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In the Wake of the SCOTUS's Affordable Care Act Decision: What's Next for Health Care Providers? [Ober|Kaler]

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In March 2010 the hotly contested Affordable Care Act (Public Law 111-148) (ACA or the Act) was signed into law by President Obama. Since its enactment, some health care providers have struggled to meet the Act's current deadlines, while others questioned if they should test new care delivery methods in anticipation of the apparent movement away from a pure fee-for-service system. When it was clear that the constitutionality of the ACA would be decided before the United States Supreme Court this summer, some health care providers forged ahead and others took a wait-and-see approach. On June 28, 2012, the Supreme Court made its decision on health care reform, keeping the law for the most part intact, and leaving health care providers to now wonder, "What's next?" Below is a summary of the Court's decision as well as some key areas under the ACA that will now need to be implemented by the Centers for Medicare and Medicaid Services (CMS) and other Department of Health and Human Services (HHS) agencies.

The Court's Decision

The Court resolved constitutional challenges to two provisions of the ACA: (1) the individual mandate and (2) the Medicaid expansion provisions. The Court held that the individual mandate is beyond Congress' Commerce Clause power, but within Congress' plenary power to "lay and collect taxes," and held that the ACA's Medicaid expansion penalty is unconstitutional because it permits the federal government to terminate current Medicaid funding if a state refuses to adopt the Medicaid expansion of the Act. Accordingly, the individual mandate provisions remains intact, along with the Medicaid expansion provisions to the extent that states are now free to accept or decline the expansion without risking their current federal Medicaid funding.

Individual Mandates

Speaking for the majority of the Court, Chief Justice Roberts first explained why the individual mandate is beyond Congress' commerce clause power but within Congress' plenary power to "lay and collect taxes." The government argued that the individual mandate addressed a "substantial and deleterious effect" on interstate commerce from individuals who refuse to purchase health insurance. The government further explained that anything with a substantial and deleterious effect on commerce was within Congress' commerce clause power. Chief Justice Roberts disagreed and held that Congress cannot compel people to become active in commerce in order to regulate that activity. Instead, Congress is limited to regulating commerce only where commercial activity already exists. Chief Justice Roberts explained that this limit on the Commerce Clause must exist or else the government could "justify a mandatory purchase to solve any problem."

Chief Justice Roberts next explained why the individual mandate passed Constitutional muster under Congress' taxing power. Chief Justice Roberts reasoned that the mandate could be "reasonably read" as a tax. Accordingly, Chief Justice Roberts and the majority concluded that the mandate is constitutional because Congress' power to tax is broader than its commerce clause power. Chief Justice Roberts explained that Congress' power to lay and collect taxes is a less effective, yet constitutional, way of affecting individual conduct. Nonetheless, the majority refrained from deciding whether such a tax was a wise policy decision.

The majority also resolved the question of whether the individual mandate is a tax or a penalty. The majority concluded that the individual mandate is a penalty for purposes of declining to enforce the Anti-Injunction Act and is also a tax for constitutional purposes because the effect of the mandate is more akin to a tax than a penalty. If the mandate were a tax, then the Anti-Injunction Act would have prohibited the states' challenge in that the Act prohibits a legal challenge until at least 2013.

Medicaid Expansion

The Court next reviewed the ACA's provision permitting the federal government to terminate current Medicaid funding if a state refuses to adopt the Medicaid expansion of the ACA. To the surprise of many, a different majority of the Court held that the Medicaid expansion penalty of the ACA is unconstitutional. This majority of the Court held that the Medicaid expansion still stands, but states can choose to accept or refuse the expansion without risking their current federal Medicaid funding.

The states argued that the Medicaid expansion exceeds Congress' authority under the Spending Clause, claiming that Congress is coercing the states to adopt the expansion by threatening to withhold all of a state's federal Medicaid grants unless that state accepted the new, expanded funding and complied with the conditions accompanying it. The Court long recognized that the Spending Clause, which grants Congress the power to pay the debts and provide for the general welfare of the United States, permits Congress to grant federal funds to the states, and condition such funds upon the states taking certain actions required by Congress. The Court noted that this power is limited to preserve each state's individual sovereignty and is legitimately exercised only when a state voluntarily and knowingly accepts Congress' conditions on the funding. While Congress may use its spending power to create incentives for states to act in accordance with federal policies, it may not compel the states to adopt a federal regulatory system.

Medicaid spending, without consideration of the ACA expansion, accounts for over 20 percent of the average state's total budget, with federal funds covering the remaining portion of a state's Medicaid program's costs. The threatened loss of such a large amount of a state's budget, the Court reasoned, left the states with no real option but to acquiesce in the Medicaid expansion.

The scope of the Medicaid expansion was critical to the majority's opinion. The Social Security Act, which includes the original Medicaid provisions, reserved to Congress the right to alter, amend or repeal any provision of that statute. The majority ultimately concluded that states could not have anticipated the Medicaid expansion would fall under that right. The majority noted that while the original Medicaid program was designed to protect the neediest among us, the ACA transformed Medicaid into an element of a comprehensive national plan to provide universal health insurance coverage. Accordingly, under the majority's analysis, the Medicaid expansion was more properly viewed as a new program and not as a modification of the traditional Medicaid program. As such, Congress was forcing states to accept this expansion by threatening to terminate their existing federal Medicaid funding, which is impermissible under the Spending Clause.

After determining the Medicaid expansion penalty was unconstitutional, the Court severed the penalty from the rest of the statute because of a severability clause found in the same chapter of the U.S. Code, rather than strike down the ACA in its entirety. While section 1396c is unconstitutional when applied to withdraw existing Medicaid funds from states that decline to adopt the expansion, the Court held that the severability clause demonstrated Congress' intent to leave unaffected the remainder of the chapter and the application of the Medicaid expansion to other, constitutional, circumstances.

The Court concluded that the federal government could offer additional funds for the Medicaid expansion under the ACA and condition acceptance of those funds on the requirements of that Act. States' failure to comply with the conditions of the ACA could result in withdrawal of those additional expansion funds. The federal government cannot penalize states that choose not to participate in the Medicaid expansion by terminating

their current federal funding under the traditional Medicaid program. In the end, "States may now choose to reject the expansion; that is the whole point."

What's Next for Health Care Providers?

Health care providers are now faced with the task of adopting and complying with ACA provisions and associated regulations. These provisions include grants, new voluntary programs, payment reductions for poor quality performance, and increased fraud and abuse enforcement. The changes to the health care system found in the ACA are diverse and impact many sectors. Below we explore several of these areas, including new and proposed regulations and upcoming deadlines.

Traditional Medicaid and Payment Issues

The traditional Medicaid program before the passage of ACA was limited to specific categories of people: financially needy individuals, children, pregnant women, disabled persons and the elderly. Childless adults are notably excluded from Medicaid coverage. Medicaid eligibility is means-tested and based generally on a percentage of income in relation to the federal poverty line (FPL). States, with some federal direction, determine what Medicaid covers. The federal government shares the cost of the Medicaid program with each state and pays approximately 50 percent or more of each state's Medicaid costs.

According to ACA and prior to the Court's opinion, each state could expand Medicaid coverage by including all persons under the age of 65 whose incomes are below 133 percent of the FPL, including childless adults. Alternatively, the state could choose not to do so and have all of its federal funding for that state's existing Medicaid program withheld. If the state chose the expansion approach, the federal government would initially pay 100 percent of the increase in cost to the Medicaid program; however, there was no guarantee that the federal portion would remain that generous—in fact that payment will decline to 90 percent by 2020.

After the Court's decision, some states may choose to decline the ACA-expansion of their Medicaid programs. Under the expansion provisions, the Medicaid program will become a larger health care safety net for people who cannot afford health insurance. States will shoulder at least 10 percent of the cost of that expansion by 2020. Individuals who attempt to purchase health insurance coverage through the soon-to-be established health insurance exchanges will be means-tested. People who have sufficient means to purchase health insurance will be offered insurance. People who are slightly above 133 percent of the FPL (up to four times) will receive a federal subsidy to purchase health insurance. Those people who fall below 133 percent of the FPL, assuming that they attempt to purchase health insurance in the first place, will be eligible for the expanded Medicaid program.

If a state chooses not to expand its Medicaid program, then that state retains control of its Medicaid program without a loss of its existing federal funds and without the increase in ACA funding. In that case, those people who fall below 133 percent of the FPL and are not part of the traditional Medicaid population will not be eligible for Medicaid and will be required to have health insurance under the individual mandate or be subject to the taxing provisions of the individual mandate. Many of these people may be exempt from paying the tax if the tax exceeds eight percent of their income. Recognizing that these people can neither afford to purchase insurance nor be required to pay the tax, these people may decline to enter the health insurance exchange, refuse to purchase health insurance, or decline to participate in the market for health insurance in a meaningful way. In this way, fewer people will have or seek health insurance, supporting the Court's foreshadowing of the ineffectiveness of levying a tax to compel activity.

States that opt out of the ACA Medicaid expansion program may also affect disproportionate share hospitals (DSH). One of the cost-saving measures of ACA was to reduce subsidy payments to hospitals that accept a

disproportionate share of Medicare and Medicaid beneficiaries. DSHs typically accept a large number of uninsured patients. Congress anticipated that many of the uninsured patients at hospitals would become Medicaid patients and that the DSH payments would no longer be needed. DSH hospitals in states that opt out of the expanded Medicaid program will likely still receive lower DSH payments and will not see a significant number of uninsured persons become Medicaid patients to offset that DSH payment reduction. Beyond this, of course, the ACA ordered a number of payment changes in traditional Medicare. For example, DSH payments, as noted above, are scheduled to be cut beginning in 2014, and Graduate Medical Education and Indirect Medical Education changes have already taken place. These changes will remain in place, absent further Congressional action.

CMS Innovation Center and ACOs

Section 3021 of the ACA established the CMS Innovation Center, which is charged with testing, evaluating and spreading new health care payment and delivery models in hopes of transforming the health care system. The Innovation Center is currently funded by Congress with $10 billion for fiscal years 2011 to 2019. The ACA also allows the Secretary HHS to implement rulemaking changes in the health care system based on information learned from the Innovation Center initiatives.

The Innovation Center has been implementing programs such as Pioneer accountable care organizations (ACOs), bundled payments and dual eligible programs, as well as grants such as the Health Care Innovation Challenge. Before the Court's decision, the sustainability of many programs and grants overseen by the Innovation Center was at question. Nevertheless, while the Court's opinion was pending, the Innovation Center moved forward with its programs and grants. These programs, presumably, will now continue.

One model, the ACO Medicare shared savings program, is being tested outside of the Innovation Center. This voluntary program, specifically found in the ACA, includes incentives to health care providers to bridge the gap in the currently fragmented health care system and bring high-quality, low-cost care to Medicare beneficiaries. On October 20, 2011, CMS released its much-anticipated final ACO rule simultaneously with several other agencies that announced guidance and regulations for ACOs. These announcements came just in time to garner participation before the January 1, 2012, statutory deadline under the ACA. The Secretary of HHS recently announced the acceptance of 89 new ACOs into the program, bringing the total number of ACOs to 154 if you count the 32 ACOs under the Pioneer ACO program. Presumably, the information learned from the ACO and other programs may transform the country's health care system into a pay-for-performance system.

Fraud and Abuse

A main aim of the ACA is to combat fraud and abuse and promote new payment and delivery models. The ACA includes more than 32 sections devoted to fraud and abuse and program integrity reforms, each of which is unaffected by the Court's decision. The most notable ACA provisions in this area are:

- *Anti-Kickback.* Section 6402(f)(2) of the ACA amends the anti-kickback statute so that a violation may be shown without establishing actual knowledge of an AKS violation or specific intent to violate the statute. The ACA confirms that a violation of the AKS constitutes a "false or fraudulent claim" under the False Claims Act (FCA). The government can now more easily allege an AKS violation as a predicate for asserting a cause of action under the FCA. Previously, some courts concluded that liability under both statutes could arise only when there was a false assertion of compliance with the AKS. The changes in the ACA also may increase downstream liability for entities insofar as they may be alleged to have "caused the submission of a false claim."
- *Stark.* The ACA amends the Stark Law by modifying some of its exceptions, such as new disclosure requirements under the in-office ancillary services exception. Further, it amends the so-called "whole hospital" exception in a manner that has curtailed the creation of new physician-owned hospitals and limited the extent of physician ownership in existing hospitals.

- *Stark Self-disclosure Protocol.* The ACA authorizes a Medicare self-disclosure protocol pertaining to actual or potential Stark *Law violations.* The subsequently released Self-referral Disclosure Protocol grants HHS discretion to resolve Stark violations and to reduce the amount levied against providers for violations after consideration of the nature of the violation, the disclosure's timeliness, the provider's cooperation, the matter's litigation risk, and the disclosing party's financial position. The Self-disclosure Protocol is a necessary compromise to the Stark Law because the Stark Law was drafted to hold physicians strictly liable for technical, or unintentional, violations.
- *Fraud Protection.* In addition to its amendments of the principal fraud and abuse statutes, the ACA prescribes new program integrity measures that focus on the prevention and detection of fraudulent activities. For example, to improve oversight and to pinpoint fraud and abuse activities, CMS integrated data repository will be expanded to include information from the several federal health care programs, and HHS is required to establish data-sharing and matching agreements with the heads of various agencies. The ACA also includes enhanced screening and enrollment requirements, including background checks, for providers participating in Medicare, Medicaid, and the Children's Health Insurance Program; by 2013, all providers will be required to undergo enhanced screening prior to enrollment. To identify and recover overpayments, the authority of the recovery audit contractors is extended to Medicaid, Medicare Advantage, and Medicare Part D programs.
- *Compliance Plans.* Pursuant to the ACA, many Medicare and Medicaid providers are now required to establish internal compliance programs designed to, among other things, educate employees about fraud and abuse laws, establish reporting mechanisms for fraudulent activity, and direct continual audits of billing and referral practices. Section 6401 of ACA makes the establishment of a compliance program a condition of enrollment under the Medicare, Medicaid, and SCHIP programs. The law requires the Secretary of HHS to establish "core elements" for compliance programs and requires providers and suppliers to establish compliance programs containing those core elements. This provision does not include a specific effective date and requires regulations. Thus, the mandatory compliance program requirement will become effective only after the government issues regulations.
- *Overpayments.* ACA also requires providers and suppliers to report and return overpayments within 60 days of the date the overpayment has been identified or the date that the provider's regular cost report is to be filed. Failure to meet this deadline may result in FCA liability. A related provision, section 6401(a), grants CMS the authority to adjust payments to providers and suppliers based on their federal tax identification numbers. Under the new program, CMS now may reduce funds due to any provider or supplier, regardless of provider number, as long as the entity shares a federal tax identification number with a provider or supplier with a past-due obligation under Medicare. This change to permit "cross-provider" recoveries is a departure from prior recoupment rules, which only allowed for recoupment on the basis of individual provider numbers.

Health Information Technology

The ACA contains a number of provisions that significantly affect health information technology (HIT or Health IT) and which were unaffected by the Court's decision. New programs establish a strong federal presence in the area of collection and use of health care data for quality assurance and bench-marking purposes. In addition, the ACA fosters the use of HIT to improve access to health care. Significant among these provisions are:

- *Operating Rules.* Section 1104 of the ACA establishes a single set of operating rules regarding eligibility and claims status, electronic funds transfers, health care payment and remittance rules, health claims, enrollment in health plans, health plan premium payments, referral authorizations, and unique health plan identifiers, for the purpose of simplifying the administration of health care.

The operating rules will be consensus-based and will reflect the business rules of health plans and health care providers, as well as operation under the standards issued under HIPAA. The National Committee on Vital and Health Statistics will advise the Secretary of HHS on the process, and audits will be performed to ensure that health plans are in compliance. A Review Committee will review the adopted standards and, when appropriate, will coordinate between the electronic health records (EHR) standards approved by the Office of the National Coordinator (ONC.)

- *Standards.* Section 1561 requires the Secretary of HHS and the HIT Policy and Standards Committees to develop interoperable and security standards for the enrollment of individuals in federal and state health service programs. These standards must allow for electronic matching against existing data, simplification of documentation, reuse of stored eligibility information, capability for individuals to manage information online, integration with new programs and rules, and other functionalities necessary to streamline the process. The Secretary of HHS retains the option to require states to implement these standards in order to receive federal funding for Health IT investments, and is required to award grants to eligible entities for the purpose of developing new or adapting existing Health IT so that compliance with standards is reached. The eligible entities then are required to share any developed technology and/or other information.

In addition, section 4302 requires federally conducted or supported health care programs or surveys to collect and report demographic data and requires HHS, with the ONC, to develop national standards for data collection, interoperability, and security for data management systems.

- *Grants.* Several provisions also provide for grants for HIt. For example, section 10410 makes available grants to eligible entities to establish national centers of excellence for depression, which are required to, among other things, use electronic health records and telehealth technology to coordinate, manage, and improve access to health care. In addition, section 5604 establishes grants for qualified community mental health programs to, among many things, provide health IT for health care professionals.
- *Testing Payment Models.* Many programs under the ACA focus on care coordination and the use of Health IT. For example, section 3024 requires the test of a payment incentive and delivery service model that reduces costs by creating physician- and nurse practitioner-directed home-based primary care teams. These teams will employ, among many things, electronic health information systems. Teams who employ electronic health records and Health IT will receive preference for approval.
- *Quality.* Section 3013 directs the establishment of new quality measures where none exist and the improvement, updating, and expansion of existing quality measures. The law requires grants to be awarded to entities for the purpose of developing quality measures that allow for the assessment of, among others, meaningful use of Health IT, health disparities, and equity of health services.

Sunshine Act and Transparency

Section 6002 of the ACA includes provisions requiring data collection and reporting regarding payments and other transfers of value to covered physicians and teaching hospitals from drug, device, and biologicals manufacturers. *Transfers of value* is defined broadly and includes such items as gifts, consulting fees, research activities, speaking fees, meals and travel. Section 6002 of the ACA originally required that manufacturers submit a report in March 2013 including data covering all "payments or other transfers of value" made to covered recipients during the "previous calendar year." Accordingly, many had been concerned that regardless of the status of the implementing regulation, manufacturers were required *by statute* to begin collecting data as of January 1, 2012. This concern heightened as the regulations were delayed into late 2011.

On December 14, 2011, CMS released a much-anticipated proposed rule implementing those provisions. The proposed rule addresses reports of payments and other transfers of value that must be made by all applicable

manufacturers and ownership reports that must be made by all applicable manufacturers and group purchasing organizations (GPOs), which include, for GPOs, a listing of all transfers of value made to physician owners and investors. The proposed regulation would require manufacturers and GPOs to report ownership interests in such organizations held by physicians and, in the case of GPOs, transfers of value made to their physician owners and investors. The information provided to CMS would be made public on a searchable website. The proposed federal obligations would preempt duplicative state reporting requirements.

CMS also proposed to delay the collection of information necessary for both reports until after the publication of the final rule. CMS explained that it was considering requiring that collection of information begin 90 days following the publication of the final sunshine regulations, but solicited comments on whether such a time frame would be sufficient for regulated entities. CMS also requested input from GPOs and manufacturers describing the challenges they might face when setting up the necessary data collection and reporting systems. CMS explained that it was considering requiring that some data be collected during the 2012 calendar year and reported on March 31, 2013, and requested comments on the feasibility of this proposal. The final rule is expected soon, but no firm date has been set.

Tax-Exempt Entities

The ACA added section 501(r) to the Internal Revenue Code, requiring tax-exempt hospital organizations to institute various new polices and procedures. Section 501(r) was effective for tax years beginning after March 23, 2010, except that the Community Health Needs Assessment requirements described below apply to tax years beginning after March 23, 2012. Section 501(r) imposes the following requirements on tax-exempt organizations.

- *Community Health Needs Assessment (CHNA).* Tax-exempt hospitals must complete a CHNA once every three years, based on input from community representatives, and make it widely available to the public. Tax-exempt hospitals must adopt an implementation strategy to meet the needs identified in the CHNA, and must report on its Form 990 how the needs identified in the CHNA are being met. The ACA provides for an excise tax penalty of $50,000 for any tax-exempt hospital that fails to satisfy the CHNA requirement.
- *Financial Assistance and Emergency Care Policies.* Tax-exempt hospitals must have written policies that address financial assistance and emergency medical care. Written financial assistance policies must address eligibility criteria, the application process, the basis for calculating patient charges, the hospital's plan for widely publicizing the policy, and (for hospitals that lack a separate billing and collections policy) a statement concerning collection-related activities in the event of nonpayment.
- *Limitations on Charges.* Under the ACA, tax-exempt hospitals are prohibited from charging individuals eligible for financial assistance more than the amounts generally billed to insured individuals for emergency or other medically necessary care. Tax-exempt hospitals are prohibited from billing individuals eligible for financial assistance "gross charges."
- *Limitation Against Extraordinary Collection Efforts.* Tax-exempt hospitals must make reasonable efforts to determine whether a patient is eligible for financial assistance before taking extraordinary action to collect. *Extraordinary action* generally includes lawsuits, liens on residences, and similar actions.

The IRS has issued guidance on CHNA requirements in IRS Notice 2011-52, and will soon issue proposed regulations that are expected to formalize the concepts in such guidance. With respect to the other requirements of section 501(r), on June 26, 2012, the IRS proposed regulations that provide guidance relating to the establishment of financial assistance and emergency medical care policies, the prohibition of gross charges and limitation on amounts charged for certain care to financial-assistance-eligible individuals, and limitations against extraordinary collection efforts. Comments and requests for a public hearing on these proposed regulations are due September 24, 2012.

It May Still Change

We know now that the ACA remains in effect and that states may decline to participate in Medicaid expansion, since they can do so without of fear losing their traditional federal Medicaid funding. While the Supreme Court decision garnered some attention, the outcome of the upcoming election may again change the form or function of the ACA through the political process. In any event, the key concepts of reduction in fraud, health information technology and transparency remain – for now.