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Legal Sidebar

Affordable Care Act Litigation Still on the Docket After *California v. Texas*

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Referred to as "the most challenged statute in American history" by some commentators, the Patient Protection and Affordable Care Act (ACA) has been the subject of numerous lawsuits since its enactment in 2010—more than 2,000 by one estimate. In June 2021, the Supreme Court dismissed the latest challenge that threatened the entire law's existence in *California v. Texas*, leaving the law intact. The dismissal also preserves other suits challenging particular ACA provisions or the Act's implementation, and these cases may have implications for health insurers, health care providers, employers, patients, and others. This Legal Sidebar provides relevant background on private health insurance requirements in Title I of the ACA, discusses several notable past or pending ACA cases, and concludes with select legal considerations for Congress.

ACA Private Health Insurance Requirements: Background

As the Supreme Court has recognized, Congress enacted the ACA to increase the number of individuals covered by health insurance and decrease health care costs. Among the ACA's key features, Title I adopts several private health insurance market reforms designed to promote access to health coverage and protect consumers against discriminatory insurance practices. These reforms include limitations on preexisting condition exclusions; a bar on lifetime and annual benefit limits; coverage of certain essential health benefits; a prohibition on health insurance rescissions (except under limited circumstances); and coverage of preventive health services without cost sharing. To facilitate health insurance enrollment, the ACA required the creation of an insurance marketplace—or Exchange—in each state. The law also imposes various requirements on plans sold on the Exchange to help ensure their quality and affordability. Additionally, to assist individuals in purchasing health insurance on an Exchange, the ACA provides that certain lower- and moderate-income taxpayers may receive federal subsidies to help offset the cost of coverage. Some of the most prominent ACA litigation has been over Title I of the Act, including the cases discussed below.

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Preventive Health Services: Contraceptive Mandate Lawsuits Continue and Litigation Takes a New Turn

The ACA generally requires most employment-based health plans and health insurers to cover certain preventive health services with no out-of-pocket costs—known as cost sharing—to participants. While the ACA does not specify each service that must be covered, the Act requires plans and insurers to cover, among other things, evidence-based items or services with a rating of "A" or "B" in the current U.S. Preventive Services Task Force (USPSTF) recommendations, vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), and women's services as specified in guidelines issued by the Health Resources and Services Administration (HRSA), an agency of the Department of Health and Human Services (HHS). Currently, there are more than 60 types of covered services, ranging from those related to diabetes, lung cancer, and depression screenings, to breastfeeding support and counseling.

Regulations implementing HRSA's guidelines on women's services—and in particular, those relating to contraceptive coverage requirements—have been the subject of voluminous litigation. The 2012 guidelines called for health plans and insurers to cover all Food and Drug Administration-approved contraceptive methods. These guidelines sparked a clash between the Obama Administration, which viewed women's contraceptive coverage access as an important public health objective, and certain employers and other groups, who argued that the mandatory provision of this coverage through their health plans violated their constitutionally and statutorily protected religious beliefs.

To strike a balance between these interests, beginning in 2012, federal regulations have exempted specified types of religious entities (e.g., churches) from the contraceptive coverage requirements. Later versions of the regulations—including those issued in response to Supreme Court decisions—also allowed other organizations (e.g., religiously affiliated universities and religious, closely-held for-profit entities) to opt-out of providing this coverage by self-certifying their religious objections. This latter approach, which the regulations refer to as an "accommodation," shifted the responsibility of providing contraceptive coverage to an insurance company that services an employer's health plan, and itself became the subject of several legal challenges.

In 2017, while challenges to the accommodation process were pending, the Trump Administration issued interim final rules, which were finalized and went into effect in 2019. The final rules made the accommodation process optional and substantially broadened the existing automatic religious exemption, allowing exemptions for any non-governmental employer that opposes providing coverage of required contraceptives based on sincerely held religious beliefs or moral objections. In 2020, in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, the Supreme Court upheld the amended regulations, concluding, among other things, that the ACA authorized the Administration to issue religious exemptions from the contraceptive mandate. However, the Court's majority opinion in *Little Sisters* left some issues unresolved, including whether the Administration engaged in "reasoned decisionmaking" when crafting the new exemptions as required by the Administrative Procedure Act. As the contraceptive coverage litigation continues, the Biden Administration has indicated its intent to initiate rulemaking and amend the regulations in the coming months. Any future changes to the regulations may alter the posture of current litigation or provoke new legal action.

Aside from the contraceptive mandate litigation, another lawsuit that has captured court watchers' attention is *Kelley v. Azar*. Unlike other cases involving the contraceptive coverage requirements, the plaintiffs in *Kelley* challenge the ACA's preventive service requirements as a whole, alleging the provision violates certain separation-of-powers principles inherent in the Constitution. Among their claims, plaintiffs in *Kelley* assert that the provision violates the Constitution's Appointments Clause because the provision authorizes members of USPSTF, ACIP, and HRSA to make binding determinations as to which preventive services must be covered by health plans and insurers. According to plaintiffs, this constitutes "significant authority" that can only be exercised by properly appointed "Officers of the

United States," and the officials do not meet those requirements. Additionally, plaintiffs insist that the preventive service requirements run afoul of the nondelegation doctrine, which restricts Congress's ability to transfer legislative power to other entities. Although the Supreme Court has previously upheld broad delegation of authority to governmental entities, plaintiffs in *Kelley* argue that the preventive service requirements are an unconstitutional delegation of legislative authority because the ACA provides no "intelligible principle" to guide USPSTF, ACIP, and HRSA on the selection of preventive services to recommend for coverage.

In February 2021, the U.S. District Court for the Northern District of Texas denied a motion to dismiss these claims, concluding that the plaintiffs successfully demonstrated plausible constitutional violations. The parties are expected to file their merits briefs beginning in late 2021. Any forthcoming decision in *Kelley* may be appealed to the U.S. Court of Appeals for the Fifth Circuit. Should the preventive service requirements ultimately be invalidated, it is possible that health plans may be able to impose cost-sharing amounts on enrollees with respect to these services, or may not be required to offer certain preventive services (although some of the ACA's essential health benefits requirements may compel the provision of at least some services for applicable plans).

Suits Remain over Agency Action That Discontinued Cost-Sharing Reduction Payments

To make plans more affordable for low-income enrollees, the ACA created two subsidies—paid by the federal government to insurers—to help reduce two types of costs that an insured individual typically bears under most insurance plans: (1) monthly premiums to maintain coverage, and (2) additional out-of-pocket costs incurred when receiving medical services. The government's payment or non-payment of the second type of subsidy—known as cost-sharing reductions (CSR) payments—has been the subject of numerous lawsuits, in large part due to differences in the two subsidy provisions' statutory text.

The premium subsidy provision under ACA Section 1401 provides a premium tax credit to certain income-qualified individuals enrolled in an Exchange plan of any level to help offset part of the monthly premiums. Plans offered on the Exchange are designated as one of four levels (bronze, silver, gold, or platinum) depending on the percent of the plan benefits the insurer pays. The CSR subsidy provision of Section 1402 requires insurers to reduce the cost-sharing payments of eligible insureds enrolled in silver-level plans offered on the Exchange. The provision, in turn, directs the HHS Secretary to "make periodic and timely payments to the [insurer] equal to the value of the [CSR]." Unlike Section 1401, however, Section 1402 does not refer to the permanent appropriation in 31 U.S.C. § 1324 for tax refund appropriation.

Before these provisions went into effect in January 2014, HHS requested but failed to obtain annual appropriations from Congress to make CSR payments. Between January 2014 and October 2017, the Treasury Department instead made advance payments of both premium tax credits *and* CSR payments to insurers from the tax refund appropriation based on the HHS and Treasury Secretaries' interpretation at the time that this permanent appropriation, as amended by the ACA, was "available to fund all components of the Act's integrated system of subsidies for the purchase of health insurance." In October 2017, however, following the change from the Obama to the Trump Administration, HHS ceased making CSR payments after the Attorney General issued a legal opinion that the tax refund appropriation cannot be used to make such payments.

The agencies' decision to make CSR payments before October 2017 and the payment cessation thereafter raised several legal questions. Foremost among these is whether CSR payments must be funded by annual appropriations, and if so, whether and to what extent insurers are entitled to damages from the federal government if Congress fails to make such appropriations.

As to the first question, two district courts—one in a decision on the merits in *U.S. House of Representatives v. Burwell*, and the other at the preliminary injunction stage in *California v. Trump*—held that the tax refund appropriation did *not* authorize CSR payments, which are subject to annual appropriations. Neither case, however, proceeded beyond these decisions. *Burwell*, filed by the U.S. House of Representatives to challenge HHS's CSR payments before October 2017, resolved by settlement after HHS reversed its position. *California*, filed by several states and the District of Columbia to challenge the payment cessation, was dismissed without prejudice at the plaintiffs' request after states began implementing a workaround strategy known as "silver-loading." Under this strategy, most state regulators allow insurers to price the value of CSRs into silver plan premiums because CSRs are available only with silver plans. Because ACA's premium tax credit amounts are calculated by subtracting each consumer's income-based premium share from the cost of the silver plan offered to the consumer, higher silver premiums—"loaded" with the value of the CSR—mean higher premium tax credit amounts paid by the federal government for not only those who purchased silver plans, but for those who purchase other plans as well. The higher premium tax credit amounts, in turn, enabled many consumers to purchase zero-premium bronze or gold plans at a cost little more than that of silver plans.

As to the second question, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit), in *Sanford Health v. United States*, held that ACA Section 1402 imposed an unambiguous obligation on the federal government to pay the CSR subsidies, and that this obligation is enforceable through a damages action in the Court of Federal Claims under the Tucker Act. In a companion case, *Community Health Choice, Inc. v. United States*, the Federal Circuit also held that the federal government must pay the full amount of unpaid 2017 CSR payments. However, the court continued, to the extent insurers began implementing silver-loading in 2018 and received additional payments from the government in the form of premium tax credits, the damages awarded to insurers must be offset by those additional payments. The Supreme Court, on June 21, 2021, denied the insurers' petition to review the Federal Circuit's decision. The cases have been remanded back to the Court of Federal Claims to determine the damages amount.

"Alternative" Coverage Arrangements: Expanded Timeframe for Short-Term Coverage Available (at Least for Now) and Association Health Plan Litigation on Hold

While the ACA greatly expanded the scope of federal regulation over private health insurance coverage, the Act's insurance market reforms do not apply uniformly to all types of health coverage. For instance, some types of coverage must only comply with a subset of ACA requirements (e.g., large group plans and insurers are not subject to the essential health benefits package requirement or restrictions on charging higher premiums based on an individual's health status), while some less common types of coverage arrangements are exempt from ACA's reforms or other federal standards. To promote coverage subject to fewer ACA private health insurance requirements (or none at all), the Trump Administration issued regulations that extended the maximum period of short-term, limited-duration insurance and encouraged the adoption of association health plans. While some Members of Congress and stakeholders applauded these efforts to expand alternative, lower cost insurance options, critics raised concerns that these initiatives support coverage that lacks important consumer protections and leads to adverse selection problems in other segments of the insurance market. Litigation ensued over these regulatory actions.

Short-term, limited duration insurance (STLDI) is health coverage designed to bridge coverage gaps when an individual moves from one health insurance arrangement to another (e.g., when a worker is in-between jobs). Given the transitional nature of this coverage, STLDI is generally exempt from federal regulation, including ACA's insurance market reforms. However, federal law does not define how long STLDI coverage can last. To restrict STLDI from being used as primary coverage, an Obama-era regulation specified that STDLI policies could have a maximum duration of three months. In 2018, to boost access to this coverage, the Trump Administration amended the rule to extend STLDI coverage to periods of less than twelve months (and renewable for up to thirty-six months). Following the rule's issuance, a health

plan trade association and other parties sued the federal government, claiming the regulation ran contrary to the ACA and other federal requirements. In *Ass'n for Community Affiliated Plans v. U.S. Department of Treasury*, the U.S. Court of Appeals for the D.C. Circuit disagreed with the plaintiffs and upheld the regulation. Following this decision, the future of STLDI remains in the spotlight, as HHS Secretary Xavier Becerra has indicated that the Department is considering future amendments to the regulations.

Association Health Plans (AHPs) are a type of insurance arrangement that allows groups of individuals or small employers to join together to purchase health coverage. While AHP advocates assert that these health plans allow small groups and individuals to pool resources and purchase coverage at better rates than they would be able to do on their own, others note numerous instances where AHPs failed to pay claims because of fraud or mismanagement. In the past, AHP coverage was generally considered subject to the ACA and other federal requirements applicable to individual and small group coverage. However, in 2018, the Trump Administration through the Labor Department issued regulations that greatly expanded the conditions under which AHPs could offer coverage to small employers and individuals, but comply with less comprehensive, large group standards. The regulations generally established broader criteria in which an AHP sponsor (e.g., a trade association or chamber of commerce) could be considered a single, large "employer" under the Employee Retirement Income Security Act (ERISA) for purposes of offering health coverage subject to the ACA and other large group requirements.

A group of eleven states and the District of Columbia sued the Labor Department, claiming the regulation contravenes the text and purpose of ERISA and the ACA, and a district court sided with the states and largely vacated the rule. The Labor Department appealed the case to the D.C. Circuit, but before the appeals court could issue a decision, it granted the Biden Administration's motion to hold the appeal in abeyance. The case now remains on pause as the Department considers further agency action.

Litigation Regarding Scope of Section 1332 Waivers

ACA Section 1332 allows states to apply for an "innovation waiver" in order to implement customized strategies to provide their residents with access to health insurance while retaining the ACA's basic protections. Through a Section 1332 waiver, states can alter key ACA requirements in the individual and small group insurance markets, subject to certain guardrails. Specifically, the HHS Secretary may grant a waiver request only if the state plan: (1) will provide the insureds with coverage that is at least as comprehensive in covered benefits and at least as affordable; (2) will cover at least a comparable number of state residents; and (3) will not increase the federal deficit. To date, most states have sought Section 1332 waivers to implement reinsurance programs to lower premiums for plans sold in the individual insurance market.

In November 2020, the Centers for Medicare and Medicaid Services (CMS) approved the broadest Section 1332 waiver to date to Georgia. Under part of this waiver known as the Georgia Access Model—the state will eliminate the use of HealthCare.gov, the federally-facilitated Exchange, in the individual market and transition to a decentralized, private-entity-based enrollment system beginning with the 2023 plan year. The state believes a decentralized system would better reach uninsured residents because the private entities, now with a larger market, will have greater incentive to engage in marketing and outreach in order to retain existing enrollees and attract new consumers to the individual market.

On January 21, 2021, two health care providers filed suit to challenge CMS's approval of Georgia's waiver. Among its claims, the lawsuits assert that the approval violates ACA Section 1332 and the Administrative Procedure Act because the second part of the waiver fails to meet Section 1332's guardrails. The plaintiffs allege, for instance, that the Georgia Access Model will not provide coverage to a comparable number of state residents and will not provide insureds with coverage that is at least as comprehensive or affordable to state residents. The lawsuit is currently stayed at HHS's request.

Following the transition to the Biden Administration, HHS requested an updated analysis from the state in order to evaluate whether the Georgia Access Model will satisfy Section 1332's statutory guardrails in light of relevant changes to federal law and policy, including the passage of the American Rescue Plan Act of 2021, that alter the uninsured consumers' incentives to seek coverage.

ACA's Antidiscrimination Provision and Sex Discrimination After *Bostock v. Clayton County*

ACA Section 1557 prohibits various forms of discrimination in federally funded or administered health programs or activities. The provision incorporates four preexisting civil rights statutes and the forms of discrimination they prohibit: (1) Title VI of the Civil Rights Act of 1964 (discrimination based on race, color, or national origin); (2) Title IX of the Education Amendments of 1972 (sex discrimination); (3) the Age Discrimination Act of 1975 (age discrimination); and (4) the Rehabilitation Act of 1973 (disability discrimination). Section 1557(c) grants HHS Secretary authority to promulgate regulations to implement this section.

Among other Section 1557 regulations, HHS's regulations implementing Section 1557's prohibition of sex discrimination have been subject to several legal challenges. In its 2016 final rule, the Agency, under the Obama Administration, defined discrimination "on the basis of sex" to include discrimination "on the basis of . . . termination of pregnancy, . . . sex stereotyping, or gender identity." In 2020, under the Trump Administration, HHS finalized a new rule that, among other changes, repealed the 2016 definition and stated that sex discrimination under Title IX "encompasses neither sexual orientation nor gender identity." HHS also incorporated Title IX's religious and abortion-neutrality exemptions. Both the 2016 and 2020 rules drew challenges that raised several legal questions, including whether Title IX's prohibition of sex discrimination encompasses sex stereotyping or gender identity, and whether Section 1557 incorporates Title IX's exemptions.

Related to the first question, the Supreme Court—three days after HHS finalized the 2020 rule—decided *Bostock v. Clayton County*. In *Bostock*, assessing Title VII of the Civil Rights Act's prohibition against sex discrimination in employment, the Supreme Court held that firing an employee for being homosexual or transgender is unlawful discrimination. In the Court's view, such a decision "necessarily and intentionally discriminates against that individual in part because of sex." Since *Bostock*, at least one circuit court has concluded that Title IX's prohibition on sex discrimination must be read similarly.

In the wake of *Bostock*, several plaintiffs—including some health care providers, several transgender women, and 23 states—filed suits seeking to extend *Bostock* to the Section 1557 context to prevent the enforcement of the 2020 rule and to revive aspects of the 2016 rule. As of August 2021, two district courts—in *Walker v. Azar* and *Whitman-Walker Clinic, Inc. v. HHS*—issued overlapping nationwide preliminary injunction orders that block some provisions of the 2020 rule. Both orders prevent the federal government from implementing the 2020 rule to the extent it excludes sex stereotyping from the definition of sex discrimination. The *Walker* order also barred the government from excluding "gender identity" from the sex discrimination definition, reinstating the 2016 requirement that prohibits providers from denying or limiting certain health services because of an individual's transgender status. In *Whitman-Walker*, the district court also enjoined the federal government from enforcing its incorporation of Title IX's religious exemption, concluding that HHS failed to provide sufficient justification for this change in position in the 2020 rule.

In May 2021, HHS, under the Biden Administration, issued a notification of interpretation and enforcement, clarifying that the Agency will interpret and enforce Section 1557's prohibition on sex discrimination to include discrimination on the basis of (1) sexual orientation and (2) gender identity. The Agency noted that in enforcing Section 1557, it will comply with the Religious Freedom Restoration Act (RFRA), which imposes a heightened standard of review for government actions that "substantially

burden" a person's religious exercise, and provides a private right of action to seek appropriate relief against the government.

As of August 2021, at least two district courts have ruled in favor of certain religious health care providers' RFRA claims and enjoined the federal government from enforcing Section 1557 in a manner that would require those plaintiffs to perform or provide coverage for gender-transition procedures. In one of those cases, the injunction also applies to abortion services. In a May 2021 status report filed in one of the pending cases, HHS stated it intends to initiate a rulemaking proceeding on Section 1557 that "will provide for the reconsideration of many or all of the changes" to the 2020 rules.

Price Transparency Litigation: Hospital Price Disclosure Rule Upheld and Insurer Rule Lawsuit Halted

The ACA also includes provisions that require hospitals and insurers to publicly disclose certain information to consumers. HHS, under the Trump Administration, invoked these provisions to issue a pair of transparency rules that require hospitals and insurers to disclose certain health care price information. Each of these rules has been subject to legal challenge.

With respect to the hospital price transparency rule, CMS issued the rule pursuant to ACA Section 2718(e), which requires that every hospital in the United States publicly disclose a list of its "standard charges for items and services" it provides. Under the rule, CMS interpreted "standard charges" to include not only a hospital's list prices for its items and services, but also—among other information—the negotiated rates that hospitals charge insurers and the standardized discounted cash prices that hospitals charge self-pay patients who do not have or opt not to use insurance. Hospitals may be subject to a civil monetary penalty of up to $300 per day for noncompliance.

In December 2020 in *American Hospital Ass'n v. Azar*, the D.C. Circuit upheld the rule against a challenge by hospitals and their trade groups. The court held that Section 2718(e) permits the HHS Secretary to adopt a rule that defines "standard charges" to encompass regular rates set in advance for identifiable groups of patients, including payer-specific negotiated charges and standardized discounted cash prices. The court further rejected the plaintiffs' argument that the rule violates the First Amendment, concluding the rule's price disclosure provision is a commercial disclosure requirement permitted under the Supreme Court's decision in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*.

Following the D.C. Circuit's decision in *American Hospital Ass'n*, the hospital price transparency rule went into effect on January 1, 2021 as planned. After CMS identified a trend towards a high rate of hospital noncompliance through samples and review during the initial months of 2021, the Agency, in July 2021, issued a proposed rule to increase the civil monetary penalty amounts using hospital bed counts as a scaling factor. If finalized as proposed, the new penalty amounts would go into effect on January 1, 2022.

With respect to the insurer transparency in coverage rule, which was initially scheduled to go into effect on January 1, 2022, CMS invoked an ACA provision requiring insurers to comply with ACA Section 1311(e)(3), which imposes certain reporting and disclosure requirements for health plans sold on the Exchange. Among the required disclosures, insurers must make publicly available, in plain language, data on enrollment, disenrollment, and number of denied claims; information on cost-sharing and payments with respect to any out-of-network coverage; and "[o]ther information as determined appropriate by the Secretary." Relying on this last clause under Section 1311(e)(3)(A)(ix), the transparency in coverage rule requires insurers to disclose, among other information: (1) in-network provider negotiated rates; (2) historical out-of-network allowed amounts; and (3) drug price information including negotiated rates and historical net prices—i.e., prices paid by insurers to drug manufacturers after deducting drug manufacturer price concessions—for prescription drugs. The disclosures must be made through three machine-readable files posted on a website.

In mid-August 2021, the U.S. Chamber of Commerce and the Pharmaceutical Care Management Association (the national trade association representing pharmacy benefit managers) separately sued to challenge the transparency in coverage rule. The plaintiffs assert, among other arguments: (1) the requirement to disclose information in machine-readable files is inconsistent with Section 1311(e)(3)'s "plaintiff language" requirement; and (2) the requirement to disclose historical net prices for prescription drugs exceeds the HHS Secretary's statutory authority to require certain consumer-facing, coverage-related disclosures under Section 1311(e)(3)(A)(ix).

On August 20, 2021, implementing agencies announced, in light of other statutory requirements enacted following the issuance of the transparency in coverage rule, the agencies will defer enforcement of the machine-readable file requirements until July 1, 2022. The agencies also state they will initiate rulemaking proceedings to determine whether the prescription drug machine-readable file requirement in particular remains appropriate in light of the later statutory enactment that imposed certain prescription drug reporting requirements. Following this announcement, the U.S. Chamber of Commerce voluntarily dismissed its suit on August 25, 2021.

Considerations for Congress

Litigation over the ACA highlights areas in which the law grants or potentially grants federal agencies with authority to implement a range of policy choices within the statutory parameters, as well as areas of statutory ambiguity. To the extent Congress determines that the relevant range of policy choices should be limited or expanded, or that the law should be otherwise clarified, Congress may amend the ACA to alter its scope or method of implementation. Congress could, for instance, further clarify: the application of ACA requirements to AHPs and certain other health insurance arrangements; the funding stream for CSR payments; the method for determining compliance with Section 1332's guardrails; the scope of Section 1557's incorporation of Title IX; and the scope of required price disclosure by hospitals and insurers.

Over the years, various bills have been introduced to address some of these issues. For instance, the Marketplace Certainty Act (S. 964) introduced in the 116th Congress would have expanded eligibility for additional CSR payments for certain enrollees, while providing permanent appropriation for CSR payments generally. Some Members of Congress have also introduced legislation that would impact accessibility to STLDI coverage, including the No Junk Plans Act (S. 942), which would restrict the current STLDI rule's implementation and enforcement, and the Health Coverage Choice Act (H.R. 31), which would codify the current STLDI rule.

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