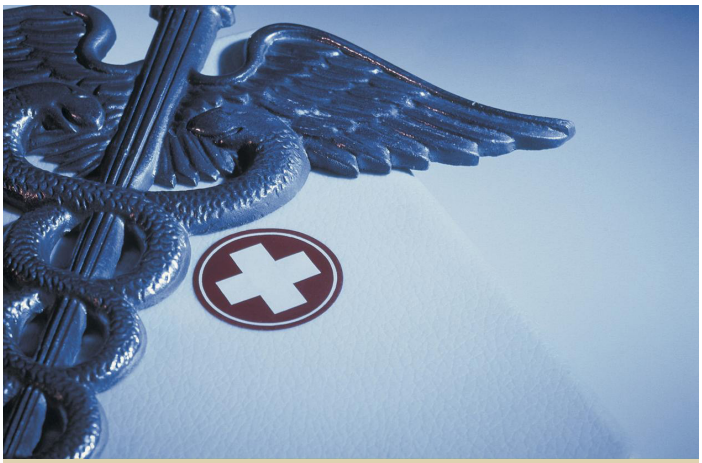

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DICKINSON WRIGHT'S

HEALTHCARE **LEGAL**NEWS

CMS ISSUES FINAL RULE ON DIRECT ACCESS OF LAB TEST RESULTS BY PATIENTS

by Rodney D. Butler, who is an Associate in Dickinson Wright's Nashville office, and can be reached at 615.620.1758 or rbutler@dickinsonwright.com

On February 3, 2014, the Centers for Medicare and Medicaid Services (CMS) released a final rule that permits patients or their representatives to have direct access to the results of their lab tests. This rule change is significant because under the prior rule, labs could only release test results directly to patients if the ordering medical provider expressly authorized the lab to do so at the time the test was ordered, or if disclosure was explicitly provided by state law.

Under the new rule, prior regulations under the Health Insurance Portability and Accountability Act (HIPAA) and the Clinical Laboratory Improvement Amendments (CLIA) that restrict patient access to lab tests will be modified. The new HIPAA regulations will require labs to provide patients with test results within 30 days of a request; however, the labs will not be required to provide an explanation of the test results. In comparison, the CLIA regulations will maintain the current role of medical providers in ordering lab tests and providing explanations of the test results to their patients.

Overall, the impact of the final rule permitting individual access to lab results will be broad. Currently, 26 states do not have a law allowing direct disclosure of test results to patients, and 13 states specifically prohibit direct access of lab results by patients. Furthermore, labs in 46 states and territories will need to update their HIPAA notice of privacy practices to show the new "direct" patient access to lab results.

Although CMS has touted the rule change as "empowering" patients with information to assist them in tracking their health, making health care decisions, and adhering to treatment plans, not everyone believes that direct access of lab results will enhance patient health care. In fact, the Association of American Medical Colleges (AAMC) is on the record as stating that there can be "serious negative consequences" because patients will have access to raw data without having the requisite medical knowledge to properly interpret the test results.

Nevertheless, despite the warning from the AAMC, the final rule is scheduled to take effect on April 7, 2014 and HIPAA covered labs will have 180 days from this date to come into compliance. Moreover, any state law which is contrary to the final rule will be preempted.

HEARING HELD ON PENNSYLVANIA'S NOVEL "ANY WILLING INSURER" LEGISLATION

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

On December 18, 2013, the Pennsylvania House Health Committee held a hearing on Pennsylvania House Bills 1621 and 1622, two bills that would require that any health provider in the state that operates as part of an integrated delivery system (*i.e.*, a health system that also has its own health plan, as many larger systems do) contract with "any willing insurer" desiring to contract with the provider. The legislation, the first of its kind in the country, is essentially the reverse of the "any willing provider" legislation that has been enacted in over 30 states over the last several decades that require health insurers to accept every provider meeting its credentialing requirements into its provider network.

As explained by the bill's sponsors, Representatives Jim Christiana (R) and Dan Frankel (D), the legislation was initially designed to force University of Pittsburgh Medical Center (a larger Western Pennsylvania provider) to contract with Highmark Blue Cross, after UPMC announced earlier this year that it intended to terminate its "in network" status with Highmark at the end of 2014. However, the bill's sponsors have stated that their legislation is not intended solely to address this dispute, nor is it limited to these parties, and they claim that "if we want to pursue the best quality, highest value health care," we must have "full patient access and complete competition in the insurance market as well as the provider market."

At the hearing on December 18, 2013, UPMC representatives opposed the bills, maintaining that forcing parties to contract against their will would have anticompetitive effects and stifle innovation – claims that health insurers have made, typically without success, when opposing "any willing provider" legislation in other states. Highmark representatives, on the other hand, supported the proposed legislation at the hearing, and others – including a representative from a benefits management company – suggested that the bills should be expanded to cover all providers, not just those in integrated systems.

Since the hearing, UPMC and Highmark announced that they had settled a long running antitrust lawsuit between them, leaving open the possibility that the settlement might lead to a voluntary resumption of the parties' contractual relationship. Nevertheless, this development may not necessarily derail the proposed legislation, particularly given the sponsors' statements that the issue is bigger than just the UPMC/Highmark dispute. The Pennsylvania legislature reconvened on January 7, 2014 for further proceedings. Stay tuned.

THE 2014 OIG WORK PLAN: SELECT PROVISIONS APPLICABLE TO PHYSICIAN PRACTICES

by Rose J. Willis, who is a Member in Dickinson Wright's Troy office, and can be reached at 248.433.7584 or rwillis@dickinsonwright.com

The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) recent issued its 2014 Work Plan outlining its intended review activities of HHS Programs for 2014. This article summarizes certain portions of the 2014 Work Plan that are of considerable importance to physician practices.

- Security of Protected Health Information. The OIG will evaluate security programs, including security controls to prevent the loss of protected health information (PHI) stored on portable devices (e.g., laptops, jump drives, etc.). The OIG will also review whether security controls over networked medical devices (e.g., dialysis machines, radiology systems and medication dispensing systems) are sufficient to effectively protect electronically protected health information (ePHI). Physician practices should ensure that their HIPAA Security Policies and Procedures are in place, up to date, and are being adhered to by their workforce members.

- Medicare/Medicaid Incentive Payments. The OIG has planned to review Medicare and Medicaid incentive payments made to eligible health care professionals and hospitals for adoption of Electronic Health Records ("EHR") and safeguards to prevent erroneous incentive payments.

- Security of ePHI. The OIG will review various covered entities that receive incentive payments and their business associates, including EHR cloud service providers, to determine whether the security measures in place adequately protect the electronic information created or maintained by the certified EHR technology. The review will include audits of cloud service providers and other downstream service providers to assure compliance with the regulatory and contractual obligations.

- Compliance with HIPAA. The OIG will review HHS's Office of Civil Rights ("OCR") oversight of covered entities' compliance with the HIPAA Privacy Rule and the HITECH Breach Notification Rule.

- Payment for Medical Equipment. The OIG will begin a new study assessing the reasonableness of the Medicare fee schedule amounts for various medical equipment items, including commode chairs, folding walkers and transcutaneous electrical nerve stimulators. The OIG will also determine the reasonableness of Medicare reimbursement rates for Parenteral Nutrition compared to amounts paid by other payers.

- Payments for Nebulizer Machines and Related Drugs. The OIG will begin reviewing Medicare Part B payments for nebulizer machines and related drugs to determine if Medicare requirements are being met.

- Documentation of Evaluation and Management (E/M) Services. The OIG will continue to determine the extent to which selected payments for E/M services were inappropriate. Also, because Medicare contractors have noted an increased frequency of medical records with identical documentation across services, the OIG will continue reviewing multiple E/M services associated with the same providers and beneficiaries to determine whether the medical records have documentation vulnerabilities.

- Coverage Criteria for Part B Drugs. The OIG will review the oversight actions that CMS and its claims processing contractors take to ensure payments for "on-label" and appropriate "off-label" uses for Part B drugs meet the appropriate coverage criteria. The OIG also plans to examine Medicare Administrative Contractors' policies and procedures for reviewing and processing Part B claims for compounded drugs.

- Ambulatory Surgical Centers (ASC). The OIG will determine whether a payment disparity exists between the ASC and hospital outpatient department payment rates for similar surgical procedures provided in both settings. The OIG will also review physicians' coding of Medicare Part B for services performed in ASCs and hospital outpatient departments to determine whether the places of service are properly coded.

- Laboratory Tests. The OIG will continue its focus on reviewing billing characteristics for Part B clinical laboratory tests to identify questionable billing practices.

- Diagnostic Radiology. The OIG will continue its focus on reviewing Medicare payments for high-cost diagnostic radiology tests to determine medical necessity and a potential increase in utilization.

- Imaging Services. The OIG will continue its focus on reviewing Medicare Part B payments for imaging services to determine whether they reflect the expenses incurred and whether utilization rates reflect industry practices. For selected imaging services, the OIG will focus on the practice expense components (e.g., office rent, wages and equipment), including the equipment utilization rate.

MISSISSIPPI GOVERNOR RESCINDS EXECUTIVE ORDER REQUIRING BLUE CROSS OF MISSISSIPPI TO GRANT "IN NETWORK" STATUS TO EXCLUDED HOSPITALS

by James M. Burns

In early November, Mississippi Governor Phil Bryant rescinded an Executive Order (Executive Order 1327), issued only weeks earlier, that would have compelled Blue Cross of Mississippi to continue to offer "in-network" status to several Mississippi hospitals with whom Blue Cross had terminated its relationship as a result of contract disputes. Governor Bryant's decision follows the initiation of a federal lawsuit by Blue Cross, claiming that Governor Bryant's Executive Order compelling it to retain its "in-network" relationship with the hospitals violated its constitutional rights. Notably, however, Governor Bryant's latest action does not put the network exclusion issue to rest, as the Mississippi Insurance Department will continue to investigate whether Blue Cross' decision violates Mississippi law.

The dispute began last summer, when Blue Cross advised ten Mississippi hospitals (all owned by HMA) that it was modifying its reimbursements to the hospitals, claiming that they were being overpaid for their services. The hospitals responded by filing a lawsuit against Blue Cross in state court (*Jackson HMA, d/b/a Central Mississippi Hospital Center, et al. v. Blue Cross Blue Shield of Mississippi*, Circuit Court of Hinds County, Mississippi) claiming that Blue Cross's decision to modify their reimbursement rates was a breach of contract, causing them more than $10 million in damages. Blue Cross responded to the lawsuit by providing 30 days notice that it was terminating its contract with each hospital altogether, removing the hospitals from its network.

The hospitals sought the Governor's assistance, claiming that Blue Cross' decision to terminate the hospitals' contracts would cause serious harm to Mississippi residents and that immediate relief was required to protect against that result. In response, Governor Bryant issued Executive Order 1327, in which he declared that "Blue Cross' exclusion of the hospitals from the BCBS network of providers threatens patient access to care" and, on that basis, ordered Blue Cross to resume the relationship pending further investigation by the Mississippi Department of Insurance. Blue Cross responded by filing a federal lawsuit challenging Governor Bryant's authority to issue the Executive Order.

Governor Bryant's subsequent decision (embodied in Executive Order 1328) rescinds the portions of Executive Order 1327 that compel Blue Cross to continue "in-network" status to the hospitals pending further examination by the Insurance Department, and comes closely on the heels of a decision by U.S. District Court Judge Henry Wingate to grant a request by Blue Cross to temporarily block the Governor's Executive Order from taking full effect. With a full hearing on Blue Cross' motion to block the Governor's Executive Order (1327) scheduled to have taken place on November 5, Blue Cross agreed to restore in-network status for four of the ten previously cancelled hospitals, and to dismiss it's lawsuit against the Governor. In exchange, the Governor issued the modified Order (1328).

As provided for in the newest Executive Order, the Department of Insurance will continue its examination into whether Blue Cross' decision to terminate its contracts with the six hospitals that remain "out-of-network" adversely impacts patient care in the state, and whether Blue Cross' decision violates Mississippi law, which, among other things, requires an insurer to have a network sufficient to serve the needs of the public and also prohibits insurers from engaging in any "trade practice which is . . . an unfair or deceptive act or practice in the business of insurance."

The Mississippi action is the latest – but likely not the last – dispute between health insurers and providers about network access. While some states have tried to resolve these difficult issues with legislation (some with "any willing provider" legislation limiting an insurer's ability to refuse network admission to a provider in several states and, in Pennsylvania, with proposed legislation requiring certain providers to contract with "any willing insurer"), while other states have chosen to let market forces sort out such disputes, these issues remain difficult ones for both providers and insurers. As health care reform drives further efforts by both insurers and providers to reduce costs and become more efficient -- a result that limited networks has the could enhance, in some circumstances -- these disputes are only likely to increase.

CMS REPORT SHOWS SOME MEDICARE COST SAVINGS THROUGH ACO MODEL

by Rodney D. Butler

A report published in late January 2014 by the U.S. Centers for Medicare and Medicaid Services (CMS) demonstrated, in the words of CMS, "encouraging results" in the reduction of healthcare costs to Medicare and improvement in the quality of care for over 5 million Medicare beneficiaries under the Affordable Care Act (ACA).

Under the ACA, the Department of Health and Human Services runs two different accountable care organization (ACO) programs. According to the report, in the larger of the two ACO programs, 54 of the 114 ACOs reached their goal of lower than expected expenditures. However, only 29 of the ACOs actually generated savings large enough to share with their providers, representing just 25% of the 114 ACOs in the program. Although this particular ACO program only produced $128 million in "net savings," the report states that the "preliminary data" showed that the Medicare ACOs generated $380 million in overall savings for the Medicare trust program when comparing 2012 to 2013.

Unfortunately, CMS declined to provide any type of context with regards to the savings, such as which hospitals were successful, the amount of the investment made by the participants in the coordination of care, and/or how the savings compared to expectations. This type of information would be valuable to any provider that is considering forming or joining an ACO.

The data contained in the report is preliminary in nature, and represents only one year's worth of data. It will be important to see if the trend continues overall, whether the same networks are able to maintain their savings from year to year, and whether additional detail will be provided regarding participant investment.

DW HEALTHCARE TEAM - NEWS & SUCCESS STORIES

The following Dickinson Wright Healthcare attorneys have recently been published or quoted in the media.

Ralph Levy, Jr. recently published "Tax Court Decision Addresses Tax Deductibility of Payments under Management Services Agreement" in the Nov/Dec. 2013 issue of ***Journal of Healthcare Compliance***.

James Burns commented on "Antitrust Issues to Watch" in the January 10, 2014 issue of ***Bloomberg BNA Pharmaceutical Law & Industry Report.***

James Burns provides comments to the ***Pittsburgh Post-Gazette*** Regarding Pennsylvania's Novel "Any Willing Insurer" Bill.

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