SUPREME COURT HEARS ARGUMENTS ON THE CONSTITUTIONAL CHALLENGE TO THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

From March 26 to 28, the U.S. Supreme Court heard oral arguments on the 26-state challenge to the Patient Protection and Affordable Care Act (PPACA or Act). The arguments covered a wide range of topics, including jurisdictional issues, core questions about PPACA’s constitutionality and the severability of PPACA’s “individual mandate” from the rest of its provisions. Court watchers can expect a decision in late June. One thing is certain: whatever the Court decides, this will be one of the most consequential cases in recent history.

The Supreme Court granted certiorari to portions of three related cross-appeals brought by the states, National Federation of Independent Business (NFIB) and the federal government, respectively. Because of the complexity and the importance of the issues involved, the Court took the unusual step of ordering three days of oral argument on a variety of topics. Thus, from March 26 to 28, the Court heard arguments on the following issues:

- Whether the Anti-Injunction Act, which generally prohibits suits to restrain the assessment or collection of taxes, bars a pre-enforcement challenge to the individual mandate and its associated penalty provision.
- Whether Congress has the power under Article I of the Constitution to enact the individual mandate.
- If the individual mandate exceeds Congress’s enumerated powers, to what extent (if any) can the mandate be severed from the remainder of PPACA?
- Whether Congress exceeds its enumerated powers (and violates the principles of federalism) by imposing requirements on the states through threats of withholding federal funding for Medicaid.

Florida and 12 other states challenged PPACA within hours of its enactment. Those plaintiffs eventually were joined by 13 additional states, NFIB and individual citizens in challenging key portions of the Act. Among the issues addressed in the lawsuit, the plaintiffs challenged the “individual mandate” found in PPACA § 1501(a)(2)(D) -- a requirement that virtually all Americans obtain and maintain congressionally approved healthcare insurance coverage for themselves and their families, or else pay a penalty.

The plaintiffs successfully argued in the lower courts that the individual mandate is an unconstitutional exercise of Congress’s power to regulate interstate commerce. The district court held the mandate to be "outside Congress' Commerce Clause power," stating bluntly that "[i]t is not Constitutional." A divided panel of the Eleventh Circuit Court of Appeals affirmed, finding that the mandate "represents a wholly novel and potentially unbounded assertion of congressional authority: the ability to compel..."
Americans to purchase an expensive health insurance product they have elected not to buy, and to make them re-purchase that insurance product every month for their entire lives.” Thus, while courts around the country have differed on the constitutionality of the individual mandate, in the 26-state lawsuit, both the trial and appellate courts rejected this broad assertion of federal power.

The trial and appellate courts differed, however, as to whether the individual mandate can be severed from the rest of PPACA. Thus, the ordinarily mundane question of severability has taken on great significance. PPACA contains hundreds of laws on a wide range of subjects -- “approximately 450 separate pieces,” according to the district court. Some of those “pieces,” including many insurance industry reforms, appear inextricably linked to the mandate and, indeed, the plaintiffs argued that was the case. Other provisions are not linked to the mandate and could potentially function should the mandate be struck.

District Judge Roger Vinson noted these facts, but compared PPACA to a finely crafted watch: “[O]ne essential piece (the individual mandate) is defective and must be removed. [The Act] cannot function as originally designed. There are simply too many moving parts in the Act and too many provisions dependent (directly and indirectly) on the individual mandate and other health insurance provisions ....” Thus, the district court held that the entire PPACA is void. The Eleventh Circuit, however, came to a very different conclusion: "The individual mandate … can be severed from the remainder of the Act’s myriad reforms.... The Act’s other provisions remain legally operative after the mandate’s excision ...." Because hundreds of provisions and an indeterminate number of regulations hang in the balance, the question of severability will be a critical issue for the Supreme Court.

The first day of arguments focused on whether or not the Anti-Injunction Act, 26 U.S.C. § 7421(a), bars a pre-enforcement challenge to the individual mandate. The Anti-Injunction Act provides that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person." Throughout the litigation, PPACA’s defenders have argued that the mandate’s associated “penalty” is a “tax,” and that the federal courts therefore may not hear challenges to either provision until the mandate takes effect and a prospective plaintiff actually pays the penalty. This jurisdictional hurdle, if accepted by the Court, would functionally delay any challenge to the individual mandate for several years.

The Justices seem skeptical of this argument. PPACA refers to the penalty provision as a "penalty," not as a "tax," even though the Act does refer specifically to taxes in other provisions. Furthermore, as Justice Ginsburg pointed out, the penalty provision “is not a revenue-raising measure.” It is designed to encourage people to purchase insurance -- "if it's successful … nobody will pay the penalty and there will be no revenue to raise.”

Day two focused on whether the individual mandate is constitutional. PPACA’s defenders consistently have argued that the requirement falls within Congress’s power to regulate interstate commerce, and that, in any event, the mandate is necessary for the proper functioning of many of PPACA’s other provisions. The challengers have argued -- and both the district court and the Eleventh Circuit agreed -- that the mandate falls beyond the reach of the Commerce Clause and the Necessary and Proper Clause.

While we should be cautious in predicting the outcome of any oral argument, it did appear that Justice Kennedy, believed by many to be the “swing vote” in this case, was uniquely focused on individual liberties. “[H]ere the government is saying that the Federal Government has a duty to tell the individual citizen that it must act, and that is different from what we have in previous cases, and that changes the relationship of the Federal Government to the individual in the very fundamental way." Justice Kennedy’s questioning suggests that he, like PPACA’s opponents, views the individual mandate as being different-in-kind from the federal government’s prior attempts to regulate interstate commerce.
On the final day of hearings, the Court heard arguments on two seminal issues: (1) severability and (2) the extent to which Congress may induce (or, from the challengers’ perspective, coerce) the states into accepting changes to the Medicaid program.

The question of severability is one of great practical importance. As noted above, PPACA contains "approximately 450 separate pieces." If the mandate falls, will the rest of the Act fall with it? Or will the Supreme Court attempt to salvage many of its other provisions? The Justices seem divided on this point. Justice Kagan suggested that "half a loaf is better than no loaf." Likewise, Justice Ginsburg indicated that, in her view, if the Court has to choose between "a wrecking operation and a salvage job, a more conservative approach would be a salvage job." Justice Scalia, on the other hand, indicated that invalidating the individual mandate would effectively "cut the guts out" of PPACA, and that, "[o]ne way or another, Congress will have to revisit [the Act] in toto."

The arguments also touched on core federalism concerns, particularly in light of the significant changes PPACA makes to Medicaid. It is common for the federal government to attach conditions to funding, leaving the states with the choice to accept the conditions (along with the funding) or reject them (and the money along with them). The 26 states have argued that Medicaid, as the nation’s single largest grant-in-aid program, is so large that the states cannot risk its funding. In short, although the states are given a "choice" to accept PPACA’s Medicaid reforms, they are functionally coerced into accepting those changes whether they want to or not.

Some Justices were skeptical of this argument. For example, Justice Kagan inquired whether "a big gift from the federal government" is "a matter of coercion." Chief Justice Roberts, however, stated that the imposition of such reforms, under the threat of withholding funds, "seems to be a significant intrusion of the sovereign interests of the State[s]."

No matter the outcome, the Supreme Court’s decision will affect not only the parties, but nearly all individuals, businesses and government entities in the nation. There are, of course, the constitutional issues themselves: What is the scope of federal power? What meaningful restraints, if any, are inherent in our federalist system of government? On a practical level, regulated businesses and other entities will face many other questions that may require professional guidance.

Baker Hostetler’s health industry, policy, tax and employee benefits attorneys are closely monitoring the Supreme Court case and are working together to provide guidance to clients now and following the decision concerning any changes that may be required. For more information or assistance, please contact Larry J. Obhof at lobhof@bakerlaw.com or 216.861.7148; Christopher J. Swift at cswift@bakerlaw.com or 216.861.7461; Susan Feigin Harris at sharris@bakerlaw.com or 713.646.1307; Robert M. Wolin at rwolin@bakerlaw.com or 713.646.1327 or any member of the Baker Hostetler Healthcare Industry Team.

FOURTH CIRCUIT DISCUSSES STARK LAW ISSUES IN TUOMEY, REMANDS FOR RETRIAL

On March 30, 2012, the U.S. Court of Appeals for the Fourth Circuit vacated a $44.9 million judgment against Tuomey Healthcare System (Tuomey) for Stark Law violations and remanded the case to federal district court for a new trial. The ruling was based on procedural grounds in that the court held Tuomey’s seventh amendment right to a jury trial was violated; however, it also discussed two substantive issues under Stark Law opined by the court as likely to be raised upon retrial: (1) whether the term “referral” includes facility fees corresponding to services personally performed by a physician in a hospital, and (2) whether an arrangement that takes into account anticipated referrals implicates the “volume or value” standard.

Facts and Case History

The Tuomey case involves a whistleblower action by a surgeon who alleged Tuomey Healthcare System violated Stark Law -- and in turn the False Claims Act -- when it entered into a series of part-time employment agreements with specialty physicians. The contracts at issue provided that each of the 19 specialist physicians would only perform outpatient procedures at Tuomey facilities and would reassign their third party payments to Tuomey. In exchange, the contracts provided the physicians with a base salary that fluctuated with the net cash collections for outpatient procedures. The physicians were eligible for a productivity bonus equal to 80 percent of net collections, as well as an additional incentive bonus. Tuomey submitted bills to the Medicare and Medicaid programs on behalf of the contracted physicians for their professional services and for hospital services furnished in conjunction with the physicians’ services.

The jury in the case, which went to trial in the U.S. District Court for the District of South Carolina, found that the hospital had violated the Stark Law but not the False Claims Act. On motion by the government, the court set aside the jury verdict.
Fourth Circuit Discussion of Stark Law Issues

Joining a discussion of two substantive Stark Law issues, two judges on the three judge panel of the Fourth Circuit first addressed "whether a facility component that results from a personally performed service constitutes a referral." Recognizing that the services personally performed by a physician in a hospital do not constitute referrals under the Stark Law, the judges opined that language in the preamble to the Stark regulations expressly includes a facility fee or technical component billed by the hospital in conjunction with the physician’s personally performed services as a "referral" for inpatient or outpatient hospital services by the physician.

The second issue discussed by the Fourth Circuit was whether an arrangement that takes into account anticipated referrals implicates the Stark Law’s volume or value standard. The court specifically addressed the definition of an indirect compensation arrangement under the Stark Law, which requires that the aggregate compensation received by a physician vary with or take into account the volume or value of referrals or other business generated by the referring physician. The court determined that, based on the regulatory definition of fair market value and applicable agency commentary, "compensation based on the volume or value of anticipated referrals implicates the volume or value standard." The court further stated that contracts that require a physician to refer patients to a particular provider may be acceptable if the compensation does not take into account the volume or value of anticipated referrals. The court also concluded that the question regarding whether the contracts took into account anticipated referrals, thus violating the volume or value standard, should be decided by a jury.

Tuomey now will face a new trial in the federal district court on the False Claims Act and Stark Law allegations.

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MORE HOSPITALS FACE EXPULSION FROM MEDICARE FOLLOWING UNANNOUNCED COMPLAINT INVESTIGATIONS

A Pennsylvania hospital faces termination from the Medicare program following an unannounced complaint investigation by state health authorities in late March that found "there was a significant threat to the well-being of the patients at the facility." A ban on new patient admissions also was put in place by the state, which determined the hospital "does not have the means to obtain the proper equipment and supplies for surgical, outpatient and emergency services." According to local news reports, state inspectors found the hospital lacked basic surgical supplies (e.g., surgical gloves, medicated soap, syringes and needles) and failed to perform routine maintenance required for electrocardiograms, defibrillators, ventilators and similar equipment. Warning that "deficiencies have been determined to be of such a serious nature that they place the patients’ health and/or safety in immediate jeopardy," the Centers for Medicare and Medicaid Services (CMS) notified the hospital, which recently filed Chapter 11 bankruptcy, that its provider agreement with the Medicare program would be terminated by April 19 "if the immediate jeopardy has not been removed by that date."

Although the situation at this hospital remains an outlier among Medicare providers, this case highlights the domino effect that an unannounced complaint investigation can have. Providers should be aware that CMS and state survey agencies have begun to employ immediate jeopardy termination rights with greater frequency. For example, last year two Texas hospitals were notified by CMS that the agency was exercising its immediate jeopardy rights following an unannounced inspection. In one of these cases, deficiencies were found in ten categories including patient privacy, unsanitary procedures, an insufficient number of signs advising patients of their rights, patient record documentation and communication involving patient grievances. This year two North Carolina hospitals were placed in immediate jeopardy by CMS with one of the facilities receiving its third immediate jeopardy status notice in as many months. Finally, an Ohio hospital was placed under immediate jeopardy status just last month by CMS for security issues within the facility.

Many of these actions follow the issuance of an October 2011 report by the HHS Office of Inspector General (OIG) on "Adverse Events In Hospitals: Medicare’s Responses To Alleged Serious Events" which found that, although complaints generally were being investigated, scrutiny of the errors defined as initiating immediate jeopardy was wanting. The OIG report further urged CMS to follow the agency’s policy of notifying accreditors when complaints are made against hospitals they accredit. Accreditors were notified by CMS only about a third of the time, according to the report.

The OIG also urged CMS to exercise greater consistency in the enforcement and monitoring of corrective actions. This more intrusive monitoring may require hospitals to implement systemic condition of participation reviews following an immediate jeopardy event to avoid a series of immediate jeopardy findings. For example, as a result of an October 2011 complaint investigation, a Florida hospital system was placed in immediate jeopardy status for events associated with the death of a patient. Subsequent to the submission of a plan of correction, CMS lifted the immediate jeopardy status after a
follow-up survey by the state confirmed compliance with the Medicare conditions of participation. However, the system also was advised at the time that “a full Medicare survey” could be expected in the future. Upon the full Medicare survey in January, immediate jeopardy was imposed again for a day as a result of quality performance, infection control and governance deficiencies. The deficiencies that led to the second immediate jeopardy -- which included construction dust from a renovation project that had not been fully sealed off from surgical patient waiting areas; a student nurse carrying a narcotic syringe in his shirt pocket; staff members using their hands to turn off the sink spigot instead of a paper towel; improper monitoring of hazardous waste in the dialysis department and improperly cleansed glucometers -- were not particularly unusual.

Providers should be on alert for such inspections, as recent OIG audits also indicate a trend toward treating violated conditions of participation -- such as minimum continued education training -- as violated conditions of payment and using such deficiencies as a basis for payment recovery.

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TRICARE PARTICIPATION NO LONGER MAKES A PROVIDER A FEDERAL SUBCONTRACTOR, BUT …

Section 715 of the recently enacted National Defense Authorization Act (NDAA) provides that a federal subcontractor relationship will not be created merely because of a provider’s participation in a TRICARE provider agreement. In the two years preceding enactment of Section 715, the U.S. Department of Labor (DOL) stated that it believed certain TRICARE agreements constituted government contracts that consequently imposed significant obligations on providers under affirmative action and Federal Acquisition Regulations. Section 715 reverses the DOL’s efforts to subject hospitals and other providers to the requirements of the Federal Acquisition Regulations and other laws applicable to federal contractors, simply because they signed TRICARE network provider support contracts.

In addition to removing the compliance burdens associated with the Federal Acquisition Regulations, the NDAA exemption applies to "any other law." Consequently, providers will not be subject, as a result of Tricare participation, to many of the EEO and affirmative action laws enforced by the DOL’s Office of Federal Contract Compliance (OFCCP) Programs.

Despite the TRICARE relief, providers still may be considered federal subcontractors and thus be subject to the Federal Acquisition Regulations and the DOL’s OFCCP jurisdiction if they participate in federal healthcare or other programs.

Despite the NDAA enactment, providers should assure they remain in compliance with applicable affirmative action obligations if they participate in other federal healthcare programs. For example, OFCCP Directive No. 293 provides that participation in Medicare Part C (Advantage) or Medicare Part D (prescription drug plans) subjects healthcare providers to OFCCP’s jurisdiction.

It also must be noted that the DOL’s Office of Federal Contract Compliance Programs has not yet acknowledged that the NDAA fully exempts TRICARE providers, despite its clear language.

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EVENTS CALENDAR

April 12

Houston partner Susan Feigin Harris will speak on “New Payment Arrangements, CMS Initiatives, What’s Happening in the Marketplace and What Do You Need to Know?” at the University of Texas School of Law 24th Annual Health Law Conference in Houston, Texas.

April 13

Houston counsel Lynn Sessions will speak on "Health Care Lawyers’ Guide to Data Privacy/Breaches: Best Practices, Risk Management and Responses" at the University of Texas School of Law 24th Annual Health Law Conference in Houston, Texas.
April 19

Houston counsel Lynn Sessions will speak on “Data Privacy & Risk” at Crains General and In-House Counsel Summit in Cleveland, Ohio.

May 11

Houston counsel Lynn Sessions will speak on "Lessons from Cutting Edge Transactions in Health Care and Life Sciences - HIPAA/HITECH Compliance" at the Current Issues in IP Contracting conference in Houston, Texas.

May 24

Houston counsel Lynn Sessions will speak on "Healthcare Data Breaches: Enterprise Impact and Enterprise Approach" at a webinar sponsored by the American Health Lawyers Association.

June 5

Houston counsel Lynn Sessions will speak on "Healthcare Highlights" at the NetDiligence® Cyber Risk & Privacy Liability Forum in Philadelphia, Pennsylvania.

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