19 public health emergency. The pandemic is impacting several of these categories and others will be important to track as the nation gradually moves into a newnormal in the months and years to come.

TWELVE HEALTHCARE AREAS TO TRACK

If President Trump were re-elected and implemented changes to healthcare, the following twelve areas would be most important to track: 1) drug price reforms and rebate cuts; 2) price transparency; 3) interoperability and information sharing; 4) Medicare Advantage; 5) telehealth; 6) value-based care; 7) surprise medical billing; 8) health savings and health reimbursement accounts; 9) Medicaid reforms; 10) Section 1332 state innovation waivers, including association and short-term plans; 11) individual marketplace enrollment and subsidies; and 12) 340B curbs. Several of these domains are highly relevant to COVID-19 or continue to be prioritized despite it. Movement on any one of these will depend on a combination of presidential, administrative, congressional, and federal court support.

PRESIDENT'S & ADMINISTRATION'S AGENDA Reform impetus can come from Congress or the Trump administration. Filtering occurs either way. Courts are proving to be an active arbitrator in most healthcare issues covered below. FEDERAL COURTS 3 PRIMARY FILTERS

Figure 1. Filtering Mechanism on Healthcare Reform Ideas

Although each of these twelve topics could merit an entire policy brief, this article will provide a panorama of the topics rather than exhaustive coverage of any specific category. Cicero Group does not endorse platforms or policies; nor does it endorse the positions we covered in our last whitepaper. Rather, Cicero Group highlights perspectives across the political spectrum to further educate and engage readers in key areas that could impact their families, businesses, and communities.

1. Drug Price Reforms and Rebate Cuts

Dating back to Trump's first campaign, the administration has been active on several fronts to engage in drug price and rebate reforms, including several recent executive orders in July. It is no secret that rising drug prices are inflating premiums and layering increasing debt on millions of families across the nation. The administration has pushed for reform in areas including drug importation, international reference-based pricing, and rebates.

Impending changes to drug importation regulations are expected to allow states to import drugs from Canada and/or allow drug makers to import products and sell them under different drug codes. And President Trump most recently announced an executive order to allow for personal drug importation from other countries that have comparable regulatory entities to the FDA. Lengthy rule-making processes will delay any near-term industry impact.

As for international reference-based pricing, Medicare currently pays about 180% more for the costliest Part B drugs than other countries. President Trump's recent executive order calls for limiting Medicare Part B payments to the lowest price charged in "any economically comparable" developed country. The administration had previously supported tying payments to an average international price. The administration has not considered further regulating drugs dispensed at pharmacy counters. They are only seeking to regulate physician-administered drugs. The proposed policy would also modify physician payments toward a fixed price for administering a drug rather than pay a percentage of the drug's average sales price.

The administration has also expressed a willingness to end pharmacy benefit managers (PBMs) ability to keep a percentage of rebates and discounts. A rule that the Trump administration supported until July 2019 would have eliminated PBM protections and placed rebates under anti-kickback review. More recently,

President Trump has decided to revive the propped rule if the HHS secretary confirms that it would not raise premiums, taxpayer spending, or out-of-pocket costs.xi

Proponents of the administration's move suggest the rebates incentivize PBMs to select drugs with high prices and rebates. Drug makers also like the idea as patients' copays would decrease. But the administration's stance faces harsh resistance among some Republicans, insurance plans, PBMs, and consumer advocacy groups who fear the rebates could raise Medicare premiums and end up costing over \$200 billion over a decade.^{xii}

These positions collectively demonstrate President Trump's willingness—at least in rhetoric—to go against the policy positions of more conservative Senate Republicans. This is particularly true on capping drug prices. XIII However, Trump has backed away from Democrat calls to allow the HHS secretary to negotiate on the highest-priced drugs as well as those with little competition. XIV

Additional areas are under debate such as whether drug manufacturers should reimburse Medicare if prices rise faster than inflation or a certain predetermined percentage.** The administration also supports requiring drug makers to disclose list prices in television adds, but courts have blocked those efforts in the name of free speech.**

Nothing significant in the drug pricing space will likely be legislatively passed this election year—especially given the COVID-19 public health emergency. President Trump has prepared an executive order requiring domestic production of some "essential" medicines—seeking to reduce the U.S.'s dependence on foreign nations for medicines during pandemics. XVIIII Addressing rising drug prices post-2020 is almost certain regardless of who wins the Presidential race.

2. Price Transparency

President Trump has advocated for transparency to control rising prices and address market inefficiencies such as demand elasticity. Consequently, the administration recently released a hospital price transparency rule effective in January 2021 that will require hospitals to disclose their charges online in a machine-readable manner. At a minimum, hospitals will need to publish prices for 300 "shoppable" services, including 70 services the Centers for Medicare and Medicaid Services (CMS) selects.

Hospitals will also need to disclose their third-party payer negotiated rates. The health plans will not only need to publicly disclose negotiated rates, but they will also need to share how much they are willing to pay out-of-network providers.** Opponents, including America's Health Insurance Plans (AHIP) and the American Hospital Association, are concerned that published prices will lead to unlawful collusion and higher prices rather than have the desired effect.**

While Trump's price transparency rule faces legal hurdles—and the administration has been successful in federal courts to date—voters can expect the administration to double down on their efforts in a hypothetical post-2020 presidency.*** Even amid COVID-19, the administration released a new proposal on May 11, 2020, that would require privately negotiated prices between hospitals and private payers to inform how Medicare pays for healthcare services.*** A new rule would also require hospitals to report the median of payer-specific negotiated rates by DRG on their Medicare cost report.***

3. Interoperability and Information Sharing

On March 9th, 2020, the Office of the National Coordinator for Health Information (ONC) and the CMS released two final interoperability rules that emphasize the need to reduce information blocking, enhance interoperability, and ultimately prioritize patients at the center of the U.S. healthcare system. While the rules have been delayed given COVID-19xxv, they facilitate providers', insurers', and patients' abilities to exchange health data, largely due to provider and insurer requirements to adopt standard application programming interfaces (API)—technology that connects third-party apps to information technology systems such as electronic health records (EHR),xxvi

The CMS will begin publicly reporting eligible clinicians and hospitals that may be involved in information-blocking, depending on what they declared in the 2019 Promoting Interoperability Program requirements. Hospitals accepting Medicare and Medicaid must also electronically let healthcare facilities or community providers know when a shared patient is admitted, discharged, or transferred.**

Providers express privacy concerns given that app developers do not have the same privacy standards as providers and insurers.**

Given the privacy concerns, some providers may turn to litigation as a possible tactic.**

EHR system developers also fear that limiting fees data-sharing suppliers charge could hamstring innovation.**

The administration clearly discourages unnecessary barriers to health data exchange and broader access of patients to their health records. President Trump invested his personal political capital in this issue when he proposed addressing interoperability at the Healthcare Information and Management Systems Society (HIMSS) conference.*** And the administration recently approved a final rule to enhance patient information sharing and care coordination for substance use disorder.***

4. Medicare Advantage

The Trump administration has strongly supported offering seniors more attractive alternatives to traditional Medicare fee-for-service, including innovative Medicare Advantage offerings with telehealth and supplemental benefits. The President signed an executive order in early October 2019 that offers seniors more affordable Medicare Advantage options. For example, monthly premiums are expected to decrease 14% in 2020 to the lowest average since 2007. ***XIIII At the same time, the average number of plan choices has increased 49% since 2017. ***XIIII At the same time, the average number of plan choices

Under the order known as "Protecting and Improving Medicare for our Nation's Seniors," seniors will be able to share more in cost savings the plans generate and ensure that traditional Medicare is not promoted or able to receive particular advantages over Medicare Advantage.xxx Additionally, Medicare Advantage plans can offer increased coverage for social determinants of health affecting conditions where people live, work, play, and learn. Examples may include a host of non-medical benefits such as offering rides to the grocery store or church, new air conditioners, in-home pest control, and fall prevention programs.xxxvi

While the announcement lacked specifics and left a lot to interpretation, it is clear the Trump administration strongly supports the privatized Medicare Advantage program and would support it post-2020. Health insurer trade associations also support the executive order, which is ultimately meant to encourage more attractive plan designs.**xxxvii

5. Telehealth

COVID-19 further intensified the administration's telehealth support. In March, the administration removed several telehealth barriers and included \$500 million in waivers for Medicare telehealth restrictions in the \$8.3 billion March coronavirus spending bill. As part of the bill, the CMS eased several restrictions on communication technology benefiting rural areas, non-face-to-face care management services, and remote patient monitoring services.**xxxviii CMS also allowed audio-only devices and has expanded the list of eligible providers.**xxxix

The longer COVID-19 continues, the harder it will be for the administration to roll back new privileges. In fact, Seema Verma recently said: "I can't imagine going back. People recognize the value of this, so it seems like it would not be a good thing to force our beneficiaries to go back to in-person visits."

President Trump issued an executive order in late July for HHS to review and continue Medicare's coverage of telehealth services. CMS subsequently proposed to permanently enable Medicare providers to use telehealth for evaluation and management services in home visits and for certain patients with cognitive impairments. CMS also temporarily extended telehealth services for emergency department visits and other services as the administration weighs the merits of permanent extensions.^{xll}

Even before COVID-19, President Trump issued a Medicare Advantage executive order that included

support for telehealth adoption among Medicare Advantage enrollees.xiii This order called on the Health and Human Services (HHS) Secretary to propose a regulation for beneficiaries to have improved access to health outcomes through telehealth services. Further, the order asks CMS to "encourage innovation for patients" by expediting the approval of telehealth so that innovative telehealth products "are appropriately reimbursed, are widely available, and are consistent with principles of patient safety, market-based policies, and value for patients."xiiii The policies are expected to encourage more cost-saving telemedicine technology and enable enrollees with greater access to care irrespective of where they live and their physical access to providers in their local markets.xiiv

Outside Medicare, the Trump administration has supported enhanced telehealth access for Veterans and for beneficiaries within the private sector.*\(^{\text{NV}}\) Given telehealth developments among Veterans and Medicare Advantage, one can expect the private insurance market to follow the federal government's lead. Post-2020 telehealth coverage and reimbursement will not revert to pre-COVID-19 levels. Telehealth costs are likely to become permanently allowable administrative costs as long as the technology is "skilled services being furnished, is outlined on the plan of care, and is tied to a specific goal indicating how such use would facilitate treatment outcomes."\(^{\text{NVI}}\) The greatest possible headwind is whether CMS would continue paying the same for virtual visits as for in-person care. Equalizing payment during the pandemic was one of the driving forces behind expansion. Reimbursement is probably not going to be a one-to-one equilibrium.\(^{\text{NVII}}\)

6. Value-Based Care

Value-based care reform efforts have avoided the partisan rhetoric so often on display in other healthcare topics. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) formalized many innovative value-based payment reforms and received over 90% support from Congress.*Viii While there is less bipartisan consensus on whether models should be mandatory in nature, there is widespread agreement that the current fee-for-service system fosters the wrong kinds of incentives.*Xlix

Updates to the Stark Law and Anti-Kickback Statute will also facilitate rather than restrict provider willingness to coordinate care, share data, and adopt risk-bearing contracts. In October 2019, CMS proposed a rule that would allow specialty groups to share patient records with primary care providers and hospitals. The administration will have to tread a difficult path of advancing value-based care without creating even greater incentives for providers to restrict care, cherry-pick low-risk patients, dump patients, and/or manipulate or falsify outcomes data.

The Trump administration has taken steps to shield ACO participants and other value-based care models from financial penalties because of costs associated with COVID-19. COVID-19 has heightened uncertainty around Medicare ACO program participation and stymied some population health efforts given providers' focus on more urgent acute care needs. Consequently, additional HHS supported value-based care initiatives may be slow coming until a vaccine is developed.

Given it is an election year, it was expected that President Trump would use any healthcare bandwidth outside COVID-19 to focus on consumer issues such as telemedicine and transparency. Even in this election climate, CMS has announced payment boosts for maternity care bundles, end-stage renal disease capitated payments, and other bundled payments. Trump also ordered HHS and CMS to form and test a new value-based payment model for rural providers.

Expect the value-based care movement to pick up even more steam after the election and after the COVID-19 situation stabilizes. In particular, the movement's acceleration will likely occur through models such as Primary Care First and direct contracting as well as more bundled programs. Alex Azar and Seema Verma have also touted "value-based competition" along the lines of cost and quality—particularly within Medicare Advantage—as a priority.

7. Surprise Medical Billing

Republicans and Democrats have supported reforms in a bi-partisan manner to protect patients from

surprise medical bills from out-of-network treatment. Will The White House issued statements in December 2019 to support legislation to lower healthcare costs through a ban on balance billing proposed by Senate Health Committee Chair Lamar Alexander (R-Tenn), House Energy & Commerce Chair Frank Pallone (D-N.J.) and Energy and Commerce Ranking Member Greg Walden (R-Ore).

Despite the months of painstakingly thorough negotiations among different committees, Senate and House leadership never brought a bill to the floor. Reports indicate that Senate Minority Leader Chuck Schumer (D-N.Y.) called Senator Patty Murray (D-W.A.), ranking member of the Senate Help Committee, to postpone the deal. Lawmakers extended funding for several Medicaid and Medicare programs until late May 2020. As a result, a surprise billing rider for the health extenders legislative deal had been the best hope for activity on this front in 2020. IIX

Then came COVID-19. HHS issued stipulations essentially banning all hospitals taking federal funds from balance billing COVID-19 patients. On its surface, it appeared the ban would only apply to COVID-19 patients, but the fine print indicated that HHS "broadly views every patient as a possible case of COVID-19."

There is clearly a bi-partisan appetite among many in Congress and the White House to get something done. The White House, however, remains neutral on the most contested issue—market-based payment benchmarks. And congressional paralysis around benchmarks make any legislation unlikely to clear the Senate in this climate. It is in Expect legislation to pass in 2021.

8. Health Savings Accounts (HSAs) and Health Reimbursement Accounts (HRAs)

Health Savings Accounts (HSAs) have been a long-time and popular Republican talking point. The Republican Study Committee (RSC) comprises 145 House GOP lawmakers, and they recently released a plan to enhance HSA contribution caps for individuals and families beyond \$3,500 and \$7,000, respectively. The committee supports proposed language from the Cato Institute to raise limits to \$9,000 per individual and \$18,000 per family. Furthermore, the proposal would allow for more services and products to be paid for with after-tax dollars. The committee supports proposed language from the Cato Institute to raise limits to \$9,000 per individual and \$18,000 per family. The proposal would allow for more services and products to be paid for with after-tax dollars.

The President has not been shy about using his authority to expand HSAs through administrative action. This past year the administration relaxed HSA rules to allow chronic care to be provided without violating high deductible requirements. The IRS also allowed the same benefits for coronavirus detection and treatment.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) also expanded the use of HSAs for thousands of over-the-counter products. While nothing more substantive is likely to happen this year, the Trump administration may work with Congress to enhance HSAs post-2020.

As for HRAs, a final rule the Trump administration released in June 2019 supports employers in providing tax-sheltered health reimbursement (HRA) money so that employees can then purchase health insurance with an individual health plan. The administration believes the rule could prompt nearly 800,000 employers to offer coverage to more than 11 million workers—800,000 of whom could be newly insured.

Employees could use the HRA money to buy ACA-compliant plans, but employers could also participate in an "excepted benefit" HRA. Ixxi The "excepted benefit" HRA would allow employees to use plans that do not comply with Affordable Care Act (ACA) rules if the employer offers a traditional group plan. Excepted benefit HRAs have an \$1,800 annual limit.

Concerns remain that employers might drop their sickest and most costly employees from the employer group plan. Additionally, it is questionable whether individuals would know how to use their HRAs to shop for insurance. However, the Trump administration believes the "final rule" includes enough safeguards, and the coverage expansion and cost savings outweigh concerns.

More recently, the CARES Act provision noted above allowed for over-the-counter reimbursement in CG / OG

HRAs. Additionally, the Internal Revenue Service released a proposed rule that would allow employers to reimburse employees through HRAs for direct primary care arrangements and healthcare sharing ministry memberships. Watch for more regulation and potential legislation action along HRA lines post-2020.

9. Medicaid: Waivers, Block Grants, DSH Cuts, and Fiscal Accountability Rule

Section 1115 Medicaid demonstration waivers allow states the flexibility to experiment with new methods in Medicaid that deviate from those the federal government mandates. Waivers allow states the option to operate their programs beyond what current laws permit. And COVID-19 has now precipitated the use of 1115 waivers as a lever to address the nation's public health emergency. CMS approved Washington's 1115 waiver request to provide them more flexibility in addressing long-term services and supports. States are also using 1135 waivers to address the COVID-19 emergency as well.

Perhaps the most controversial area of 1115 waivers involve work requirements. The administration has reversed actions of previous Democratic and Republican administrations by supporting states in making work requirements a precondition for eligibility. As of March 2020, the Trump administration has approved 12 states that have created work requirement conditions, but courts have struck down several of the programs. Litigation challenges to waivers in states such as Kentucky and Arkansas are ongoing. IXXX

As for the ACA's Medicaid expansion, Republicans have sought to roll Medicaid back since its inception and they came closest to accomplishing their goal when the House passed the American Health Care Act (AHCA) in 2017. Republicans would like to remove the enhanced federal matching rate for the Medicaid expansion population to pre-expansion levels. They would also support replacing the current open-ended federal match with a fixed-block grant. Given the political challenges of enacting federal block grant legislation, the administration is exploring 1115 waivers as a potential way for states to do it on their own. For example, Tennessee has submitted its own block grant proposal through an 1115 waiver but is waiting on federal approval. |xxxi| Utah could follow. |xxxi|

Current plans are considering newer and potentially more palatable iterations such as a "flex-grant" that would increase funding to states that adopt work requirements. One-half of any new funding would need to support the purchase of private plans for low-income individuals.

With regards to Medicaid and disproportionate share (DSH) cuts, COVID-19 kickstarted legislation to eliminate the cuts for 2020 and to significantly reduce cuts for FY 2021. While developing solutions to DSH cuts have been delayed and procrastinated for years, it appears even more activity could happen postelection.

Finally, according to changes to the upper payment limits introduced in the Medicaid fiscal accountability rule (MFAR), states that want to add or renew supplemental payments would have to report considerably more information and go through an intensive review process. It is addition, states would need to have their payments re-approved by the CMS every three years and would have to quantify their yearly audits of disproportionate-share hospital payments. IXXXXIV

Under the same rule, supplemental payments to doctors under the upper payment limit would be capped at 50% of base payments or 75% in rural areas and other regions with clinician shortages. CMS estimates the change would cut Medicaid payments by \$222 million nationwide. CMS would rein in the ability of states to raise their portion of Medicaid money by clamping down on states ability to impose healthcare taxes, such as provider taxes. CMXXXVIII The rule would also limit states power to raise funds from intergovernmental transfers, certified public expenditures, and provider donations. These changes would likely cut Medicaid spending overall by lowering state-generated Medicaid funds and the corresponding matching federal dollars.

Even if there is consensus that more accountability is needed, MFAR has and will face continued pushback, especially given COVID-19 and concerns around key stakeholders' abilities to effectively respond to the epidemic. IXXXIX Demands on state Medicaid programs will not be subsiding anytime soon.

10. Section 1332 State Innovation Waivers, Including Association and Short-Term Health Plans Section 1332 allows states to waive certain ACA requirements, subject to approval from HHS and the Treasury. These innovation waivers enable states to consider different coverage methods within the individual and small-group markets that conforms to ACA goals. As a funding mechanism, the federal government can share the money it would have spent on premium tax credits, cost sharing reductions, and small employer credits. The Trump administration has already relaxed Section 1332 guardrails by enhancing access to association and short-term plans (more below). Support will not likely change in a post-2020 re-election scenario.

Association Health Plans (AHPs) enable small business, such as dairy farmers, car dealers, and accountants, to pool resources to buy health insurance on the premise that more enrollees would offer a more attractive and less costly healthcare benefit for employees. AHPs have been around for decades, but the Affordable Care Act (ACA) heightened oversight of AHPs, subjecting them with little exception to individual and small-group market rules requiring essential health plans.

Through the Department of Labor (DOL), the Trump administration significantly expanded AHP's scope and reach. In 2018, the DOL increased the number of circumstances where aggregated small groups could be labeled as large groups. While recent federal court decisions have found that the health plans violate federal law, AHPs are likely to receive continued support under the Trump administration. **Color of the Court federal law in the country of the Court federal law in the Court federal law i

The Trump administration has also loosened restrictions on short-term health plans, and a final rule released in July of 2018 reversed an Obama administration mandate that short-term plans be limited to 90 days. As a result, short-term plans are legal for up to 12 months and can also be renewed for up to three years. Opponents have expressed concerns that those within the ACA plan marketplace will see higher premiums. Although legal challenges followed the short-term plan rule, courts have upheld the plans to date. A re-elected Trump could seek to expand short-term plan availability in the coming years.

11. Individual Market Enrollment and Subsidies

The Trump administration has withheld wholehearted support for the ACA individual marketplace. Despite COVID-19, the administration has so far refused requests to create a nationwide enrollment opportunity.**
In recent years, the administration also pulled several levers that directly impacted the individual market, including eliminating cost-sharing subsidies, reducing advertising dollars, and removing the individual mandate.

In 2017, the Trump administration eliminated cost-sharing reduction subsidies that had served as motivators for insurers to continue providing ACA marketplace coverage and keep premiums down.**

This change forced insurers to offer subsidies to low-income individuals without any federal government reimbursement. Many individual market payers decided to increase silver plan pricing on the exchanges, which ironically increased the expenses that the federal government paid to subsidize consumers' premiums. Consequently, some individuals who earn too much income to receive subsidies may be priced out of exchange plans.**

Example 1.1

Example 2.1

**Example

The administration also significantly cut advertising dollars and navigator program funding meant to help people sign up for ACA marketplace coverage. And it lowered the tax burden to \$0 for those without insurance, which opened the entire ACA to risk in the courts.**

Evolution

**Evol

Another big question will be regarding the ACA's future and how changes would impact the individual market. After the election, the Supreme Court will hear arguments on the ACA's constitutionality and severability. **CIX** Justice Roberts may cast the pivotal vote again, but he might feel disinclined to strike down the entire law given that he upheld it previously and he wants to avoid jeopardizing the court's perception as a neutral umpire.**

12.340B Curbs

The Trump administration has recently been mired in litigation involving controversial 340B hospital payments for drugs. CMS had planned to cut reimbursements nearly 30%. National hospital groups have challenged the administration on grounds that they overstepped their legal authority in the 2018 outpatient prospective payment system (OPPS) rule. Because courts initially supported the hospitals, the administration pushed forward with smaller but continued 340B cuts in its 2020 OPPS rule. On July 30th, a federal appeals court ruled that the original HHS policy is legal—reversing a lower court decision. A newly released 2021 proposed rule states that payment for drugs acquired under the 340 program would be at an average sales price (ASP) minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent.

In late July, President Trump also announced an executive order that requires community health centers that receive 340B drug discounts to reduce patients' expenses for Epi-pens and insulin. The administration's rulemaking authority is limited, but it would seek to restrict future grants to community health centers unless they offered discounts to patients with high-cost sharing requirements or who were uninsured.civ

Other buzz has surrounded the Trump administration's controversial survey that requires hospitals to provide cost data. The administration has yet to delay the survey's completion despite hospitals' focus on COVID-19 and the time it would take to fill out.^{cv}

Additionally, CMS' recent proposed rule to encourage value-based drug contracts could materially impact the 340B program by reducing the amounts drug manufacturers can charge hospitals. Hospitals who get 340B discounts could benefit while those who do not are worried they may receive less for administering drugs if copay coupons are counted toward Medicaid drug discounts. The 340B fight will continue post-2020.

B. Mechanisms for Change

This article outlined several hypothetical changes above for a re-election scenario, but how could these changes occur? If Trump is re-elected, he may pursue healthcare reforms via legislative and/or regulatory mechanisms. While changing some policy and legislative domains would require federal legislation, Trump could implement other reforms through administrative rulemaking or executive orders. In some circumstances, the administration could pursue joint legislative and regulatory paths. Figure 2 below highlights where different policy priorities might fall in the legislative and regulatory landscape.

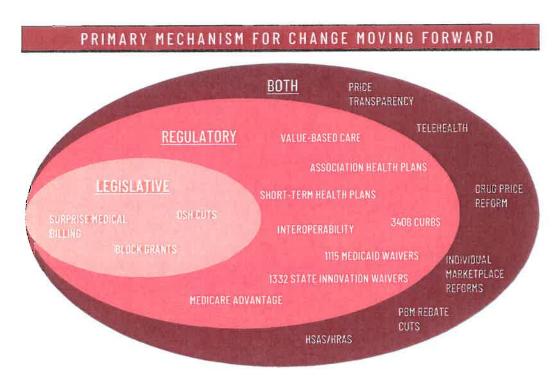


Figure 2. Policy Priorities in Legislative and Regulatory Landscape

Several political conditions would need to be met for President Trump's proposed healthcare policies to be put in place. To pass legislation to enact partisan policies, the Republicans would have to hold the Senate and retake the House in 2020, and, of course, President Trump would need to be reelected. Even then, Senate support and filibuster avoidance could affect whether a bill could proceed via reconciliation and a 50-vote majority.

Some domains face more bi-partisan political support than others. Consequently, laws and/or rules that have general collective political support have a better chance of moving forward despite any one focused interest group's opposition. Figure 3 below highlights some of these dynamics.

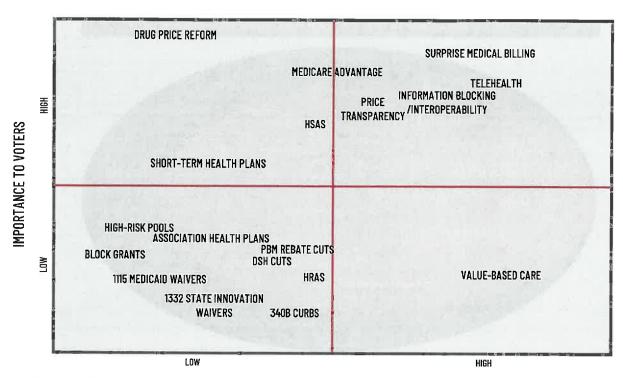


Figure 3. Degree of Bi-Partisan Consensus

Further, court rulings could decide if administrative rules and/or legislation allegedly runs afoul of existing legislative, regulatory, and/or constitutional provisions. Figure 4 below underscores areas in which the courts are hearing litigation challenges to administration policies.

RELEVANT LITIGATION AREAS INCLUDE:

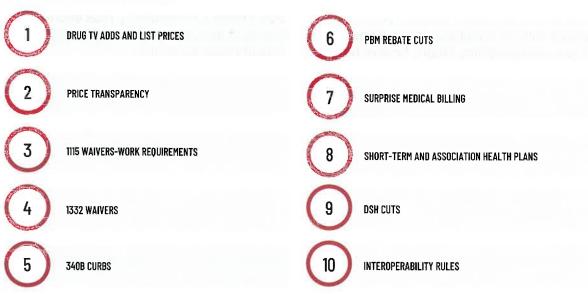


Figure 4. Litigation Regarding Challenges to Administration Policies

CONCLUSION

In conclusion, the twelve-item list outlined above clearly does not cover all the Trump administration's healthcare focus areas. For example, the administration has also supported efforts to help nurse practitioners and physician assistants practice at the top of their license and be reimbursed based on the services offered as opposed to their medical titles. cvii The administration has sought to curb fraud, waste, and abuse. cviii Site-neutrality continues to move forward, and CMS leaders are exploring Medicaid supplemental benefit cuts. Further, COVID-19 will significantly impact the healthcare horizon for the next several years in material ways that are difficult to predict at this point.

On top of the political battles and industries' interactions with the Administrative rule-making process, Federal district and appellate courts will continue to weigh in on several of these matters (as shown in Figure 4 above). The Supreme Court could also play a wild card role since it will hear arguments on the ACA after the election. The Trump administration has urged the Court to overturn the ACA, and overturning all or some of the ACA would materially impact the administration's priorities and focus areas. cix

While one cannot predict future specifics, this article has analyzed past trends to illuminate likely focus areas moving forward. Some areas are significant to voters and consequently may influence public platforms. But, even if an issue is not top-of-mind for consumers, it may still matter immensely to focused interest groups with a lot at stake and with a lot of leverage. While COVID-19 has clearly shaken the healthcare agenda, the issues listed above will not be going away. Some have become even more relevant given the pandemic. Others will gradually return to the forefront as COVID-19 headlines subside. Regardless, it is important to map the impact of possible scenarios, to defensibly stress test projections, minimize risk, and maximize the potential to create a sustainable business model that serves the healthcare community well into the future.

ENDNOTES Cicero Group. The State of Healthcare if the Democrats Sweep in November," (July 8, 2020). https://cicerogroup.com/the-state-of-healthcare-if-the-democrats-sweep-innovember/ ii STAT News. "Donald Trump says Medicare should negotiate drug prices," (January 26, 2016). https://www.statnews.com/2016/01/26/trump-negotiate-drug-prices/ iii Modern Healthcare. Trump issues drug pricing executive orders on 340B, outpatient drug pay,"(July 24, 2020). https://www.modernhealthcare.com/politics-policy/trump-issues-drugiv U.S. Food & Drug Administration. "Trump administration takes historic steps to lower U.S. prescription drug prices." (December 18, 2019). https://www.fda.gov/news-events/ pres cements/trump-admInistration-takes-historic-steps-lower-us-prescription-drug-prices
Mcdern Healthcare. Trump issues drug pricing executive orders on 340B, outpatient drug pay," (July 24, 2020). https://www.modernhealthcare.com/politics-policy/trump-lssues-drug-p Health Affairs. "International Pricing Index: Outsourcing Negotiations Will Continue the US Drug Cost Crisis," (March 11, 2019). https://www.healthaffairs.org/do/10.1377/ hblog20190307.887201/fu vii Modern He Modern Healthcare. Trump issues drug pricing executive orders on 340B, outpatient drug pay," (July 24, 2020), https://www.modernhealthcare.com/politics-policy/trump-is-Health Affairs. "Administration Outlines Plan to Lower Pharmaceutical Prices in Medicare Part B," (October 26, 2018). https://www.healthaffairs.org/do/10.1377/ viii hblog201810 ix The Hill. "Trump draws ire after retreat on drug prices pledge," (November 24, 2019). https://thehill.com/policy/healthcare/471735-trump-draws-ire-after-retreat-on-drug-prices-pledge Modern Healthcare. Trump issues drug pricing executive orders on 340B, outpatient drug pay, (July 24, 2020). https://www.modernhealthcare.com/politics-policy/trump-issues-drug-pricing-executive-orders-340b-outpatient-drug-par Modern Healthcare. Trump issues drug pricing executive orders on 340B, outpatient drug pay, "(July 24, 2020), https://www.modernhealthcare.com/politics-policy/trump-isχij The Wall Street Journal. "Trump Administration Drops Plan to Curb Drug Rebates," (July 11, 2019). https://www.wsj.com/articles/trump-administration-drops-plan-to-curbdrug-rebate xiii The Hill. "Pelosi aide hopeful White House will support drug-pricing bill despite criticism," (November 13, 2019). https://thehill.com/policy/healthcare/4/70310-pelosi-aidethinks-white The Hill. Trump draws ire after retreat on drug prices pledge," (November 24, 2019), https://thehill.com/policy/healthcare/471735-trump-draws-ire-after-retreat-on-drug-pricχίν es-pledge Health Affairs. "Prescription Drug Legislation in Congress: An Update," (December 12, 2019), https://www.healthaffairs.org/do/10,1377/hbloq20191211,602562/full/ χvi The New York Times. "Judge Blocks Trump Rule Requiring Drug Companies to List Prices in TV Ads," (July 8, 2019). https://www.nytimes.com/2019/07/08/health/drug-pricestv-ads-trump.html xvii Modern Healthcare. "Appeals judges quash HHS rule requiring drug prices in TV ads." (June 16, 2020). https://www.modernhealthcare.com/law-requiation/appeals-judgesiiivx Modern Healthcare. "Trump to boost domestic production of drugs, medical supplies," (August 6, 2020). https://www.modernhealthcare.com/supply-chain/trump-boost-domestic-pro drugs-medical-supp U.S. Department of Health & Human Services. Trump Administration Announces Historic Price Transparency Requirements to Increase Competition and Lower Healthcare Costs for All Americans," (November 15, 2019). https://www.hhs.gov/about/news/2019/11/15/trump-administration-announ care-Modern Healthcare. "CMS may not have power to make hospitals disclose negotiated prices," (November 5, 2019). https://www.modernhealthcare.com/law-regulation/ xx ems-may-not-have Health Payer Intelligence. "AHIP: HHS Proposed Price Transparency Rule Not Actionable, Secure," (February 4, 2020). https://healthpayerintelligence.com/news/ahlp-hhs-proxxi posed-price-transparency-rule-not-actionable-secure Modern Healthcare. "Hospitals must prepare for price transparency, experts say," (June 27, 2020), https://www.modernhealthcare.com/law-regulation/hospitals-must-preiiixx Axios. "Trump administration doubles down on hospital price transparency," (May 12, 2020). https://www.axios.com/trump-hospital-price-transparency-medicare-rule-2021-63cd8275-98 xxiv Modern Healthcare. "5 things you don't want to overlook in the IPPS rule," (May 12, 2020). https://www.modernhealthcare.com/medicare/5-things-you-dont-went-overlookipps-rule CMS.gov. "CMS Interoperability and Patient Access final rule," (April 21, 2020). https://www.cms.gov/Requiations-and-Guidance/Guidance/Interoperability/index
Healthcare IT News. "HHS publishes final regs on info blocking, interoperability," (March 9, 2020). https://www.healthcareitnews.com/news/hhs-publishes-final-regs-in-XXV xxvi iivxx Ibid. Modern Healthcare. "Provider groups say privacy, not liability, is top concern with patient apps," (October 26, 2019). https://www.modernhealthcare.com/technology/providxxviii er-groups-Modern Healthcare. "Azar: 'Scare tactics won't stall interoperability rules," (January 27, 2020). https://www.modernhealthcare.com/information-technology/azar-scare-tacxxix tics-wont-stall-interoperability-rul-Modern Healthcare. "Developers, providers question ONC's stance on data-sharing fees," (June 4, 2019), https://www.modernhealthcare.com/information-technology/develop-XXX ers-provider xxxi Healthcare IT News. "President Donald Trump set to speak at HIMSS 20." (March 2, 2020). https://www.healthcareitnews.com/news/president-donald-trump-set-speakhimss20 Modern Healthcare. "HHS approves substance abuse care coordination rule," (July 13, 2020). https://www.modernhealthcare.com/law-regulation/hhs-approves-subxxxii stance-abus xxxiii CMS.gov. "Trump administration drives down Medicare Advantage and Part D premiums for Seniors," (September 24, 2019). https://www.cms.gov/newsroom/press-releases/ trump-admir istration-drives-down-medicare-advantage-and-part-d-premiums-seniors xxxiv VXXX The White House. "Executive Order on Protecting and Improving Medicare for Our Nation's Seniors," (October 3, 2019). https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors xxxví xxxvii Modern Healthcare. "Trump executive order sparks questions about impact on Medicare spending," (October 5, 2019). https://www.modernhealthcare.com/medicare/ trump-execu Becker's Hospital Review. "Trump's \$8.3B coronavirus spending bill lifts Medicare telehealth restrictions," (March 6, 2020). https://www.beckershospitalreview.com/telehealth/ xxxviii trump-s-8-3 xxxix Center for Connected Health Policy. "Telehealth coverage policies in the time of Covid-19," (April 30, 2020). https://www.cchpca.org/resources/covid-19-telehealth-coverage-policies Stat. "1 can't imagine going back': Medicare leader calls for expanded telehealth access after Covid-19," (June 9, 2020), https://www.statnews.com/2020/06/09/seema-verχİ ma-teleheal

xli Modern Healthcare. "Trump orders HHS to make telehealth expansion permanent," (August 3, 2020). https://www.modernhealthcare.com/operations/trump-orders-hhs-make-telehealth-expansion-permanent

xlii The White House, "Executive order on protecting and improving Medicare for our nation's seniors," (October 3, 2019). https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-paties-seniors/
White House, "Executive order or our nation's seniors," (October 3, 2019). https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-paties-seniors/
White House, "Executive order or protecting and improving Medicare executive order," (October 3, 2019). https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-paties-seniors/
White House, "Executive order on protecting and improving Medicare executive order," (October 3, 2019). https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-paties-seniors/
White House, "Executive order on protecting and improving Medicare executive order," (October 3, 2019). https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-paties-seniors/
White House, "Executive order or protecting and improving medicare order or protecting-improving-medicare-paties-seniors/
White House, "Executive order or protecting and improving medicare order or protecting-improving-medicare-paties-seniors/
White House, "Executive order or protecting and improving medicare or protecting in protecting and improving medicare or protecting in protecting i

xliii mHealth Intelligence. "Trump pushes telehealth, mHealth adoption in Medicare executive order," (October 4, 2019). https://mhealthintelligence.com/news/trump-pushes-tele-health-mhealth-adoption-in-medicare-executive-order

xliv lbid.

xiv TechHealth Perspectives. "Telehealth outlook under the Trump administration," (March 10, 2017). https://www.techhealthperspectives.com/2017/03/10/telehealth-outlook-under-the-trump-administration/
Xivi Modern Healthcare. CMS: Permanent telehealth changes coming to home health." (June 25, 2020). https://www.modernhealthcare.com/payment/cms-permanent-telehealth-

xivi Modern Healthcare. CMS: Permanent telehealth changes coming to home health,"(June 25, 2020). https://www.modernhealthcare.com/payment/cms-permanent-telehealth-changes-coming-home-health
shades-coming-home-health
stail: (June 25, 2020). https://www.staineys.com/payment/cms-permanent-telehealth-changes-coming-home-health
shades-coming-home-health
shades-coming-home-health
shades-coming-home-health-changes-coming-home-health
shades-coming-home-health-changes-home-health-changes-home-health-changes-home-health-changes-home-health-changes-home-health-chan

xivii Stat. "1 can't imagine going back': Medicare leader calls for expanded telehealth access after Covid-19," (June 9, 2020). https://www.statnews.com/2020/06/09/seema-ver-ma-telehealth-access-covid19/2
xiviii Care Allies. "Medicare Access and CHIP Reauthorization Act (MACRA)," (2016). https://www.careallies.com/static/docs/careallies-macra-fact-sheet.pdf

xlix Modern Healthcare. "Congress will try to score drug pricing, surprise billing wins in 2020," (January 4, 2020). https://www.modernhealthcare.com/politics-policy/congress-will-try-score-drug-pricing-surprise-billing-wins-2020

U.S. Department of Health and Human Services. "HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care," (October 9, 2019). https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html

```
lì
               CMS.gov. "Medicare and Medicaid Programs, basic health program, and exchanges," (April 29, 2020). https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.
pdf
               Modern Healthcare. "Trump orders HHS to make telehealth expansion permanent," (August 3, 2020). https://www.modernhealthcare.com/operations/trump-or-
III
 ders-hhs-make-telehealth-expansion-permanent
liii
               Medicare Agent News. "CMS wants primary-care docs to take on financial risk," (November 26, 2019). http://medicareagentnews.blogspot.com/2019/11/cms-wants-primary-
liv
               Modern Healthcare. "Congress will try to score drug pricing, surprise billing wins in 2020," (January 4, 2020). https://www.modernhealthcare.com/politics-policy/congress-
lν
 will-try-score
               Forbes. What could value-based healthcare look like next?," (March 14, 2020). https://www.forbes.com/sites/jasonarora/2020/03/14/what-will-value-based-healthcare-look-
 like-un
               House Committee on Energy & Commerce. "Bipartisan House and Senate Committee Leaders Announce Agreement on Legislation to Lower Health Care Costs," (December 8,
lvii
 2019). https://energycom
               energycommerce,house.gov/newsroom/press-releases/bipartisan-house-and-senate-committee-leaders-announce-agreement-on
Associated Press. "White House backs emerging deal on consumer health costs," (December 9, 2019). https://apnews.com/3dac32daee5fa5c474cf2c0ecc064c5c
!viii
11x
               Modern Healthcare. "How Congress' surprise billing compromise fell short," (December 23, 2019). https://www.modernhealthcare.com/politics-policy/how-congress-surprise-
billing-
               HHS.gov. "CARES Act Provider Relief Fund," (March 27, 2020). https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html
lxi
               NPR. 'Congress considers bipartisan compromise legislation on surprise medical bills," (December 17, 2019). https://www.npr.org/sections/health-shots/2019/12/17/788624387/
congress-co
               Modern Healthcare. "Surprise billing fix faces major hurdles in last-minute push," (July 30, 2020). https://www.modernhealthcare.com/politics-policy/surprise-billing-fix-fac-
               Fierce Healthcare. "A group of Republicans has unveiled its healthcare plan. Here is what's new and what isn't," (October 22, 2019). https://www.fiercehealthcare.com/payer/a-
lxiii
group-republicans-have-a-new-healthcare-plan-here-what-new-and-what-isn-t
lxiv
lxv
               lbid.
lxvi
               Modern Healthcare, "Trump administration eases access to chronic disease treatment," (July 17, 2019), https://www.modernhealthcare.com/law-regulation/trump-administra-
tion-eases-
               IRS.gov. "IRS: High-deductible health plans can cover coronavirus costs," (March 11, 2020). https://www.irs.gov/newsroom/irs-high-deductible-health-plans-can-cover-coro-
lxvii
               Congress.gov."H.R.748-Cares Act." (March 27, 2020). https://www.congress.gov/bill/116th-congress/house-bill/148/text
Federal Register. "Health reimbursement arrangements and other account-based group health plans," (June 20, 2019). https://www.federalregister.gov/docu-
Ixviii
Ixix
               6/20/2019-12571/health-reimbursement-arrangements-and-other-account-based-group-health-plans
ments/2019
lxx
               Ibid.
               lbid.
lxxi
iixxl
               Health Affairs. "Final rule on health reimbursement arrangements could shake up markets," (June 14, 2019). https://www.heaithaffairs.org/do/10.1377/hblog20190614.388950/
lxxiii
               lhid
               Modern Healthcare. "Employers can fund workers' individual plans under new Trump rule," (June 13, 2019). https://www.modernhealthcare.com/insurance/employers-can-
IXXIV
fund-workers
              -individual-plans-under-new-trump-rule
lxxv
               Ibid.
Ixxvi
               Congress.gov. "H.R.748-Cares Act." (March 27, 2020). https://www.congress.gov/bill/116th-congress/house-bill/748/text
               Modern Healthcare. "New tax rule could boost HRAs, but don't expect a big impact," (June 10, 2020), https://www.modernhealthcare.com/healthcare-economics/new-tax-
ixxxii
               Kalser Family Foundation. "What does CMS approval of first COVID-19 Section 1115 Waiver in Washington mean for other states," (May 1, 2020). https://www.kff.org/medicaid/
lxxviii
               nat-does-cms-approval-of-first-covid-19-section-1115-waiver-in-washington-mean-for-other-states/
CMS.gov. "CMS Approves Medicaid Section 1135 Waivers for 11 Additional States in Response to COVID-19," (March 23, 2020). https://www.cms.gov/newsroom/press-releases/
issue-brief/v
cms-a
                                                               tates-response-covid-19
               Kaiser Family Foundation. "Section 1115 Medicaid Demonstration Waivers: The current landscape of approved and pending waivers," (February 12, 2019). https://www.klf.org/
lxxx
medicaid/iss
                                              demonstration-waivers-the-current-landscane-of-approved
lxxxi
               Fierce Healthcare. 'A group of Republicans has unveiled its healthcare plan. Here Is what's new and what isn't, "(October 22, 2019), https://www.fiercehealthcare.com/payer/a-
group-repub
              icans-have-a-new-healthcare-plan-here-what-new-and-what-isn-l
iixxxl
lxxxiii
               American Hospital Association. "Senate White House reach agreement on relief package responding to Covid-19," (March 25, 2020). https://www.aha.org/advisory/2020-03-
25-senat
                                  greement-relief-package-responding-covid
               Kaiser Family Fund. "What you need to know about the Medicaid Fiscal Accountability Rule (MFAR)." (January 27, 2020). https://www.kff.org/medicaid/issue-brief/what-you-
lxxxiv
need-to-kno
               -about-the-medicaid-fiscal-accountability-rule-mfar/
lxxxv
               Federal Register. "Medicaid Program; Medicaid Fiscal Accountability Regulation," (November 18, 2019). https://www.federalregister.gov/documents/2019/11/18/2019-24763/
ivxxvi
               Kalser Family Fund. "What you need to know about the Medicaid Fiscal Accountability Rule (MFAR);" (January 27, 2020), https://www.kff.org/medicaid/issue-brief/what-you-
Ixxxvii
need-to-kno
              -about-the-medicaid-fiscal-accountability-rule-mfar/
lxxxviii
Ixxxix
               Modern Healthcare. "CMS should toss proposed MFAR rule, experts say," (April 28, 2020). https://www.modernhealthcare.com/payment/cms-should-toss-proposed-mfar-rule-
experts-say
               Health Affairs. "Feds dramatically relax Section 1332 Waiver guardrails," (October 23, 2018). https://www.healthaffairs.org/do/10.1377/hblog20181023.512033/full/
xci
               The Commonwealth Fund. The past and future of Association Health Plans," (May 14, 2019), https://www.commonwealthfund.org/blog/2019/past-future-associa-
tion-health-plans
               Kaiser Health News. "Trump administration loosens restrictions on Short-Term Health Plans," (August 1, 2018). https://khn.org/news/trump-administration-loosens-restric-
xcii
xciii
               Modern Healthcare. "Appeals court upholds Trump's short-term plan expansion," (July 17, 2020). https://www.modernhealthcare.com/insurance/appeals-court-upholds-
trumps-shor
               Health Affairs. "Court upholds rule on Short-Term Plans," (July 20, 2019). https://www.healthaffairs.org/do/10.1377/hblog20190720.816648/full/
               Politico. "Trump rejects Obamacare special enrollment period amid pandemic," (March 31, 2020). https://www.politico.com/news/2020/03/31/trump-obamacare-coronavi-
XCV
rus-157788
xcvi
               White House. "Remarks by President Trump and Prime Minister Tsipras of Greece in Joint Press Conference." (October 17, 2017). https://www.whitehouse.gov/briefings-state-
ments/rem
xcvii
               NPR. Trump is trying hard to thwart Obamacare. How's that going?" (October 14, 2019). https://www.npr.org/sections/health-shots/2019/10/14/768731628/trump-is-trying-
hard-to-thwart-obamacare-hows-that-going
xcviii
xcix
               Health Affairs. "Supreme Court to hear challenge to ACA," (March 2, 2020). https://www.healthaffairs.org/do/10.1377/hblog20200302.149085/full/
С
               Vox. "The fate of Obamacare is in the Supreme Court's hands yet again," (March 2, 2020), https://www.vox.com/2020/3/2/21147037/obamacare-supreme-court-texas-john-rob-
erts
               Kaiser Health News. "CMS crafts Plan B over 340B hospital reimbursement cuts in response to judge's ruling," (July 31, 2019). https://khn.org/morning-breakout/cms-crafts-
plan-b-over-
               Modern Healthcare. "HHS 340B hospital pay cuts are legal, appeals court rules," (July 31, 2020). https://www.modernhealthcare.com/politics-policy/surprise-billing-fix-faces-
cli
major-hurd
ciii
               Modern Healthcare. "CMS to boost outpatient payments, cut 340B again," (August 4, 2020). https://www.modernhealthcare.com/payment/cms-boost-outpatient-payments-
cut-340b-ad
civ
               Modern Healthcare. "Trump issues drug pricing executive orders on 340B, outpatient drug pay," (July 24, 2020). https://www.modernhealthcare.com/politics-policy/trump-is-
sues-drug-pi
              FlerceHealthcare. "340B Health renews calls for CMS to scrap controversial hospital survey," (May 11, 2020). https://www.fiercehealthcare.com/hospitals-health-sys-
C٧
tems/340b-
               Modern Healthcare. "Medicaid drug rule could have 340b, Medicare pay Implications," (July 20, 2020). https://www.modernhealthcare.com/policy/medicaid-drug-rule-could-
cvi
have-340b
cvii
              Modern Healthcare. "Trump executive order aims to encourage new Medicare benefits," (October 3, 2019). https://www.modernhealthcare.com/medicare/trump-executive-or-
              ourage-new-medicare-benefit:
der-aims-er
```

Modern Healthcare. "Trump administration urges end to ACA in latest court filing," (June 26, 2029), https://www.modernhealthcare.com/government/trump-administra-

cviii

tion-urges-end-aca-latest-court-filing