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Supreme Court Preserves ACA's Insurance Subsidies for Federal Exchange Enrollees

The United States Supreme Court issued its ruling in *King v. Burwell*, maintaining income-based subsidies that allow millions of Americans to purchase individual health insurance policies from the federal healthcare.gov insurance exchange. In a 6-3 decision, authored by U.S. Chief Justice John G. Roberts, Jr., the Court deferred to the legislative intent of Congress when it drafted and passed the Affordable Care Act more than five years ago.

What's in dispute

The case centered around one sentence in the law suggesting that subsidies should only be offered through health insurance exchanges established by individual states. Four individuals challenged that provision because they didn't want to be eligible for the subsidies. If they received the subsidy, they'd be obligated to obtain coverage because the cost of health insurance wouldn't be more than eight percent of their income. Without the subsidy, insurance would cost them more than eight percent of their income and they would fall within an exemption. So they argued that individuals in their home state of Virginia, which had a Federal Exchange, didn't qualify for the tax subsidies because the language in the statute provided tax credits to anyone who enrolled in an Exchange "established by the State."

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Medicare Fraud Takedown Touted as Largest in Strike Force History

The U.S. Department of Health and Human Services (HHS), its Office of Inspector General, the Federal Bureau of Investigation, and the Justice Department's Criminal Division announced a nationwide "takedown" of 243 individuals in connection with an alleged Medicare fraud scheme involving more than $700 million in false billings. The individuals charged include 46 doctors, nurses and other licensed health care professionals. "This coordinated takedown is the largest in Strike Force history, both in terms of the number of defendants charged and the loss amount," according to an HHS press release. "This record-setting takedown sends a message to

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How the court interpreted the law

Declaring that sentence ambiguous, the Court said it must look to the "broader structure of the Act" to interpret its meaning—noting its job is to interpret statutes, not just "isolated provisions." In doing so, the Court found interpreting the language to exclude subsidies for individuals enrolling in a federal exchange would "destabilize" state insurance markets and "likely create the very 'death spirals' that Congress designed the Act to avoid." Additionally, it wasn't in keeping with the intent of the Act to treat state and federal exchanges differently—making coverage more affordable for individuals accessing a state exchange but not for those accessing a federal exchange. The Court rejected the argument that the legislature's express use of the phrase "established by the State" would be superfluous if it didn't limit tax credits to state exchanges. While acknowledging that the Court's usual "preference" is to avoid "'surplusage constructions,'" that wasn't warranted in this case it said, in particular because the Act "contains more than a few examples of inartful drafting."

The Majority rejected the argument that the legislature's express use of the phrase "established by the State" would be superfluous if it didn't limit tax credits to state exchanges.

For example, the Court found it "implausible" that the legislature intended the tax credit and two other reforms to be applicable only in states with a state exchange but not those relying on the federal exchange. Explaining the purpose of the legislation, the Court noted that there were three reforms, based on Massachusetts health care reform: guaranteed health insurance coverage for all individuals who apply in a state for coverage, an insurance coverage requirement mandating individuals purchase health insurance or make a payment to the IRS, and finally, tax credits to help finance that mandatory purchase. The court found these three reforms were "closely intertwined" and the legislation couldn't work without all three.

The problem arises, the Court explained, from the legislation's language which "initially provides that tax credits 'shall be allowed' for any 'applicable taxpayer.' 26 U. S. C. §36B(a)" but then later "provides that the amount of the tax credit depends in part on whether the taxpayer has enrolled in an insurance plan through 'an Exchange established by the State under section 1311 of the Patient Protection and Affordable Care Act [hereinafter 42 U. S. C. §18031].' 26 U. S. C. §§36B(b)–(c) (emphasis added)." IRS regulations provide, however, that the tax credits are available to anyone who enrolls in an exchange created by a state or by the Department of Health and Human Services. So it's the IRS rule that the plaintiffs challenged, arguing it conflicts with the language in the Act that says subsidies are for those enrolled in an exchange "established by the State."

The Court broke down the eligibility for subsidies into three requirements: the individual be enrolled in an exchange, the exchange be established by the State, and established under section 42 U.S.C. 18031. The Court observed that the legislation requires all exchanges to provide coverage to all qualified individuals but then defines qualified individuals to be those who reside in the state that established the exchange. If taken literally, the Court explained, that would mean the Federal Exchanges would have no qualified individuals entitled to the coverage guarantee—"But the Act clearly contemplates that there will be qualified individuals on every Exchange."

Therefore, the Court concluded the tax credits apply to both State and Federal Exchanges: "Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter. Section 36B can fairly be read consistent with what we see as Congress's plan, and that is the reading we adopt."

A study released last year by the Urban Institute concluded that an adverse ruling in *King v. Burwell* would have eliminated subsidies worth $28.8 billion to 9.3 million people, likely causing many to give up their coverage.

Reaction to the Court's decision

Not surprisingly there is mixed reaction to the Court's interpretation. Justices Samuel Alito, Clarence Thomas and Antonin Scalia cast the dissenting votes in the case. Scalia read his dissent from the bench after the decision was announced, suggesting his deep disagreement over the decision, which he called the result of "interpretative somersaults" and ultimately "absurd." He argued: "Words no longer have meaning if an Exchange that is not established by a State is 'established by the State.' It is hard to come up with a clearer way to limit tax credits to state Exchanges than to use the words 'established by the State.' And it is hard to come up with a reason to include the words 'by the State' other than the purpose of limiting credits to state Exchanges." Thus, he argued the Majority was rewriting the law in order to preserve the Affordable Care Act. To support his interpretation, Scalia pointed out that excluding subsidies for the Federal Exchange provides motivation for States to establish State Exchanges. As possible support for this argument, note that Pennsylvania's governor announced the state would withdraw its plan to set up a state exchange, a contingency plan put in motion in case the subsidies were ruled inapplicable to Federal Exchange enrollees. Scalia further argued the express reference to subsidies for exchanges established by the State was deliberate and was used several times in the Act. The American Center for Law and Justice, similarly criticized the Court for rewriting the law rather than adhering to its constitutionally provided role of interpreting the law. However, not surprisingly, many other organizations—particularly within the health care industry—as well as state and federal government representatives, issued statements praising the decision preserving the subsidies.

Impact on laboratories

Roughly two-thirds of states rely on the federal exchange for individual health insurance policies. A study released last year by the Urban Institute concluded that an adverse ruling in *King v. Burwell* would have eliminated subsidies worth $28.8 billion to 9.3 million people, likely causing many to give up their coverage. That loss of coverage could have a significant impact on the laboratory sector, as some larger laboratory ventures have reported moderate volume increases connected to the Affordable Care Act—though a significant amount of those increases have been connected to the expansion of Medicaid eligibility in many states.

Takeaway: A major legal challenge to the ACA has failed, protecting health insurance coverage subsidies for residents of states without a State Exchange. G2

Accountable Care: Final Shared Savings Rule and Updates to ACO Model

The centers for Medicare and Medicaid continue to emphasize coordination of care through accountable care organizations (ACOs), finalizing a rule on shared savings and expanding eligibility for the Investment model for ACOs.

A proposed rule updating the Shared Savings Program was issued last December, received 270 public comments and was finalized earlier this month. Last December, *NIR* detailed the proposed Track 3 performance-based risk option for shared savings and prospectively assigning beneficiaries to ACOs "rather than preliminarily assign[ing] to ACOs with a retrospective reconciliation." (See the Dec. 11, 2014 issue of *NIR*). That Track 3 was solidified in the final rule issued June 4, 2015, offering a higher level of sharing than the first two Tracks. Other changes in the rule address:

- Increased "emphasis on primary care services in the beneficiary assignment."
- Facilitating better data access to improve quality of care by doing away with confusing ACO letters to patients about data sharing and relying on point of care signage and notices and having patients stipulate their data sharing preference directly to CMS.

> *"Accountable Care Organizations have shown early but exciting progress in improving quality of care, while providing more patient-centered care at a lower cost."*
>
> — Andy Slavitt, acting CMS Administrator

- Giving ACOs in performance-based risk tracks symmetrical thresholds for savings and losses.
- Permitting renewal of one-sided ACO model agreements (Track 1) for a second term after the first three-year agreement. Track 1 includes shared savings but not losses. Previously, participants would have to renew for a two-sided risk track after that initial Track 1 period. To be eligible for this renewal, the ACO must have met "the quality performance standard in at least one of the first two years" of the initial three-year agreement.
- Waiving the three-day skilled nursing facility stay rule "for beneficiaries that are prospectively assigned to ACOs under Track 3."
- Refining the way benchmarks are reset at the start of subsequent agreement periods.

CMS issued a Fact Sheet summarizing the major changes the Final Rule makes to the program. "Accountable Care Organizations have shown early but exciting progress in improving quality of care, while providing more patient-centered care at a lower cost," said CMS Acting Administrator Andy Slavitt, in a press release announcing the Final Rule. "The ACO rules today strengthen our ability to reward better care and lay the groundwork for more providers to become successful ACOs."

ACO Investment Model Update

Shortly after the release of the Final Rule, CMS also updated eligibility criteria for its ACO Investment Model for participants in the Medicare Shared Savings Program. This model involves "pre-paid shared savings that builds on experience with the Advanced Payment Model to encourage new ACOs to form in rural and underserved areas and current Medicare Shared Savings Program ACOs to transition to arrangements with greater financial risk," according to a CMS Fact Sheet regarding the Investment Model.

New ACOs joining in 2015 or 2016 can take advantage of the model that provides "pre-payment of shared savings in both upfront and ongoing per beneficiary per month payments." "CMS believes that encouraging participation in areas of low ACO penetration may spur new markets to focus on improving care outcomes for Medicare beneficiaries," the agency said in June 25, 2015 fact sheet. The model is also open to ACOs joining the Shared Savings Program in the years 2012, 2013 or 2014, to encourage a shift to higher risk sharing.

The model involves three types of payments for new ACO participants (joining January 1 of 2015 or 2016):

- Upfront, fixed payment;
- Upfront variable payment (variation is based on "the number of its preliminarily prospectively-assigned beneficiaries"); and
- Monthly payment (which varies based on ACO's number of "preliminarily prospectively-assigned beneficiaries").

"CMS will also give preference to ACOs that provide high quality of care, achieved their financial benchmark, and demonstrate exceptional financial need."

— CMS Fact Sheet

Pre-existing ACO participants that joined the Shared Savings Program on dates in 2012, 2013 and 2014, receive either an upfront variable payment or a monthly payment. Both payments vary based on "the number of its preliminarily prospectively-assigned beneficiaries."

The Investment model is only open to ACOs already participating in the Shared Savings Program and which also:

- Had its first performance year in any year from 2012 to 2016;
- Reported quality measures in the most recent performance year, if it joined the program in 2012, 2013 or 2014;
- Has 10,000 or fewer beneficiaries for the most recent quarter, unless the ACO joined the program in 2015 (or joins in 2016) and is from a rural area using the application selection criteria (in which case it can have more than 10,000 beneficiaries);
- Don't include a hospital participant or provider/supplier (except critical access hospitals or inpatient prospective payment system hospitals having 100 or fewer beds);
- Isn't operated by a health plan; and
- Doesn't participate in the Advance Payment Model.

The Fact Sheet indicates CMS will prefer ACOs serving rural areas and those with low ACO penetration and ACOs moving to higher risk levels. "CMS will also give preference to ACOs that provide high quality of care, achieved their financial benchmark, and demonstrate exceptional financial need." The application period is July 1-31, 2015 for ACOs that start in 2014, 2015 or 2016.

Takeaway: The focus on ACOs as the engine for reforming health care delivery continues. G2

For information about the role of laboratories in ACOs, see G2 Intelligence's report *Laboratory Services in Accountable Care Organizations*. To obtain a copy of the report, please contact G2 customer service at 1-888-729-2315 or visit www.g2intelligence.com.

Health Diagnostic Laboratory Files for Bankruptcy Protection

What perhaps can be considered, in part, fallout from the OIG's Fraud Alert issued last year regarding payments by laboratories to referring physicians and vigorous government enforcement efforts in the sector, Health Diagnostic Laboratory (HDL) has filed for bankruptcy protection. On June 25, 2014, the U.S. Department of Health and Human Services' Office of the Inspector General (OIG) issued a fraud warning regarding payments by laboratories to physicians for processing samples. The OIG warned those payments could constitute an illegal kickback. According to the bankruptcy filing, even before that, the Department of Justice had issued a subpoena to HDL seeking information about its business practices.

Last year's revenue of $320 million was 15 percent below 2013's $375 million, and net income declined by two-thirds, from $45.2 million to $15.3 million.

Less than three months later, the Wall Street Journal published a front-page story highlighting the fraud alert and putting HDL in the spotlight. In April of this year, the company entered into a $47 million settlement with the U.S. Department of Justice regarding how it would process samples. The settlement includes a five-year Corporate Integrity Agreement that requires HDL to implement specific procedures and actions with regard to Focus Arrangements—that is, arrangements that involve any payment or other benefit to referral sources. Those requirements include a review and approval process for such arrangements as well as a tracking system that will monitor all such arrangements including any payments to referral sources and will ensure services contracted for are provided according to the terms of such arrangements.

"The confluence of these events and associated media coverage, as well as certain payer issues and changes in billing practices in certain states that affected the fees earned by HDL from each sample test, caused significant disruption to the Company's business and negatively impacted HDL's recent financial performance," the company said in its bankruptcy filing.

Last year's revenue of $320 million was 15 percent below 2013's $375 million, and net income declined by two-thirds, from $45.2 million to $15.3 million. By the first quarter of this year, the average daily sample test volume dropped to half of what it was in 2013. The eroding numbers broke a covenant with at least one of HDL's lenders, causing a credit squeeze and necessitating the filing.

Facing lawsuits from both private payers and the federal government, its revenue dropping precipitously, in default of lending covenants and even the ability to pay its employees in question, HDL filed for bankruptcy protection earlier this month.

HDL filed for bankruptcy under Chapter 11 on June 7 in the Eastern Virginia district of U.S. Bankruptcy Court.

"While we regret the necessity of seeking protection under Chapter 11, it is the right path for us to take, and we see it as an opportunity to better position our company for continued growth and success while strengthening our finances—ensuring our viability as a company for decades to come," said Chief Executive Officer Joseph McConnell in a statement. "As we have seen in any number of industries—the airlines, automakers and retailers—Chapter 11 can lead to bright, self-sustaining and competitive futures."

In addition to the issues with its creditors, HDL is also fighting lawsuits from Cigna, Aetna, its former sales/marketing arm, as well as a whistleblower suit filed by Chris Riedel, a California-based lab owner who now specializes in qui tam lawsuits against competitors, claiming they are gaming how contracts are negotiated with private and public payers.

Takeaway: Department of Justice investigation and subsequent $47 million settlement leaves Health Diagnostic Laboratory attempting to remake itself after filing for bankruptcy protection. G2

Sequenom Loses Patent Dispute on Appeal

The Federal Circuit appeals court affirmed that Sequenom's Patent No. 6,258,540 (referred to as the '540 Patent) relating to cell-free fetal DNA (cffDNA) didn't assert claims that were patent eligible and was thus invalid. The decision confirms a trial court ruling that addresses a dispute between Sequenom and Ariosa Diagnostics, Inc., Natera Inc., and DNA Diagnostics Center, Inc. regarding alleged infringement of that patent. Sequenom's patent relates to its MaterniT21 test. Sequenom claimed Ariosa's Harmony Prenatal Test and Natera's Non-Invasive Paternity Test (licensed to DNA Diagnostics Center, Inc.) violated the '540 Patent. The trial and circuit appeals courts agreed that the patent claims addressed a natural phenomenon that wasn't patentable subject matter.

The dispute arises out of a discovery of cffDNA in maternal plasma and serum. Two doctors took pre-existing, known technologies and applied them to this new discovery for diagnostic purposes. Doing so could avoid more risky and invasive tests previously used prenatally. The '540 patent didn't claim patent eligibility for the cffDNA discovery but rather the methods for using that cffDNA. Relying on U.S. Supreme Court decisions regarding patentable subject matter in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics*, the appeals court agreed with a trial court's finding of patent ineligibility, explaining the '540 Patent "focused on the use of a natural phenomenon in combination with well-understood, routine, and conventional activity"—that is, routine methods applied in using the cffDNA found in maternal plasma and serum.

The court acknowledged Sequenom's arguments that no one else was using maternal plasma or serum (which had typically been discarded) to find paternally-inherited cffDNA and that the discovery of cffDNA was a "significant human contribution" to the medical field. However, quoting the Supreme Court decision in *Myriad*, the court concluded that "'groundbreaking, innovative or even brilliant discovery'" and significant contributions to the medical field don't necessarily mean there is a patentable subject matter.

Ariosa Diagnostics, Inc. v. Sequenom, Inc., Fed. Cir., No. 2014-1139, No. 2014-1144, 6/12/15.

Takeaway: Looking to the Supreme Court's Mayo and Myriad decisions, another court has refused to uphold a patent linked to a naturally occurring phenomenon. G2

Ariosa's Harmony Test Challenged by Illumina

Although Ariosa scored a victory in its battle with Sequenom (see above) it still faces a battle in a patent infringement lawsuit brought by Illumina. The San Diego-based Illumina filed suit in mid-May against Ariosa Diagnostics, claiming the microarray-based version of its Harmony prenatal assay infringes on a patent for "multiplex nucleic acid reactions." Illumina offers a similar test under its verifi® brand.

Medicare Fraud Takedown Touted as Largest in Strike Force History, *Continued from bottom of p.1*

would-be perpetrators that health care fraud is a risky way to line your pockets," said HHS-OIG Inspector General Daniel R. Levinson in the release. "Our agents and our law enforcement partners stand ready to protect these vital programs and ensure that those who would steal from federal health care programs ultimately pay for their crimes."

The allegations in this case include anti-kickback violations, money laundering and aggravated identity theft relating to home health care, psychotherapy, physical and occupational therapy, durable medical equipment and prescription drugs.

The Affordable Care Act is credited with providing new enforcement resources and $350 million in funding that financed additional prosecutors and expanded Strike Force activities enabling enforcement initiatives such as this takedown. Assistant Attorney General Leslie R. Caldwell also explained in the release how the Department of Justice has become "more strategic" in finding and prosecuting fraud: "We obtain and analyze billing data in real time. We target hot spots—areas of the country and the types of health care services where the billing data shows the potential for a high volume of fraud—and we are speeding up our investigations." For discussion of Caldwell's prior comments on new strategies for fighting fraud, see the May 28, 2015 issue of *National Intelligence Report*.

The allegations in this case include anti-kickback violations, money laundering and aggravated identity theft relating to home health care, psychotherapy, physical and occupational therapy, durable medical equipment and prescription drugs. The government alleges that the individuals charged billed for equipment, care and services not actually provided. Those charged include 78 people in Florida, 29 in Texas, eight in Los Angeles, nine in New York, 11 in New Orleans, and 16 in Detroit. While the cases involve allegations only at this point and must be proved in court, with these new charges, the Department of Justice said national takedown operations to date have yielded charges for over 900 individuals and involved more than $2.5 billion in billings.

This latest takedown emphasizes the increased attention and resources devoted to health care fraud enforcement efforts and prosecution of physicians and other individuals in addition to large organizations. "In the days ahead, the Department of Justice will continue our focus on preventing wrongdoing and prosecuting those whose criminal activity drives up medical costs and jeopardizes a system that our citizens trust with their lives," said Attorney General Loretta E. Lynch in the DOJ statement.

Takeaway: Fraud enforcement continues at a brisk pace utilizing the advantages of current technology and targeting not just large organizations but individual professionals as well. G2

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