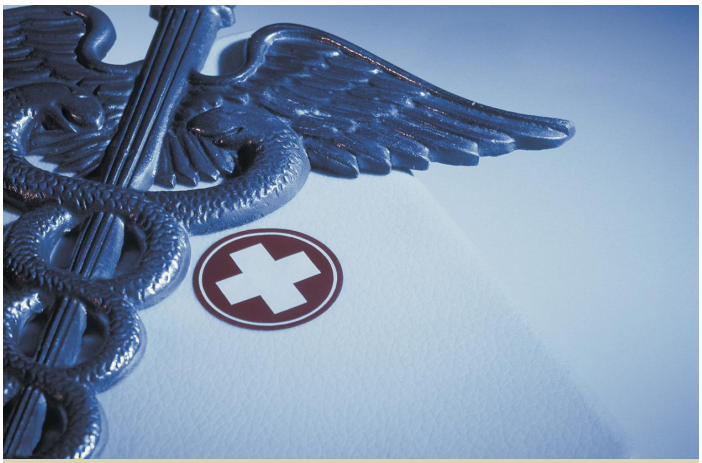

August 7, 2013 • Volume 3, Number 2

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HEALTHCARE **LEGAL**NEWS

IRS ISSUES TRANSITION RELIEF ON THE ONE-YEAR DELAY IN ACA'S INFORMATION REPORTING AND EMPLOYER SHARED RESPONSIBILITY RULES

by Jordan Schreier, who is a Member in Dickinson Wright's Ann Arbor office, and can be reached at 734.623.1945 or jschreier@dickinsonwright.com

On July 9, 2013, the IRS issued Notice 2013-45 which provides additional information regarding the delay in the information reporting and employer shared responsibility provisions of the ACA announced earlier in July. Notice 2013-45 does not provide much in the way of substantive detail other than to confirm the delay in the implementation of these requirements and relief from penalties for not complying with these requirements in 2014. Specifically, the Notice provides:

- The IRS expects to issue proposed rules later this summer related to the information reporting requirements for employers that sponsor self-insured group health plans, insurers and certain others under Code Section 6055 related to the minimum essential coverage they offer and by applicable large employers have to make under Code Section 6056 related to the coverage offered to full-time employees. Once the proposed rules are issued, the IRS encourages employers, insurers and others to voluntarily comply with the rules for 2014 (by filing reports in 2015 related to 2014). The IRS notes that real world testing of reporting systems and plan designs through voluntary compliance for 2014 will help with a smoother transition to full implementation for 2015. However, there will be no penalty for not voluntarily reporting as suggested by the IRS.

- The information reporting and employer shared responsibility rules will take effect for 2015.

- Under the employer shared responsibility requirements, an applicable large employer must generally offer affordable, minimum value health coverage to its full-time employees or pay a tax penalty under Code Section 4980H if one or more of its full-time employees purchases coverage through the Health Insurance Marketplace and receives a premium tax credit. The IRS recognizes that because an employer will not typically know if a full-time employee received a premium tax credit, the employer will not have the information it needs to know if it will owe a tax penalty (for not providing sufficient coverage to its full-time employees). Importantly, employers will not be required to calculate tax penalties or file returns submitting tax penalties

under Code Section 4980H. Rather, the IRS will assess tax penalties following a process roughly sketched out in the Notice. After the IRS receives the information reporting from employers under Code Section 6056 and information from employees claiming the premium tax credit, the IRS will determine if any of an employer's full-time employees received the premium tax credit and if so, whether an employer owes a tax penalty. If the IRS concludes a tax penalty is due, the IRS will contact the employer and the employer will have an opportunity to respond to the IRS before a tax penalty is assessed.

- Individuals will still be eligible for the premium tax credit in 2014 if they enroll in a qualified health plan through the Marketplace and they otherwise qualify for the tax credit based on household income and lack of other qualifying health coverage.

- The transition relief does not impact other provisions of the ACA. Specifically:

    - The Patient-Centered Outcomes Research Fee was due by July 31, 2013. Sponsors of self-insured plans should have paid the fee by filing IRS Form 720.
    - Employers subject to the Fair Labor Standards Act must still provide notice of the existence of the Marketplace to existing employees no later than October 1, 2013. The Department of Labor has issued a model notice for employers to use (see Technical Release No. 2013-2 at http://www.dol.gov/ebsa/newsroom/tr13-02.html). Any employer subject to the Fair Labor Standards Act must distribute the notice even if it does not offer a group health plan.
    - The Summary of Benefits and Coverage must be provided annually at the group health plan's open enrollment.
    - As noted above, the premium tax credit will still be available to qualifying individuals.
    - Most individuals in the U.S. will still be required to have health coverage in 2014 or potentially be subject to a tax.
    - The 90-day maximum eligibility waiting period will still take effect January 1, 2014 and applies to all plans.
    - The prohibition on all pre-existing condition limitations will apply effective for plan years beginning on or after January 1, 2014.
    - The new HIPAA wellness rules will apply in 2014, including the increase in the maximum wellness incentive percentage.

Much of what is contained in Notice 2013-45 repeats what the Department of Treasury said, in early July, when it initially announced the implementation delay. A number of commentators and government officials (e.g., members of Congress) have stated that President Obama did not have the legal authority to delay the implementation of the employer shared responsibility rules and the House of Representatives has held hearings on the implications of the delay, including how the delay impacts individuals still subject to the individual mandate. We should expect to hear more about the implementation delay in the near future.

THE SUPREME COURT HOLDS HUMAN GENES ARE UNPATENTABLE

by Joan Ellis, Ph.D., who is a Member in Dickinson Wright's Washington, DC office, and can be reached at 202.659.6929 or jellis@dickinsonwright.com

In a unanimous decision written by Justice Thomas, the Supreme Court held that naturally-occurring DNA sequences are unpatentable. The Court has long held that certain subject matter is not patent eligible under 35 USC § 101. Patent exempt subject matter includes laws of nature, natural phenomenon, and abstract ideas. In this case, the Court found that human genes are products of nature. The Court further found that cDNA sequences, which are copies of non-intron containing mRNA sequences created in the laboratory, are patent eligible.

The case before the Court involved several patents issued to Myriad Genetics, Inc. ("Myriad") that were directed to two genes known as BRCA1 and BRCA2. Mutations in these genes can increase a woman's risk of developing breast and ovarian cancer. The scientists at Myriad had discovered the genes, determined their nucleotide sequence and their chromosomal location. The Court found that locating and isolating the genes did not make them new compositions of matter. The Court acknowledged that the genes were important and useful, but nevertheless concluded that "Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them." Thus, the "genes and the information they code are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material."

The Court found that cDNA sequences stood on a different footing. Although the Court acknowledged that cDNA contains naturally-occurring coding sequences of DNA known as exons, it involves the removal of intervening non-coding sequences by a lab technician. Consequently, the Court held that cDNA is not a product of nature and may be patent eligible.

The Court went to great pains to point out that the decision was limited to the genes themselves. The Court explicitly stated that it was not passing judgment on patent claims directed to methods of isolating or manipulating genes. Although they noted that the isolation methods used by Myriad were "well understood, widely used, and fairly uniform in so far as any scientist engaged in the search for a gene would likely have utilized a similar approach."

Of paramount importance is that Court's decision did not encompass patent claims directed to "new applications of knowledge about the BRCA1 and BRCA2 genes" or "scientific alteration of the genetic code." After all, it is the potential use of a DNA sequence that is the raison d'être for isolating it in the first instance. The ultimate goal of all DNA research is for the gain, financial or otherwise, that is obtained in developing a new diagnostic assays, gene therapy, therapeutics, herbicide resistance, etc. that use the DNA. The practical application of a DNA sequence has always been where the true value lies.

The *Myriad* decision will have a tremendous impact on the biotechnology industry. Tens of thousands of existing patents having claims that are exclusively directed to DNA sequences and fragments thereof can now be challenged and invalidated. The United States Patent and Trademark Office (USPTO) has already published new interim guidelines for the patent examiners. Referring to the Supreme Court's decision in *Myriad*, the new guidelines instruct the examiners to "now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101."

In the wake of the *Myriad* decision, biotech companies should review their intellectual property by immediately examining their patent portfolios. Claims in pending patent applications should be amended and/or new claims added that are directed to cDNA sequences and methods of using said sequences. Steps should be taken to safeguard from litigation those patents that have already been issued. To that end, companies should consider amending the claims in issued patents by filing a request for reissue or reexamination.

HEALTH INSURERS IN RHODE ISLAND AND WESTERN NEW YORK ARE SUED BY PROVIDERS FOR ALLEGED ANTITRUST VIOLATIONS

by James M. Burns, who is a Member in Dickinson Wright's Washington, DC office, and can be reached at 202.659.6945 or jmburns@dickinsonwright.com

In the last two months, two new antitrust actions have been filed against health insurers that raise interesting issues about an insurer's obligation to contract with a health care provider that it chooses not to deal with, and whether a refusal to do so can give rise to antitrust liability.

In the first case, filed in early June, Steward Health System, a Massachusetts-based health system, commenced an antitrust case against Blue Cross Blue Shield of Rhode Island in the federal district court in Rhode Island. Steward contends that for anticompetitive reasons, BCBS-RI derailed Steward's proposed acquisition of Landmark Medical Center, a Woonsocket, Rhode Island hospital that was in financial distress. Specifically, Steward alleges that it has a reputation for providing low-cost health care in Massachusetts, and does so by partnering with low cost health insurers who offer consumers lower cost, limited network insurance products. According to Steward, BCBS-RI, the dominant insurer in Rhode Island, feared that Steward's entry into the Rhode Island market would jeopardize BCBS-RI's market position, and therefore BCBS-RI refused to negotiate an in-network contract with Landmark at "reasonable" rates, knowing that the absence of such a contract would ensure that Steward could not go forward with its announced acquisition. Steward's complaint further alleges that BCBS-RI also terminated an existing network contract that it had with St. Anne's, a Steward hospital located near the Massachusetts/Rhode Island border that served both Rhode Island and Massachusetts patients. The fact that this action took place despite Steward's offer to continue the relationship on terms that were favorable to BCBS-RI, indicated that this conduct was taken in furtherance of the alleged anticompetitive scheme to ensure that Steward would not make inroads into the Rhode Island market. Because this case raises interesting issues about how the antitrust laws treat an alleged monopolist's refusal to deal with third parties, it will be a closely watched case going forward.

The second case, filed in the Western District of New York on June 25, raises similar issues, albeit in a different context. In *Insource Development Services v. HealthNow*, the plaintiff, an urgent care center, alleges that health insurer HealthNow, the dominant insurer in the region, conspired with United Memorial Health Center to ensure the demise of Insource. (United operates the only competing urgent care centers in the area, and has a network contract with HealthNow for both its hospital services and the urgent care centers it operates.) According to the plaintiff, after Insource had engaged in extensive discussions with HealthNow about a network contract, United reached an anticompetitive agreement with HealthNow to terminate the negotiations and exclude Insource from the HealthNow network. Insource further alleges that United and HealthNow engaged in similar conduct against another potential rival urgent care center, Lakeland, which successfully kept Lakeland out of the market. This case, like the *Steward* case, will require the court to consider what obligations, if any, the antitrust laws impose upon a dominant insurer that chooses not to contract with a provider. Stay tuned.

FTC COMMISSIONER ADDRESSES TENSION BETWEEN THE ACA, ACOs, AND ANTITRUST LAW

by Scott F. Roberts, who is Of Counsel in Dickinson Wright's Troy office, and can be reached at 248.433.7211 or sroberts@dickinsonwright.com

In a recent speech to a healthcare trade group in Washington, Federal Trade Commissioner Julie Brill addressed an issue of concern to many in the healthcare industry—the apparent tension between the Affordable Care Act ("ACA"), Accountable Care Organizations ("ACOs"), and antitrust law. As Commissioner Brill acknowledged, critics of the ACA contend that the federal government is speaking "out of both sides of its mouth" when it comes to Accountable Care Organizations and antitrust enforcement. Specifically, they contend that while the ACA is encouraging providers to "collaborate" and "consolidate," the Federal Trade Commission's ("FTC") enforcement of antitrust laws seem to impede their ability to do so.

Addressing this perceived tension, Commissioner Brill sought to distinguish between what she views as "legitimate collaborative activities", which she maintains do not present antitrust problems, and joint conduct that fails to promote lower costs or improved quality, which may raise antitrust concern. She further indicated that the antitrust laws "align naturally with the goals of ACOs" by permitting providers to coordinate patient care for improved outcomes, provided such coordination does not have anticompetitive effects.

Relying on well-settled antitrust doctrine, Commissioner Brill explained that "agreements among competitors that limit some aspect of their rivalry are permissible where the restraint at issue is 'reasonably necessary' to produce procompetitive benefits to the market that outweigh any loss of competition among participants."

Her explanation reinforced the view that this was the standard that the FTC would be applying to provider collaborations. Commissioner Brill also noted that, instead of merging, some providers might be better off entering into contractual relations that are well short of a merger, such as a joint venture or other ACO arrangements, and observed that CMS rules permit ACO participants "to use a variety of collaborative organizational structures, including collaborations short of merger" to achieve their goals.

To further illustrate her point, Commissioner Brill noted that more than 250 ACOs have already been established under the Medicare program and that hundreds of additional ACO-like organizations have been formed outside of Medicare. She also pointed to the procedures established by the FTC/DOJ to provide expedited guidance to providers on the antitrust issues raised by a proposed ACO, but stated that few providers have, at least so far, elected to submit to such voluntary reviews.

Finally, Commissioner Brill addressed recent FTC enforcement actions in the health care arena. Commissioner Brill asserted that the FTC addresses antitrust enforcement using a "scalpel" and not a "sledgehammer" in order to cause as little disruption to the market as possible while also ensuring procompetitive outcomes. She noted that while the FTC has recently challenged several hospital mergers, many more have been allowed to proceed unchallenged. She ended her speech by commenting that the FTC has increased its enforcement activity with respect to hospital acquisitions of physician practice groups. With respect to these acquisitions, one common theme identified by Commissioner Brill was the aggregation of a large share of specialists at a single hospital. Commissioner Brill reasoned that such a grouping would give that hospital too much market power in the specialty area, which would give rise to antitrust concerns.

REMINDER: COMPLIANCE DATES FOR REVISING YOUR BUSINESS ASSOCIATE AGREEMENTS FOR COMPLIANCE WITH THE HIPAA OMNIBUS RULE

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The required compliance dates for revising business associate agreements ("BAA") between covered entities and business associates, or business associates with subcontractors, respectively, to reflect the new requirements of the Health Insurance Portability and Accountability Act ("HIPAA") "omnibus" regulations issued on January 17th, 2013 (the "Final Rules") are approaching. As a reminder, the "transition" rules with respect to such revisions are briefly summarized below:

- If, prior to January 25, 2013, the covered entity or business associate had in effect an existing BAA with a business associate or subcontractor, respectively, that complied with the prior provisions of the HIPAA Privacy and Security Rules, and such BAA was not renewed (except by automatic renewal pursuant to its terms) on or after March 26, 2013, then the BAA is considered "grandfathered" for one year and may continue to be used without modification until the earlier of (i) the date after September 23, 2013 on which the BAA is renewed or modified, or (ii) September 23, 2014.
- If a BAA existed on January 25, 2013, but is renewed (without automatic renewal pursuant to its terms) or otherwise modified prior to September 23, 2014, the BAA must be revised to comply with the new requirements of the Final Rules as of September 23, 2013.
- If a new BAA is entered into after January 25, 2013, the terms of that BAA must comply with the new requirements of the Final Rules as of September 23, 2013.

These compliance dates apply only to the technical requirement to amend BAAs; they do not affect the effective date of the compliance obligations of business associates and subcontractors under the HIPAA Privacy and Security Rules, which continues to be September 23, 2013.

For more information on the requirements of the Final Rule, please see our "DW Healthcare Legal News Archive" which is accessible through our DW Health Law Blog, at www.dwhealthlawblog.com.

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