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Sound Health Policy Objectives Achieved

Health Policy in the Courts

This year, federal courts across the country will issue consequential rulings that will impact a broad range of health policy subjects, from specific Affordable Care Act (ACA) provisions to the constitutionality of the entire landmark 2010 legislation. As part of our 2020 Policy Forecast series, we have identified and analyzed select prominent cases that will impact Medicaid, Medicare and the ACA.

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TEXAS V. UNITED STATES

Overview

In this case, 18 conservative attorneys general and two Texas residents argue that the 2017 Tax Cuts and Jobs Act (TCJA), which zeroed out the individual mandate penalty, rendered the entire Affordable Care Act (ACA) unconstitutional. On December 14, 2018, a Texas federal district judge Reed O'Connor agreed. Judge O'Connor determined that the individual mandate was no longer permissible under Congress' taxing power because the TCJA has eliminated the fine for individuals who failed to comply with the mandate. The district judge also concluded that the individual mandate is essential to and "inseverable" from the ACA, and therefore the entire law is unconstitutional.

Almost exactly a year later, the Fifth Circuit Court of Appeals agreed in part with the district court's decision. The three-judge panel of the Court of Appeals agreed that the individual mandate is unconstitutional because the provision can no longer be regarded as a tax. However, the Fifth Circuit remanded the case back to the district court to decide whether the ACA's other provisions can be separated from the individual mandate, or whether the individual mandate is so fundamental to the ACA's design that the entire law should be found unconstitutional. The decision was reached by a 2-1 ruling, with two Republican appointees forming the majority opinion.

Next Steps

On January 3, 2020, a coalition of Democratic state attorneys generals, US House of Representatives members, and governors appealed the 5th Circuit's decision to the Supreme Court. Each party also requested that the Supreme Court expedite their review schedule in order to hear the case and issue a decision before the end of 2020. A week later, a group of 18 Republican attorneys general and governors—as well as the Department of Justice and two individual plaintiffs—responded, urging the Supreme Court not the hear the case until after district court has further analyzed the question of the individual mandate's severability from the broader ACA.

On March 2, 2020, the Supreme Court granted review in *Texas v. United States*, but declined to hear the case on an expedited basis. This decision means that at least four justices voted to take the case. The Court will likely hear oral arguments in October during the first argument session of the 2020-2021 term, though Chief Justice Roberts has the authority to set oral arguments for after the November election. A decision in the case will not be announced until at least February 2021, and could come as late as April or May.

Analysis

The stakes of the lawsuit remain significant. Because the individual mandate has already been zeroed out by the TCJA, a ruling finding the mandate unconstitutional would have little impact on current health insurance markets. However, if the Supreme Court were to rule that the ACA is unconstitutional, health insurers could once again refuse coverage or otherwise discriminate against patients who have preexisting conditions. Coverage could be terminated for the roughly 20 million Americans who have obtained insurance through the ACA exchanges and expanded Medicaid coverage. Loss of insurance for these individuals would likely mean a rise in uncompensated care for providers, especially in large rural communities that expanded Medicaid coverage through the ACA. The fate of institutions like the Center for Medicare and Medicaid Innovation—which was established through the ACA—is unclear. The Supreme Court may opt for a ruling that deems the ACA unconstitutional while preserving the bulk of the institutional and administrative apparatus that both the Obama and Trump Administrations have built through the law's mechanisms.

From a political standpoint, the Fifth Circuit's decision further complicates the landscape around the ACA and the 2020 presidential election. A ruling in favor of Texas could have allowed Democrats to more clearly and forcefully campaign on the consequences of striking down the ACA and the importance of Supreme Court appointees. A decisive ruling striking down the entire ACA could have accelerated the

need for Supreme Court review. With the Supreme Court's decision not to review the case until after the late fall, the case's impact on the election will remain somewhat muted.

However, the pending nature of this case will continue to put the issue of protections for people with pre-existing conditions front and center, an issue that Democrats campaigned on successfully in the 2018 midterm elections and hope to repeat in 2020. In the House of Representatives, Republican legislators are attempting to move a legislative proposal that would preserve the ACA's protections for patients with preexisting conditions, should the Supreme Court invalidate the entire law. Efforts by House Republicans to quietly push this bill—as well as House Democrats showing no support for it—demonstrate that this issue could, once again, play in Democrats' favor come November.

CONTRACEPTIVE MANDATE

Overview

Under the Affordable Care Act (ACA), employers and educational institutions are required to cover the cost of female contraception for beneficiaries. However, nonprofit religious organizations and other religious employers can qualify for an exemption from this requirement. On November 7, 2018, the Department of Health and Human Services (HHS) finalized two rules expanding religious and moral exemptions from these coverage requirements to non-governmental organizations that have a sincerely held religious or moral objection to the provision.

On July 12, 2019, the Third Circuit Court of Appeals blocked HHS' rules from going into effect by upholding a preliminary injunction. This ruling has prevented the Trump Administration from enforcing its regulations in all 50 states and DC. The Third Circuit's ruling was followed in October by a similar determination from the Ninth Circuit Court of Appeals.

Next Steps

A Catholic institute for women has asked the Supreme Court to take up the question of whether the ACA's contraceptive mandate violates the Religious Freedom Restoration Act. On January 17, 2020, the Court announced that it would consider the contraceptive mandate and the Trump Administration's final rule, combining appeals to the Third and Ninth Circuit Court decisions into a single case. The justices are likely to hear arguments on the case in April 2020 and decide it by late June.

Analysis

According to a National Public Radio poll from June 2019, abortion ranks as the second most important issue for Republicans in their vote for president, behind immigration. For Democrats, the issue ranks fifth. Polling like this signals that the contraceptive mandate and its legal challenge could serve as a galvanizing force for both liberals and conservatives in 2020, regardless of how the Supreme Court rules. The question of which organizations can be compelled by the government to cover contraception is a polarizing topic, and it isn't going away any time soon.

PROVIDER CONSCIENCE

Overview

In May 2019, the US Department of Health and Human Services (HHS) finalized a rule that would expand and consolidate enforcement authority over a variety of federal healthcare conscience laws, including three parts of the Affordable Care Act (ACA). These federal laws protect providers, individuals, and other health care entities from having to provide, participate in, pay for, provide coverage of, or refer for, services such as abortion, sterilization, or assisted suicide. The final rule also expands conscience protections with respect to advance directives. Before the rule could go into effect on November 22, 2019, it was vacated by three separate judges. On November 6, 2019, Judge Paul A. Engelmayer, a federal district court judge in the Southern District of New York, decided that the rule included "numerous, fundamental, and far-reaching" violations of the Administrative Procedure Act (APA). The next day, Judge Stanley Bastian in the Eastern District Court of Washington issued an oral ruling during a hearing, with the same conclusion.

Finally, on November 19, Judge William Alsup—a federal district court judge in the Northern District of California—found that HHS had overstepped its regulatory authority in issuing the provider conscience rule. In the view of Judge Alsup, statutes enacted by Congress have attempted to strike a balance between offering protections to providers who felt a moral objection to performing abortions and sterilizations, and the need to preserve the delivery of health care to Americans, including to those seeking abortions and sterilizations. "Every doctor or nurse, for example, who bowed out of a procedure for religious or ethical reasons became one more doctor or nurse whose shifts had to be covered by someone else, a burden on the healthcare system," wrote Judge Alsup. Because the provider conscience rule "significantly expands the scope of protected conscientious objections," the court determined that it would place "a burden on the effect delivery of health care to Americans in derogation of the actual balance struck by Congress."

Analysis

On January 3, 2020, the Department of Justice filed a notice of appeal in the southern district of New York. No date has been set for the Appeals Court to hear the case.

Next Steps

Because the Trump Administration's final rule and the surrounding litigation once again bring up the subject of abortion, this issue has the potential to be an animating force for both parties ahead of the 2020 election, regardless of whether we see an Appeals or Supreme Court decision this year.

SHORT-TERM LIMITED DURATION INSURANCE PLANS

Overview

Short-term limited duration insurance (STLDI) plans cover beneficiaries for a limited period of time, and are not subject to Affordable Care Act (ACA) regulations including requirements about pre-existing conditions, premiums, annual limits, and benefits. Traditionally, short-term plans have appealed to students and workers between jobs, offering stopgap coverage. On August 1, 2018, the Department of Health and Human Services (HHS) issued a final rule extending STLDI coverage from three to 36 months.

Some stakeholders have expressed concerns that STLDI plans will undermine traditional ACA marketplace plans. Because they are not bound by the same regulations—essential benefits, protections for patients with preexisting conditions—STLDI plans can be cheaper than exchange plan offerings, and therefore attract younger and healthier consumers. Industry groups have reported that the Administration's extension of STLDI options would increase premiums by 1.7% in traditional ACA markets. The Administration has countered that short-term plans offer health care consumers more affordable and flexible coverage options.

The Trump Administration's guidance was challenged in court in September 2018 by a coalition of seven safety net plans and consumer advocates, including the Association of Community Affiliated Plans, and National Alliance on Mental Illness, Mental Health America. Plaintiffs argued that the final rule guidance subverted the intent of Congress—who limited and regulated short-term plans in both the ACA and the Health Insurance Portability and Accountability Act (HIPAA)—by turning a narrow exemption for short-term health plans in a larger, parallel market for non-ACA-compliant plans. On July 19, 2019, the rule was upheld by Judge Richard J. Leon of the DC District Court. Judge Leon determined that the rule would allow STLDI to be sold "side by side" with ACA coverage, but determined that these plans would not significantly destabilize the ACA markets.

Next Steps

The plaintiffs are expected to appeal the decision to the DC Court of Appeals. In the meantime, STLDI plans under the final rule continue to be sold in states that allow them.

Analysis

In May 2019, House Democrats passed the Protecting Americans with Preexisting Conditions Act, which would prohibit the Trump Administration's regulation from going into effect. In addition, the House Energy and Commerce Committee has announced an investigation into 12 companies selling short-term policies, which Democrats often refer to as "junk plans." Arguments that STLDI plans drive up premiums for ACA enrollees, offer less benefits, and do not protect those with pre-existing conditions add fuel to the narrative that Republicans want to take away health insurance, a strategy that Democrats employed successfully in the 2018 election to retake the House of Representatives. These steps indicate that Democrats are prepared to campaign on the promise of protecting the ACA once again.

ASSOCIATION HEALTH PLANS

Overview

On June 21, 2018, the Employee Benefits Security Administration, a division of the Department of Labor (DOL), published a final rule entitled Definition of "Employer" under Section 3(5) of ERISA—Association Health Plans. The rule modifies the definition of "employer" under the Employee Retirement Income Security Act (ERISA) to allow include a broader range of entities, including associations. Specifically, the rule would allow associations to be formed solely for the purpose of offering a health plan to its association members, as long as an association can demonstrate a "commonality of interest" among its members.

In response, twelve Democratic attorneys general (AGs)—led by New York AG Letitia James—sued the Trump Administration. The plaintiffs argued that the DOL final rule violates ERISA and the Administrative Procedure Act, and allows employers to circumvent the essential benefits they are required to cover for employees under the Affordable Care Act (ACA). The attorneys general argued that the rule was designed to undermine and destabilize the ACA markets, and would force states to devote resources to monitoring an influx of new, fraudulent plans offered by associations.

In turn, proponents of the final rule argued that it would provide consumers will greater levels of choice, while expanding coverage to employees of small businesses. The Congressional Budget Office estimated that, by expanding use of AHPs, the final rule would extend insurance coverage to 400,000 previously uninsured people. The Congressional Budget Office (CBO) analysis also determined that the rule would increase premiums for enrollees in the fully regulated ACA markets by 2%.

On March 28, 2019, District Judge John Bates of the district court in Washington, DC, ruled with the plaintiffs in *State of New York v. U.S. Department of Labor*, striking down the Trump Administration's final rule. In his opinion, Judge Bates described the rule as "clearly an end run around the ACA," designed to let employers "avoid the most stringent requirements of the ACA."

Next Steps

The DC District Court's opinion was appealed to a three-judge panel of the US Court of Appeals for the DC Circuit. The Appeals Court heard oral arguments in November 2019, and the questions asked by two of the three judges indicate to health law experts that the panel could issue a narrow ruling that would uphold the DOL's final rule without commenting on the regulation's potential conflict with ACA regulations. No decision has been announced yet.

"Do we have to say anything about the Affordable Care Act in this case?" asked Judge David Tatel, who was appointed by President Bill Clinton. Judge Tatel suggested that the court limit its decision to whether the DOL's expanded definition of "employer" complied with ERISA. Given such a limited ruling, CMS would be left to decide whether the newly authorized AHPs would qualify as large-groups health plans free of ACA mandates.

Analysis

As with the legal battle surrounding short-term limited duration insurance plans, *State of New York v. U.S. Department of Labor* could bolster Democratic rhetoric that Trump Administration is actively working to undermine the ACA, increase premiums, and reduce access to health care. However, because the DOL's broader definition of "employer" would, in fact, lead to an expansion of coverage, this narrative is not so simple. As demonstrated by Secretary of Labor Acosta's comments, above, Republicans are already portraying their efforts as pro-expansion and pro-consumer choice, especially for small business owners and employees. Expect Republicans to portray liberal opposition to the final as evidence that Democrats are motivated by partisanship, rather than an altruistic effort to expand coverage.

RISK CORRIDOR PAYMENTS

Overview

The risk corridor program was designed to reduce the risk faced by insurers in the individual and small-group markets established through the Affordable Care Act (ACA) during the first three years of the program: 2014, 2015, and 2016. Typically, these payers would add a risk premium to existing consumer costs in order to account for uncertainty and volatility in the markets. The risk corridor program was designed to protect insurers in the individual and small-group markets, preempting the need for additional premiums.

Risk corridor payments are made by the government to individual and small-group plans whose actual costs for medical claims exceed their expected costs by certain percentages. Those percentages are the "corridors." At the same time, risk corridor collections are paid to the government by those individual and small-group plans whose actual costs for medical claims fall short of their expected costs by certain percentages.

In February 2014, the Congressional Budget Office (CBO) estimated that risk corridor payments would exceed collections by $8 billion over the three-year program. Though Congress appropriated no funds for the program, the Department of Health and Human Services (HHS) assured payers, in March 2013, that they would be properly compensated for individual and small-group costs, regardless of risk corridor collections. "The risk corridors program is not statutorily required to be budget neutral," HHS wrote in response to stakeholder comments. "Regardless of the balance of payments and receipts, HHS will remit payments as required under section 1342 of the Affordable Care Act."

Section 227 of the 2015 appropriations bill, however, prevented the Centers for Medicare and Medicaid Services (CMS) from transferring funds from other accounts to pay for the risk corridor program. In other words, Congress required the program to be budget neutral. By this point, however, insurers had already set their rates for 2014 and 2015 with the understanding that the government would cover any risk premium. Congress renewed this appropriations rider for 2016 and 2017.

The desire to make the risk corridor program revenue neutral was further complicated by CMS' decision in late 2013 to allow individuals and small groups to keep their 2013 ACA-noncompliant plans. The plans, which are less comprehensive and therefore cheaper, attracted young and healthy beneficiaries away from the individual and small group ACA risk pool. Without these beneficiaries to spread risk and offset costs, insurers' claim under the program exceed government collections by $12.3 billion

More than 50 lawsuits were filed in the US Court of Federal Claims (Court of Claims) by insurers who had losses under the risk-corridor program, including a class action suit with about 150 claimants. These cases were aggregated into four cases which were decided by Court of Claims judges: one decision for the insurers and three for the government. These cases were appealed to the US Court of Appeals for the Federal Circuit. In a divided opinion, the Court of Appeals determined that the government did have an obligation to insurers under section 1342 of the ACA, but that Congress relieved this obligation through its appropriations rider. Appellants had also claimed that the government had violated a contractual agreement with the insurance companies, but the court found that no contractual obligation was created by the risk-corridor program.

Next Steps

The Supreme Court agreed to take up all four cases. Oral arguments for the cases, which are being argued together, began on December 10, 2019. A decision is expected by summer 2020.

Analysis

The resolution of these cases has ramifications well beyond the affected insurers. Many government programs, including health care programs such as Medicare Advantage and Medicaid managed care, but

also housing, transportation, infrastructure, and energy programs, rely on public-private partnerships. As Judge Newman said in her Federal Circuit dissent, "[t]he government's ability to benefit from participation of private enterprise depends on the government's reputation as a fair partner. By holding that the government can avoid its obligations after they have been incurred, by declining to appropriate funds to pay the bill and by dismissing the availability of judicial recourse, this court undermines the reliability of dealings with the government."

One example of how this lawsuit could establish a broader precedent can be seen in the litigation surrounding the cost-sharing reduction (CSR) payments. Similar to the risk corridor payments, the dispute over CSRs was initiated by an ACA payment structure—designed to compensate insurers for risk incurred in the marketplace and keep premiums artificially low—that was not fully paid to insurers. A Supreme Court ruling in the risk corridor case could settle both payment disputes by determining whether the ACA creates a binding obligation (either a statutory obligation or an implied contract) that would entitle insurers to payments.

COST-SHARING REDUCTION PAYMENTS

Overview

The Affordable Care Act (ACA) requires insurers to reduce out-of-pocket costs, deductibles, and coinsurance for silver plan enrollees whose household incomes are below 250% of the federal poverty level. These reduction cost insurers around $7 billion per year. In order to offset these costs, the ACA reimburses payers through cost-sharing reduction (CSR) payments.

In November 2014, the Republican-led House of Representatives sued the Department of Health and Human Services (HHS), arguing that HHS did not have explicit congressional appropriation to make CSR payments. In 2016, Judge Rosemary M. Collyer of the District of Columbia agreed with the House, concluding that HHS could not constitutionally reimburse insurers for CSRs without such an appropriation. This litigation, which has a lengthy history, was resolved in May 2018.

While the Trump Administration stopped making CSR payments to insurers in October 2017—citing Judge Collyer's ruling—12 lawsuits have been filed by insurers against HHS for unpaid CSRs in 2017 and 2018. The government has consistently argued that Section 1402 of the ACA does not obligate the federal government to make CSR payments.

Six of these cases have been decided, including a class action lawsuit that encompasses nearly 100 insurers. In every decided case, judges concluded that insurers are entitled to unpaid CSRs under Section 1402 of the ACA, even in absence of an explicit congressional appropriation. In the class action suit, Judge Margaret M. Sweeney found that the plaintiffs are owed nearly $1.6 billion in unpaid CSRs for 2017 and 2018, though the insurers had previously asked for $2.3 billion.

Next Steps

Four of these cases have already been appealed to the Court of Appeals Federal Circuit. These lawsuits were brought by Montana Health CO-OP, Sanford Health Plan, Community Health Choice, and Maine Community Health Options. Due to the similarity in their legal grievances, the Federal Circuit determined that all four cases should be heard and decided together by the same panel of judges. All other lawsuits have been stayed pending the Federal Circuit's decision.

On January 9, 2020, the three-judge panel heard oral arguments in the four consolidated cases. During the oral arguments, judges questioned whether the four cases could all be determined by a Supreme Court ruling in the risk corridor case. Similar to the CSR litigation, the dispute over risk corridor payments was initiated by an ACA payment structure—designed to compensate insurers for risk incurred in the marketplace and keep premiums artificially low—that was not fully paid to insurers. A Supreme Court ruling in the risk corridor case could settle both payment disputes by determining whether the ACA creates a binding obligation (either a statutory obligation or an implied contract) that would entitle insurers to payments.

Analysis

This case is inextricably linked to another lawsuit where insurers are suing the government over missed risk corridor payments. Both areas of litigation stem from ACA payment structures designed to compensate insurers for risk incurred in the marketplace and keep premiums artificially low. In both cases, anticipated payments were not made in full to insurers. These cases carry the same questions about what obligation the federal government owes to organizations with whom it joins in a public-private partnerships, especially when the presidential administration that initiated the agreement is no longer in office and the underlying statutes have been modified. A Supreme Court ruling in the risk corridor case—which is expected before a CSR decision—could settle both payment disputes by determining whether the ACA creates a binding obligation (either a statutory obligation or an implied contract) that would entitle insurers to payments. This decision could set a judicial precedent for decades to come.

From a policy standpoint, the Trump Administration's decision to stop reimbursing payers for CSRs has not resulted in the ACA Marketplace instability that analysts anticipated. Insurers are still required under the ACA to provide CSRs to low-income beneficiaries enrolled in silver-tier Marketplace plans. To offset the lost CSR reimbursements, payers have built the cost of CSRs into premiums, typically silver-tier premiums only. This practice—known as silver loading—has actually decreased premiums for many other consumers.

This is because the ACA bases premium tax credits (PTCs) on the second lowest-cost available silver plan, known as the benchmark plan. Since silver loading increases silver premiums but not premiums for other tiers, the increase in PTCs reduces net premiums for these non-silver plans, often substantially. According to analysis, in a typical state, silver loading reduced annual premiums for non-silver plans by about $1,100 in 2018 for a 45-year-old, PTC-eligible consumer. These premium reductions have actually increased enrollment in ACA plans, contrary to initial projections. For PTC-eligible silver plan enrollees, premiums and PTCs have increased by roughly the same amount, keeping these beneficiaries from facing substantially higher out-of-pocket costs.

MEDICAID WORK REQUIREMENTS

Overview

Section 1115 demonstration waivers give states the opportunity to test innovative approaches to Medicaid delivery and payment and waive certain provisions of the Medicaid (and CHIP) statute. In general, 1115 waivers can be comprehensive—such as expanding Medicaid to the new adult group—or narrowly target a specific benefit or population. Section 1115 waivers must be budget neutral, meaning the waiver cannot exceed the federal costs that would have been incurred if the waiver never existed. Proposals and concepts in 1115 waivers are developed at the state level. CMS and the state then negotiate the terms of the waiver application. Typically, 1115 waivers are approved for five years and then renewed for up to three years at a time.

States have used 1115 waivers to implement a variety of programs and delivery mechanisms through the Medicaid program. However, allowed program designs through 1115 waivers vary by administration. Under the Trump Administration, for example, states have begun using 1115 waivers to implement waiver work requirements for certain populations. This would have been a non-starter under the Obama Administration.

So far, ten states have received approval from the Trump administration to impose work requirements. Of those, four states—Arkansas, Kentucky, Michigan, and New Hampshire—have had their waivers temporarily halted by challenges in federal court, with Medicaid enrollees arguing that these waivers would restrict coverage and therefore violate the statutory goals of Medicaid. Another 10 states currently have waiver applications pending.

In a pair of March 2019 decisions, Judge James Boasberg of the District Court of the District of Columbia determined that Kentucky and Arkansas' waiver programs were "arbitrary and capricious." The ruling resulted from what Judge Boasberg saw as a failure by CMS to consider the waiver's impact on coverage and care delivery for low-income populations. In July 2019, that same judge rejected New Hampshire's waiver under similar logic.

Next Steps

In May 2019, the Trump Administration appealed Boasberg's March decisions on the Kentucky and Arkansas work requirements to a three-judge panel of the US Court of Appeals for the DC Circuit. During oral arguments, one judge argued that Congress would have included work requirements as part of the original 2010 ACA if it had deemed them appropriate. Another judge agreed with plaintiffs that financial independence is not an objective of the ACA and Medicaid, saying that the government was "looking for objectives that are not in the statute."

On February 14, 2020, the US Court of Appeals for the DC Circuit struck down the Trump Administration's approval of Medicaid work requirements in Arkansas. By unanimous ruling, the three-judge panel affirmed the district court's ruling that the approval of the work requirements was "arbitrary and capricious. On March 4, Michigan's work requirement was also struck down by a federal judge. Utah is now the only state in the country with active Medicaid work requirements, though penalties for non-compliance do not kick in until later this year.

The decision brings the case closer to possible review from the Supreme Court.

Analysis

Ten states currently have work requirement waivers pending. Seven states have an approved work requirement waiver but have not yet implemented the provision. Other states are considering following suit. For all of these states, the Court of Appeals' decision will have practical and political implications. Some state legislatures may wait and see how the case plays out before they move forward. However, the Trump Administration continues to move forward with approving and promoting work requirements.

The recent Healthy Adult Opportunity initiative, for example—which allows states to implement a block grant or per capita cap in the Medicaid program—also allows states to implement Medicaid work requirements. Additionally, the President's FY 2021 budget proposes the addition of a 20-hour work requirement to qualify for Temporary Assistance for Needy Families (TANF), Supplemental Nutrition Assistance Program (SNAP), and rental assistance programs.

340B Reimbursements Reductions

Overview

Under the 340B Drug Pricing Program, prescription drug manufacturers participating in Medicaid provide outpatient drugs to select providers—called "covered entities"—at a front-end discounted rate, allowing these hospitals to stretch scarce federal resources. In 2018, CMS decreased 340B hospital reimbursement for certain Part B drugs from average sales price (ASP) plus six%, to ASP minus 22.5%, a reduction of nearly 30%. Children's hospitals, cancer hospitals, and rural sole community hospitals were exempted from the payment cut.

In September 2018, a hospital association filed a lawsuit in the US District Court for the District of Columbia, arguing that the cuts exceeded the government's authority under the Medicare statute. On January 10, 2019, the Federal District Court ruled with the plaintiff, determining that the Department of Health and Human Services (HHS) had exceeded its authority. The court determined that the agency did, under statute, have the power to adjust payments for 340B hospitals, but found that a 30% reduction amounted to "fundamental changes in the statutory scheme" and exceeded the agency's adjustment authority. The court also granted a permanent injunction on the 2018 cuts.

The Administration continued the 340B payment cuts under the 2019 OPPS final rule and extended the reduced rates to 340B drugs administered in non-exempt, off-campus hospital outpatient departments. The plaintiffs asked the district court to also declare the 2019 payment reduction unlawful and, in May, the district court ruled in favor of the hospitals for a second time. The court also ruled that the plaintiffs are entitled to relief, but has yet to determine an appropriate amount.

Next Steps

On July 15, 2019, HHS appealed the decision to the DC Circuit Court of Appeals. The court heard oral arguments in early November 2019.

In its 2020 OPPS final rule, HHS continued its policy to pay for drugs acquired through the 340B program at ASP minus 22.5%. However, the agency also solicited comment on a proposal to reimburse at ASP plus 3%, indicating a potential path forward. The agency requested comment on whether this alternate rate would be appropriate for future payments, as well as for remedying underpayments in 2018 and 2019, should the DC Circuit Court of Appeals rule in the plaintiff's favor. Hospitals are likely to seek full reimbursement for 2018 and 2019 at ASP plus 6%.

Analysis

Despite losing two cases at the district court level, CMS has consistently maintained that it has the authority—through the annual OPPS rule—to substantially adjust reimbursement for 340B covered entities. Covered Entities maintain that the 340B program was designed the help providers stretch scarce resources, and that this reimbursement cuts hinders their ability to do so. With both sides standing firm, this case is likely to continue rising through the judicial system.

HHS' decision to reduce 340B hospital reimbursement comes as part of a broader effort to reform the program. While efforts to restructure the program were limited in 2019, 340B Covered Entities should be prepared for increased scrutiny, oversight, and the potential for additional 340B Program compliance requirements in 2020.

SITE NEUTRALITY

Overview

Under Medicare Part B, the Centers for Medicare & Medicaid Services (CMS) pays hospital outpatient departments a rate set in the annual Outpatient Prospective Payment System (OPPS) regulation. CMS concluded the rate for certain clinic-visit services at a specific subset of these outpatient departments—specifically grandfathered off-campus provider-based departments (PBDs)—was too high and that patients could receive similar services from freestanding physician offices at lower cost to the government and to taxpayers. To address this discrepancy, CMS issued the 2019 OPPS final rule, which lowered the payment rate for clinic-visit services at grandfathered off-campus provider-based departments to match the rate for similar services at physician offices. In 2019, this policy was equivalent to a $380 million decrease in reimbursement for hospitals operating off-campus departments. In 2020, the projected cut is $760 million.

Provider groups and hospital associations came together to challenge the final rule in December 2018. In September 2019, US District Judge Rosemary Collyer agreed with the plaintiffs, ruling that CMS exceeded its authority by extending site-neutral payment policy to clinic visits performed at off-campus, provider-based hospital departments. The Trump Administration had argued that the OPPS final rule grants power to the secretary to "develop a method for controlling unnecessary increases in the volume of covered outpatient department services." However, Judge Collyer determined that the agency's rule exceeded the definition of a "method." The law, she wrote, "does not make clear what a 'method' is, but it does make clear what a 'method' is not: it is not a price-setting tool, and the government's effort to wield it in such a manner is manifestly inconsistent with the statutory scheme."

CMS requested that the court reconsider overturning the rule, arguing that "there remains considerable doubt over the correct legal outcome." The agency also pointed to the logistical challenges the decision would pose to the OPPS payment system." In October 2019, Judge Collyer reaffirmed her decision.

Next Steps

In late 2019, CMS announced that the agency will automatically reprocess claims for hospital outpatient services performed in CY 2019. Reprocessing started on January 1, 2020. However, the Department of Health and Human Services, which oversees CMS, appealed the US district court's decision. The Appeals Court is set to hear oral arguments on April 17, 2020. In the meantime, CMS is moving forward with the cuts in the 2020 OPPS final rule.

Analysis

The site-neutral regulation comes as part of a broader Trump Administration effort to reduce national health care costs. Proposed regulatory changes on hospital transparency and the 340B Drug Discount program are other policies that have placed the Administration in conflict with hospitals and hospital advocacy groups.

Congressional action could also play a role in addressing site-neutral payments. H.R.2552, the Protecting Local Access to Care for Everyone Act of 2019, would reverse the site-neutral regulation that the Administration has advanced through OPPS final rules. The bill, introduced by Rep. Derek Kilmer (D-WA-06), currently has two co-sponsors in the House of Representatives.

DRUG PRICING TRANSPARENCY

Overview

On May 8, 2019, the Department of Health and Human Services (HHS) released a final rule requiring drug manufacturers to disclose drug prices in direct-to-consumer (DTC) television advertisements. The new regulation applies to drugs covered by Medicare and Medicaid that have a wholesale acquisition cost (WAC) of at least $35 for a 30-day supply. The "WAC Disclosure Rule" is designed to increase transparency of pharmaceutical pricing, building on current laws requiring manufacturers to disclose drug side effects in televised advertisements. HHS pointed to its general power under the Social Security Act to efficiently administer the Medicare and Medicaid programs as the source of its authority to issue the final rule.

A group of pharmaceutical companies challenged the transparency rule in court, contending that the Trump Administration's action violated their First Amendment rights by compelling them to disclose proprietary information. Manufacturers added that WACs are not the same costs that patients will see at the drug store, meaning that the rule will not meaningfully inform consumers.

Before the rule could go into effect in July 2019, Judge Amit Mehta of the US District Court for the District of Columbia ruled in favor of the drug manufacturers and struck down the final rule. However, Judge Mehta made clear that his decision stemmed less from agreement with the manufacturers' case than from concern about the precedent established by the rule. “This case is not just about whether HHS can force drug companies to disclose their list prices in the name of lowering costs," wrote Judge Mehta in his decision. "Rather, the WAC Disclosure Rule represents a significant shift in HHS’s ability to regulate the health care marketplace. Congress surely did not envision such an expansion of regulatory authority when it granted HHS the power to issue regulations necessary to carry out the ‘efficient administration’ of the Medicare and Medicaid programs.”

Next Steps

HHS filed a notice of appeal in August 2019, and the three-judge panel of the US Court of Appeals for the DC Circuit heard oral arguments in January 2020. In questioning, the judges expressed skepticism with the government's rationale behind the rule. Judge Karen LeCraft Henderson, an appointee of President George H.W. Bush, questioned whether the WAC would meaningfully address the cost of prescription drugs. The list price “is not the price I’ll ever pay. Why is that not adding confusion?" Judge Henderson asked. No date has been set for the Court of Appeals to issue a ruling.

Analysis

Politically, President Trump’s efforts to lower the cost of prescription drugs appeal to a wide swath of voters. In a recent survey from the nonpartisan Kaiser Family Foundation, a plurality (22%) of respondents ranked lowering prescription drug costs as their top issue, and 87% said that it is very important that Congress work on lowering the costs of prescription drugs. However, the same polling found that just 30% of respondents approve of the president’s response to escalating drug costs, signifying that Americans might want more action and less rhetoric on the issue. Polls like these point to building pressure on the White House to deliver meaningful prescription drug pricing reform before November.

In this context, the Trump Administration’s price transparency rule is low-risk, high-reward tactic. While the WAC Disclosure Rule is opposed by drug manufacturers, it has bipartisan support on Capitol Hill. Whether the rule would meaningfully help consumers make informed health care decisions is less important than whether voters believe that the President is actively taking steps to lower the cost of drugs. The WAC Disclosure Rule send this message by altering a format that every American who owns a television is familiar with: the direct-to-consumer advertisement. For these same reasons, Senators Chuck Grassley (R-IA) and Dick Durbin (D-IL) have co-sponsored a bill mandating price transparency in prescription drug advertisements, though the path forward for their legislation is uncertain.

The Administration's final rule comes as part of a broader push among both Republicans and Democrats to address the rising prescription drug costs and health care spending. In July**,** President Trump issued an Executive Order directing HHS to propose a series of rules requiring hospitals to publicize their negotiated charges. The Executive Order called HHS to furnish a second proposed rule that would require payers, providers, and self-insured group health plans to provide out-of-pocket cost information before a patient receives care. On Capitol Hill, broader prescription drug pricing efforts are expected to begin to take shape in the lead up to a May 22, 2020, funding deadline.

HOSPITAL PRICING TRANSPARENCY

Overview

On November 15, 2019, the Centers for Medicare and Medicaid Services (CMS) announced a new rule intended to increase transparency around hospital pricing. The CY 2020 Outpatient Prospective Payment System (OPPS) requires hospitals to provide patients with accessible information about the "standard charges" they should expect to face for the items and services the hospital provides. The regulation is designed to make it easier for consumers to shop and compare across hospitals so that they can find the lowest cost option for their health needs.

Hospitals will be required to make public payer-specific negotiated charges, the amount the hospital is willing to accept in cash from a patient for an item or service, and the minimum and maximum negotiated charges for 300 common “shoppable services,” 70 of which are CMS-specified, with the remaining 230 selected by the hospital. A procedure is shoppable if it can be scheduled in advance by a consumer (*i.e.* x-rays, laboratory texting, or bundled services like a cesarean delivery, including pre- and post-delivery care). Hospitals must make this information available in a single, machine-readable file, and update the information at least annually.

The CY 2020 OPPS final rule added enforcement tools to the transparency requirements, allowing CMS to monitor and audit hospitals, as well as impose civil monetary penalties of up to $300 per day for non-compliant providers.

CMS has finalized an effective date of January 1, 2021, to provide hospitals time to comply with these policies. Four hospital groups have sued the Trump Administration, arguing that the transparency requirements violate the providers’ First Amendment rights and oversteps the government’s legal authority. Plaintiffs added that the broad range of data hospitals are being told to release has the potential to confuse consumers.

Next Steps

Plaintiffs and the Trump Administration submitted their preliminary statements to the US District Court for the District of Columbia in early January 2020. Oral arguments have yet to be scheduled.

Analysis

President Trump campaigned heavily on the promise of increasing transparency in health care. As President, he has continued this agenda, signing an Executive Order that prompted both the hospital and insurer transparency regulatory actions. “We’re going to make the consumer even stronger yet, with transparency, because they’re going to get much better pricing at hospitals,” said President Trump in public remarks. “We wouldn’t expect our employees to go buy a car or a house without knowing the price up front. Why should their healthcare be any different?” Regardless of the US District Court’s ruling, the President is expected to continue to push forward on broad transparency efforts.

PUBLIC CHARGE

Overview

In October 2018, the Department of Homeland Security (DHS) announced a proposed rule, entitled "Inadmissibility on Public Charge Grounds," that allows the federal government to deny an individual entry into the US or an adjustment to their legal permanent resident status (*i.e*. green card) if he or she is deemed likely to become a "public charge." The rule directs US immigration officials to take into account an individual's usage of previously excluded programs, including non-emergency Medicaid for non-pregnant adults, the Supplemental Nutrition Assistance Program (SNAP), and several housing programs. Other considerations allowed by the proposed rule included an applicant's English-speaking ability, their debt history and their poverty level. If an individual is expected to earn less than 125% of the federal poverty level, that would count against them in their application process.

Immigrant rights groups and attorneys general from more than a dozen states challenged the proposed rule, arguing that it is discriminatory against low-income immigrants and immigrants of color. Plaintiffs added that the rule would have a chilling effect on usage of critical public services like SNAP and Medicaid, which provide green card holders and their families with access to nutritional and health care services. Nationwide, over 13.5 million Medicaid and CHIP enrollees, including 7.6 million children, live in a household with at least one noncitizen or are noncitizens themselves and may be at risk for decreased enrollment a result of the rule.

Prominent provider groups across the country have also opposed the proposed rule, citing uncompensated care costs that would likely increase.

The Trump Administration maintains that the rule only clarifies existing statute, citing public charge legislation dating back to the Immigration Act of 1882. "Under long-standing federal law, those seeking to immigrate to the United States must show they can support themselves financially," said then-DHS Secretary Kirstjen Nielsen. "This proposed rule will implement a law passed by Congress intended to promote immigrant self-sufficiency and protect finite resources by ensuring that they are not likely to become burdens on American taxpayers."

The rule was set to go into effect on October 15, 2019, but four federal district courts issued temporary injunctions. In California, US District Judge Phyllis Hamilton ruled that Trump Administration officials "acted arbitrarily and capriciously during the legally-required process to implement the changes they propose" in violation of the Administrative Procedure Act.

In Washington, US District Judge Rosanna Malouf Peterson issued a nationwide injunction ruling that DHS had "not cited any statute, legislative history, or other resource that supports the interpretation that Congress has delegated to DHS the authority to expand the definition of who is inadmissible as a public charge or to define what benefits undermine, rather than to promote, the stated goal of achieving self-sufficiency."

In his ruling, which also instituted a nationwide injunction, Judge George B. Daniels of the Southern District of New York wrote that the public charge rule "is simply a new agency policy of exclusion in search of a justification."

In a statement, the White House expressed its disappointment with the rulings, especially the nationwide injunction. "Congress has also made clear that aliens should 'not depend on public resources to meet their needs,'" the statement said. The rulings today will "allow non-citizens to continue taking advantage of our generous but limited public resources reserved for vulnerable Americans. These injunctions are the latest inexplicable example of the Administration being ordered to comply with the flawed or lawless guidance of a previous administration instead of the actual laws passed by Congress."

Next Steps

The Trump Administration appealed all three decisions and was successful in getting the nationwide and New York injunctions removed. On January 27, 2020, the Supreme Court removed the nationwide injunction, put in place by Judge Daniels' decision. The 5-4 ruling, which was divided along partisan lines, will allow the public charge rule to go into effect while the case is returned to the 2nd US Circuit Court of Appeals for a final decision. Regardless of the 2nd Circuit's ruling, the case will end up back in the Supreme Court. On February 13, the Trump Administration requested a stay on the only injunction still in effect, imposed by an Illinois district court.

The Public Charge rule went into effect on Monday, February 24.

Analysis

The public charge rule has not gotten the mainstream attention that other Trump-era immigration policies have received. This could change in the general election, where a Democrat is likely to challenge the President on the merits of this policy. Immigration remains a key issue for both Democrats and Republicans. For President Trump's base, tighter control of public resources and wider discretion around who can enter this country legally is a popular strategy. The Trump Administration has already described the New York, California, and DC ruling as the result of "activist judges," making decisions based on partisanship rather than statute. Democrats, in turn, have introduced legislation to block the public charge rule. In short, this is a polarizing issue, one that might animate both sides ahead of the 2020 election, regardless of how the 2nd Court and, eventually, the Supreme Court rule in this case.

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