Health Care Practice Group

Cinde Warmington
Chair
cwarmington@shaheengordon.com

William E. Christie
wchristie@shaheengordon.com

Steven M. Gordon
sgordon@shaheengordon.com

Lucy J. Karl
lkarl@shaheengordon.com

Donald Crandlemire
dcrandlemire@shaheengordon.com

Clara Dietel
cdietel@shaheengordon.com

Benjamin Siracusa Hillman
bsiracusahillman@shaheengordon.com

www.shaheengordon.com

Tenacity, Creativity and Results are the three words that best describe Shaheen & Gordon's approach to addressing complex legal issues. Our health care team closely monitors the rapidly changing legal environment so that our clients are prepared to meet the challenges of today as well as tomorrow. Relying on a wealth of experience, we offer practical advice and assist in implementing recommendations tailored specifically to meet the needs of both large and small health care clients.

FEDERAL DEVELOPMENTS

Affordable Care Act Implementation

Supreme Court Rules in Hobby Lobby Case That Contraceptive Coverage Requirement, As Promulgated, Cannot Be Applied to Closely-Held For-Profit Corporations Whose Owners Have Religious Objections

On June 30, the Supreme Court ruled in the case of *Burwell v. Hobby Lobby Stores, Inc.*, that the contraceptive coverage requirement could not be applied to closely held for-profit corporations whose owners have religious objections to providing the coverage.

The contraceptive coverage requirement at issue is contained in regulations issued under the Affordable Care Act, which require employer-provided health insurance and health plans to include access to certain types of contraceptives without cost-sharing.

The Court's decision was based on the Religious Freedom Restoration Act, a law that prohibits the government from substantially burdening a person's exercise of religion unless it can show that the law is the least restrictive means of furthering a compelling governmental interest. The Court held that "person" under RFRA included for-profit corporations, and that the First Amendment protects the free exercise rights of for-profit corporations. The Court also determined that the contraception mandate imposed a substantial burden on the corporation's free exercise of its religion in the form of the penalties that would be imposed on the corporation if it did not provide contraception.

The Court assumed that the government had a compelling government interest in the provision of no-cost contraception, but decided that a less restrictive method was available for furthering that interest, such as providing no-cost contraception directly, or by utilizing an accommodation that was already being employed in the case of religious nonprofit organizations with objections to providing contraceptive coverage. That method, discussed in more detail below, allows a third-party insurer or plan administrator to provide benefits (at the expense of the insurer or government) without the direct involvement of the objecting employer.

Supreme Court Issues Interim Order Prohibiting Enforcement of Contraceptive Coverage Mandate Against Religious Nonprofit Organization

On July 3, the Supreme Court issued an interim order in the matter of *Wheaton College v. Burwell.* The Order provided that the federal government could not require a religious nonprofit organization with objections to contraceptive coverage to use or send in a form, Form 700, in order to avail itself of an accommodation process by which contraceptive coverage is provided directly by the insurer or third-party plan administrator (at the expense of the insurer or government). Instead, the Court said, an

objecting organization need only inform the Department of Health and Human Services "in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services."

Administration Issues Interim Final Rule and Proposed Rule Regarding Accommodating Nonprofit Religious Organizations and Closely-Held For Profit Entities that Object to Contraceptive Coverage

On August 27, the Departments of Health and Human Services, Labor, and Treasury published an interim final rule promulgating a new alternative accommodation process that is designed to be consistent with the *Wheaton* order. The rule simply requires nonprofit organizations with religious objections to notify the Department of Health and Human Services of their objection to providing coverage; if they do so, they need not complete Form 700, the form to which Wheaton College objected. The insurer or plan will then be obligated to provide coverage to the organization's employees, and in the case of a plan, can seek reimbursement for such costs from the federal government.

On August 27, the same Departments published a proposed rule seeking comments on how to accommodate closely-held for-profit entities that object to contraceptive coverage, while still ensuring access to contraceptive coverage for those organizations' employees. The proposal includes amending the regulations so that closely-held for-profit entities with a religious objection to providing contraceptive coverage will be able to avail themselves of the same (now modified) accommodation process available to religious nonprofit organizations.

Courts of Appeals Reach Conflicting Conclusions on Whether Individuals Can Claim Subsidies for Health Insurance Purchased on Federally-Operated Health Insurance Marketplace

On July 22, the U.S. Court of Appeals for the District of Columbia Circuit, and the U.S. Court of Appeals for the Fourth Circuit, issued separate rulings in challenges to an IRS regulation that allows individuals to claim premium subsidies for the purchase of insurance on the marketplaces. While the regulation permits subsidies for insurance purchased on both state-based and federally-facilitated health insurance marketplaces, the challengers argue that a provision of the Affordable Care Act providing that premium subsidies are available on marketplaces "established by the State under Section 1311" of the Affordable Care Act prevents the federal government from making subsidies available for participants in the federal marketplace.

While the Fourth Circuit upheld the IRS regulation as consistent with the Affordable Care Act, the D.C. Circuit rejected the provision of subsidies for insurance purchased on the federal marketplace as inconsistent with the statutory language at issue. The challengers in the Fourth Circuit promptly filed a petition asking the Supreme Court to hear the case, on July 31. However, the federal government, on August 1, asked the full D.C. Circuit to rehear the case there through a process known as "rehearing en banc," and on September 4, the D.C. Circuit granted the petition to rehear the case and vacated the prior decision. Oral argument will be held in the D.C. Circuit on December 17. The challengers in the D.C. case have argued that the Supreme Court should resolve the matter without waiting for the full D.C. Circuit to weigh in, but the Supreme Court will almost certainly wait for the decision of the full D.C. Circuit before determining whether or not to review the issue. If the full D.C. Circuit agrees with the Fourth Circuit, the Supreme Court is unlikely to review the issue, as the two courts will have agreed, but if the full D.C. Circuit reinstates its earlier ruling, then the Supreme Court will almost certainly review the decision in light of the conflict between the D.C. Circuit and Fourth Circuit decisions. In the meantime, premium subsidies remain available for users of the federal marketplace.

Other Federal Developments

2015 Proposed Physician Fee Schedule

On July 11, CMS published the proposed 2015 Medicare Physician Fee Schedule. The comment period for the Proposed Rule closed on September 2 and the Final Rule is expected to be published on or around November 1. New rates will be effective beginning January 1, 2015. We summarize some essential provisions below.

Sustainable Growth Rate

The proposed rule does not address the Sustainable Growth Rate (SGR). A press release accompanying the rule indicates that CMS predicts a 20.9 percent decrease without legislative action.

Misvalued Codes

CMS identifies 65 "potentially misvalued" CPT codes that are associated with high Medicare spending and have not been reviewed since 2009. These include skin biopsies, ultrasound therapy, hearing tests, and chest and knee x-rays. In addition, the proposed rule sets out a new timeline and process for the publication and implementation of changes in physician codes and relative values.

Telehealth Services

CMS proposes the addition of several new services to its list of covered telehealth services, including psychoanalysis, family psychotherapy, prolonged services in an outpatient setting, and annual wellness visits (initial and subsequent visits).

Chronic Care Management

In 2014, CMS finalized a policy to pay for complex chronic care coordination as of 2015. For FY2015, CMS proposes to revise the physician supervision requirements for such services, and proposes to require chronic care management practitioners to utilize electronic health record technology certified to meet at least the 2014 Edition meaningful use criteria.

Physician Compare

Under the Affordable Care Act, CMS is required to establish a Physician Compare website, populated with information on Medicare-enrolled physicians and other eligible providers who participate in the Physician Quality Reporting System (PQRS). For 2015, CMS proposes to expand the scope of publicly available physician performance data and will publicly report data in 2016 for physician groups with as few as two physicians.

Physician Quality Reporting System (PQRS)

For 2015, CMS is proposing to add 28 new individual measures and two measures groups to fill existing gaps in measurement. The agency is also proposing to remove 73 measures from PQRS. These changes would bring the number of PQRS measures to 240.

In 2015, PQRS will transition from payment incentives for reporting to penalties for not reporting. Specifically, CMS proposes that eligible professionals who do not satisfactorily report through one of the reporting mechanisms in 2015 will receive a 2 percent penalty to the fee schedule amount in 2017. CMS proposes to increase the requirements for satisfactory reporting in the 2015 PQRS and for avoiding the 2017 PQRS penalty. CMS, however, is maintaining all of the existing reporting options for 2015.

Beginning in 2015, eligible providers in critical access hospitals may participate in the PQRS using all reporting mechanisms available, including the claims-based reporting mechanism.

Clinical Labs

CMS proposes to make substantive changes to the local coverage decision (LCD) process for clinical lab tests. Under the revised process, the public comment period for physicians and others to respond to changes in coverage would be reduced from 45 days to 30 days; Carrier Advisory Committee meetings would be optional; and the final LCD would be published within 45 days of the close of the draft LCD comment period with the LCD becoming effective immediately. The new process would not apply to LCDs that are being revised for the following reasons: to liberalize an existing LCD; for a compelling reason; to make a non-substantive correction; to provide a clarification; to make a non-discretionary coverage or diagnosis coding update; to make a discretionary diagnosis coding update that does not restrict; or to effectuate an Administrative Law Judge's decision.

Medicare Shared Savings Program

CMS proposes to expand and modify the list of quality performance standards from the current 33 measure set to a 37 measure set by adding 12 new measures and retiring 8 measures. The stated purpose of the changes is to improve alignment with reporting requirements under PQRS and the electronic health record incentive program. Performance under the new measures would be assessed by CMS based on claims data or from a patient survey.

CMS Publishes FY 2015 Inpatient Prospective Payment System (IPPS) Final Rule

On August 4, CMS released the final IPPS rule for FY 2015, which will affect discharges occurring on or after October 1. The final rule increases payments to inpatient acute care hospitals by 1.4 percent. This figure is a net number, as it comprises a 2.9 percent market basket increase, a 0.8 percent cut for documentation and coding adjustments, a 0.5 percentage point decrease for productivity adjustment, and a 0.2 percentage point reduction required by the ACA. Hospitals that either do not submit quality data or are not Electronic Health Record (EHR) meaningful users will receive only a 2.175 percent market basket increase; hospitals that do not meet either of these requirements will receive only a 1.45 percent market basket increase, rather than the 2.9 percent increase applicable to hospitals meeting both requirements. CMS projects that total Medicare spending on inpatient hospital services will decrease by about $756 million in FY 2015.

CMS Issues Proposed Rule for FY 2015 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System (OPPS)

CMS has proposed to increase OPPS payments by 2.1 percent in FY 2015 for those hospitals that publicly report data on 22 quality measures. This update is based on a projected market basket increase of 2.7 percent, less a productivity adjustment of 0.2 percent and a 0.2 percentage point reduction required by the ACA. Those facilities that do not report the data would see payments rise by only 0.1 percent. The proposed rule affects hospital outpatient departments and ambulatory surgical centers beginning January 1, 2015.

CMS Releases Final Rule for Meaningful Use Flexibility

On September 4, CMS published a final rule that will extend stage 2 of meaningful use through 2016 and delay the start of stage 3 until 2017. The final rule also grants flexibility to providers who are unable to fully implement the 2014 Edition certified electronic health record (EHR) technology (CEHRT) to meet meaningful use requirements in 2014. For 2014, providers and hospitals may use EHRs that have been

certified under the 2011 Edition or a combination of 2011 and 2014 Edition CEHRT. CMS explained in the final rule that it is not considering changes to the EHR report periods or the edition of CEHRT required for 2015 or subsequent years.

New Law Would Allow Veterans to Seek Care from Non-VA Providers

On August 7, President Obama signed the Veterans Access, Choice, and Accountability Act of 2014, which will allow eligible veterans to receive care from health care providers unaffiliated with Veterans Health Administration facilities if the Department of Veterans Affairs (VA) cannot provide the veteran with timely access to care. This new program, called Veterans Choice, is temporary and will expire in three years or when the $10 billion allocated to the Veterans Choice Fund has been spent. Under the Act, reimbursement for services provided through the Veterans Choice program will be determined through negotiated contracts with the VA and cannot exceed the amount Medicare would pay for such services, except when the veteran receiving the care resides in a "highly rural area."

CMS Announces Limited Restart of Recovery Auditory Contractor (RAC) Program

On August 4, CMS announced that, due to the continued delay in awarding new RAC contracts, CMS will modify its current RAC contracts to allow for a limited number of reviews of Medicare fee-for-service claims. According to the CMS announcement, RAC reviews will restart this month with the current RACs conducting a "limited number" of automated reviews as well as a small number of complex reviews of certain types of claims. However, in accordance with Congress' previous delays of the full implementation of the "Two Midnight Rule" until March 31, 2015, CMS confirmed that the RACs will not conduct any inpatient hospital patient status reviews during this "limited restart" period.

New ICD-10 Compliance Date Set for October 1, 2015

On July 31, CMS issued a rule finalizing October 1, 2015 as the new compliance date for health care providers, health plans, and health care clearinghouses to transition to ICD-10 code sets. This is the earliest possible date set by the Protecting Access to Medicare Act of 2014, which Congress passed in April. In adopting October 1, 2015 as the new compliance date, CMS concluded that extending the delay beyond 2015 "would be significantly more costly and have a damaging impact on industry" and "could render current ICD-10 system updates and releases obsolete."

CMS Open Payments System Review, Dispute and Correction Process Underway

On July 14, the Open Payments review, dispute and correction process began. Under the Sunshine Act, physicians and teaching hospitals have the ability to review and dispute payments and other transfers of value that pharmaceutical, biotechnology and medical device manufacturers and group purchasing organizations (GPOs) reported to CMS, before CMS publicly discloses this information by September 30. In early August, CMS took the Open Payments system offline temporarily to resolve a technical issue that resulted in physicians being able to view data that had been reported about other physicians with the same name. As a result of the temporary suspension, CMS extended the time for physicians and teaching hospitals to review and dispute payments until September 8. Manufacturers and GPOs will then have 15 days, until September 23, to submit corrections. Despite the suspension, CMS has stated that the public website will still launch on September 30 as planned.

CMS Proposes Changes to Sunshine Act Reporting Requirements

On July 3, CMS released four proposed changes for comment to the implementing regulations of the Physician Payments Sunshine Act. First, the proposed rule would eliminate the exclusion for payments to physicians for speaking at certain accredited continuing education programs. Currently, these speaking fees

do not have to be reported so long as the program meets the accreditation requirements and standards for continuing education of one of five listed organizations; the manufacturer does not select the covered recipient speaker or provide the third party with a distinct, identifiable set of individuals to be considered as speakers for the program; and the manufacturer does not pay the physician speaker directly. CMS indicates that its "apparent endorsement or support" of the five organizations sponsoring continuing education events was an unintended consequence of the final rule and notes that it proposes to delete the exclusion because it is redundant of the general reporting exclusion for payments or transfers of value where the manufacturer is unaware of the identity of the covered recipient. Thus, under the proposed rule, if the manufacturer does not directly select or pay the speaker and does not provide a list of speakers to the continuing education provider, these indirect payments would be excluded under the general exclusion for payments where the manufacturer is unaware of the recipient's identity.

The proposed rule would also require manufacturers of devices and medical supplies to report the market name for devices or medical supplies related to a particular payment or transfer of value. Currently, the regulations permit a manufacturer to report either the marketed name of the product, the product category, or the therapeutic area. In addition, the proposed rule would separate the exiting form descriptor for "stock, stock options, or any ownership interest" into three distinct form descriptors, "stock," "stock options," and "other ownership interests." Finally, the rule would delete the definition of "covered device" because CMS believes it is redundant in light of the definition of "covered drug, device, biological or medical supply," which is also codified in the final rule.

The proposed changes, if adopted, would take effect for data collection beginning January 1, 2015 and would not impact current data collection efforts for the calendar year 2014 reporting period. Comments closed on September 2.

OIG Advisory Opinions

The U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued three advisory opinions this summer. In Advisory Opinion No. 14-05, the OIG said it would not impose administrative sanctions for violations of the anti-kickback statute against an arrangement involving a prescription drug manufacturer selling a brand-name drug directly to patients. Under the proposed arrangement, the drug manufacturer sells the brand-name drug to patients who have a prescription and are either uninsured, have private insurance coverage or are covered by Medicare Part D or a similar federal health-care program. Although the brand-name prescription is covered under Medicare Part D, the drug manufacturer said it is not included on most third party payor formularies due to the presence of generic equivalents.

In Advisory Opinion 14-06, the OIG concluded that a proposed arrangement by a specialty pharmacy might generate prohibited remuneration under the Federal anti-kickback statute and would pose a risk of fraud and abuse. Under the proposed arrangement, the specialty pharmacy would pay local retail pharmacies a fair market value, per-fill fee for services provided to patients by the retail pharmacy for prescriptions that the retail pharmacy could not fill but instead referred to the specialty pharmacy. The OIG concluded that there is a significant risk that the per-fill fees would represent compensation for the retail pharmacies generating business, including Federal health care programs business, rather than solely compensation for bona fide commercially reasonable services.

In Advisory Opinion 14-07, the OIG again addressed the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance (Medigap) policies offered by a health insurer. Under the

proposed arrangement, the health insurer would indirectly contract with hospitals for discounts on the otherwise-applicable Medicare inpatient deductibles for its policyholders and, in turn, the insurer would provide premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay. This advisory opinion is very similar to Advisory Opinions No. 14-02, issued in February, and 14-04 issued in April, in which the OIG came to the same conclusion about similar proposed arrangements from anonymous requesting parties.

As in the prior opinions, the OIG concluded that, in combination with the Medigap coverage, the discounts offered on inpatient deductibles by the network hospitals and the premium credits offered by the insurer would present a sufficiently low risk of fraud or abuse under the anti-kickback statute because: (1) neither the discounts nor the premium credits would increase or affect per-service Medicare payments; (2) the arrangement would be unlikely to increase utilization; (3) the arrangement would not unfairly affect competition among hospitals, because membership in a contracting hospital network would be open to any accredited, Medicare-certified hospital; (4) it would be unlikely to affect professional medical judgment because the policyholders' physicians would receive no remuneration; and (5) the insurer would make clear to its policyholders that they have the freedom to choose any hospital without incurring additional liability or penalty.

FDA Releases Guidance for Drug and Device Information on Social Media

On June 17, the FDA issued two draft guidance documents relating to the use of social media and the Internet to promote prescription drugs and medical devices. The first outlines recommendations for the presentation of risk and benefit information in character-limited forums such as Twitter. The FDA emphasized that, despite the small space, companies must include risks along with the benefits in each individual message or tweet. The second guidance addresses how to respond to incorrect or misleading information posted on the Internet by independent third parties. The agency stressed that a company has no obligation to respond to content generated by entities over which it has no control, even if the information is posted on a forum supplied by the company, provided that the company does not substantively screen or edit the posts.

HHS Announces $800,000 Settlement for HIPAA Violation

On June 23, HHS entered into an $800,000 settlement with Parkview Health System, Inc. (Parkview), a nonprofit community health system servicing northeastern Indiana and northwest Ohio, for a potential violation of the HIPAA Privacy Rule arising from its handling of patient records on behalf of a retiring physician. In 2009, a retiring physician filed a complaint with HHS against Parkview alleging that it had violated the Privacy Rule in September 2008 when it received and took custody of medical records pertaining to 5,000 to 8,000 of the retiring physician's patients in order to transition the patients to new providers. When Parkview later tried to return those records to the physician, the physician refused delivery. According to OCR, on June 9, 2009, Parkview employees, with notice that the retiring physician was not at home, left 71 cardboard boxes filled with medical records unattended and accessible to the public on the driveway of the physician's home. The boxes were left within 20 feet of the public road and a short distance away (four doors down) from a heavily trafficked public shopping venue. OCR found that by leaving the records unattended in the physician's driveway, Parkview failed to appropriately and reasonably safeguard all PHI in its possession, in violation of the requirement that PHI be safeguarded from the time it is acquired through its disposition.

In addition to the $800,000 payment, Parkview agreed to a corrective action plan requiring it to revise its policies and procedures, train staff, and provide an implementation report to OCR.

HHS Releases Two Reports to Congress on Breaches and HIPAA Compliance

On June 11, the U.S. Department of Health and Human Services, Office of Civil Rights issued two reports required by the Health Information Technology for Economic and Clinical Health (HITECH) Act. The first, the Annual Report to Congress on Breaches of Unsecured Protected Health Information (Breach Report), details the number and nature of breaches reported to HHS and the actions taken in response to those breaches. The second, the Annual Report to Congress on HIPAA Privacy, Security and Breach Notification Rule Compliance (Compliance Report), summarizes complaints HHS received of alleged violations of the HIPAA Privacy and Security Rules. These recently released reports cover relevant activities in calendar years 2011 and 2012. Some highlights from each report follow.

Breach Report

- Between 2011 and 2012, HHS received 458 reports of breaches affecting 500 or more individuals. Approximately 14.69 million individuals were affected.

- Theft was the most common cause of reported data breaches, followed by unauthorized access or disclosure.

- In 2012, 68 percent of breaches affected 500 individuals or more occurred at health care providers, while 25 percent occurred at business associates and 7 percent occurred at health plans.

- The majority of compromised PHI was stored on laptop computers (27 percent), followed by paper (23 percent), network servers (13 percent), computer desktops (12 percent), and portable electronic devices (9 percent).

- The Office of Civil Rights opened investigations into all of the 458 reported breaches affecting 500 individuals or more and as of the date of the report, HHS has entered into agreements totaling more than $8 million in settlements.

Compliance Report

- From April 2003 to December 2012, OCR received more than 77,000 complaints alleging violations of the HIPAA Rules. As of December 31, 2012, over 70,000 (91 percent) of the complaints have been resolved. The majority of complaints received are resolved within one year of their receipt.

- In almost 43,000 of the resolved cases, OCR determined that the complaint did not present an eligible case for enforcement under the HIPAA Rules.

- From 2003 to 2012, OCR investigated more than 27,000 complaints. Of those, OCR resolved almost 19,000 cases by requiring covered entities to take corrective action and/or provided technical assistance to covered entities to resolve areas of noncompliance. In the remaining complaints investigated, OCR found that no violation of the HIPAA Rules occurred.

- The Compliance Report also provides an overview of the audits required of covered entities and business associates by the HITECH Act and HHS to ensure compliance with the HIPAA Privacy and Security Rules. These audits were divided into four categories of covered entities depending upon

the type of entity and or size of entity. To date, 115 covered entities have been audited: 47 health plans, 61 health care providers, and seven health care clearinghouses.

OIG Releases Special Fraud Alert Regarding Laboratory Payments to Referring Physicians

On June 25, the OIG issued a Special Fraud Alert addressing compensation paid by laboratories to referring physicians and physician group practices under specimen processing arrangements and registry arrangements. The OIG said these types of arrangements "present a substantial risk of fraud and abuse under the anti-kickback statute."

The fraud alert first addressed specimen processing arrangements under which clinical laboratories, either directly or indirectly, pay physicians to collect, process and package patients' specimens. The OIG states that certain characteristics of a specimen processing arrangement may evidence the requisite intent to violate the anti-kickback statute. Such evidence may include:

- Payment that exceeds the fair market value for services actually rendered;
- Payment for services that are covered by a third party, such as Medicare;
- Payment made directly to the ordering physician rather than to the ordering physician's group practice;
- Payment made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals;
- Payment conditioned on a specified volume or type of tests or test panel, especially if the panel includes duplicative tests; and
- Payment made to the physician or group practice, even though the specimen processing is actually performed by an in-office phlebotomist.

The OIG also stated that specimen processing arrangements that apply only to specimens collected from non-Federal health care program patients may still violate the anti-kickback statute if they are merely an attempt to disguise payment for Federal health care program business. The OIG noted that such arrangements may be intended to induce physicians' referrals of Federal health care program business to offering laboratories.

The OIG then addressed registry arrangements, under which laboratories establish, coordinate or maintain databases on patients who have undergone, or who may undergo, certain tests. The OIG sets forth a list of some of the characteristics that of these arrangements that may be evidence of an unlawful purpose to induce or reward referrals of Federal health care business:

- The laboratory requires physicians to perform tests with a stated frequency to be eligible to receive compensation;
- The laboratory collects comparative data from multiple tests that are duplicative or otherwise not reasonable or necessary and bills for these tests;

- Physician compensation is based on a per-patient or other basis that accounts for the value or volume of referrals;

- Physician compensation is not fair market value for the physician's efforts in collecting and reporting patient data;

- Physician compensation is not supported by documentation, submitted by the physician, which memorializes the physician's efforts;

- The laboratory offers registry arrangements only for tests (or disease states associated with tests) for which it has obtained patents or that it exclusively performs;

- When a test is performed by multiple laboratories, the laboratory collects data only from the tests it performs;

- The laboratory's requisition displays tests in a manner that makes it more difficult for the physician to make an independent medical necessity decision with regard to each test for which the laboratory will bill.

The OIG noted that while the anti-kickback statute does not prohibit laboratories from compensating physicians for legitimate research activities, even registry arrangements that exclude federal health care beneficiaries will violate the statute if even one purpose of the arrangement is to induce or reward referrals.

OIG Finds Privacy and Security Risks with EHR Certification Process

In August, OIG released a report titled, "The Office of the National Coordinator for Health Information Technology's (ONC) Oversight of the Testing and Certification of Electronic Health Records." In the report, the OIG concludes that the process the ONC uses to certify EHR is not sufficient to ensure the privacy and security of electronic patient information contained in EHRs. The OIG recommended that the ONC require the authorized testing and certification bodies to develop procedures to periodically evaluate whether certified EHRs continue to meet Federal standards and develop a training program to ensure that their personnel are competent to test and certify EHRs and to secure proprietary or sensitive EHR information. It also recommended that ONC work with the National Institute of Standards and Technology to strengthen EHR test procedure requirements so that the authorized testing and certification bodies can ensure during testing that EHR vendors incorporate a baseline set of security and privacy features into the development of EHRs to address common security issues.

OIG Audit Report of Questionable Billing for Medicare Part B Clinical Laboratory Services

On July 10, OIG released its report, Questionable Billing for Medicare Part B Clinical Laboratory Services, which analyzes Medicare Part B claims for laboratory services with dates of service in 2010. The OIG found that in 2010, over 1,000 laboratories exceeded the thresholds (i.e., had unusually high billing) for five or more measures of questionable billing for Medicare lab services. In 2010, Medicare allowed $1.7 billion for questionable claims across all labs. Almost half of the laboratories that exceeded the thresholds for five or more measures of questionable billing – compared to thirteen percent of all laboratories – were located in California and Florida. As a result of its findings, OIG recommended to CMS that it (1) review the labs identified as having questionable billing and take appropriate action, (2) review existing program integrity strategies to determine whether these strategies are effectively identifying program vulnerabilities

associated with lab services, and (3) ensure that existing edits prevent claims with invalid and ineligible order-physician numbers from being paid. CMS concurred with all the recommendations.

One-year Transition for Business Associate Agreements Expires on September 23, 2014

September 22 is the date by which all HIPAA business associate agreements need to be in compliance with the HIPAA omnibus rule. The omnibus rule went into effect on March 26, 2013, but certain then-existing HIPAA business associate agreements were grandfathered and did not have to be updated immediately. That grandfathering ends and up-to-date business associate agreements must be in place starting September 22.

STATE DEVELOPMENTS

Healthcentric Advisors of Rhode Island to Become New QIN-QIO for Maine, New Hampshire and Vermont

Beginning August 1, Healthcentric Advisors of Rhode Island is the designated Quality Innovation Network-Quality Improvement Organization (QIN-QIO) for Maine, New Hampshire, and Vermont. Northeast Health Care Quality Foundation (NHQCF), which previously held the QIO contract, was unsuccessful in its bid to renew its contract.

N.H. Insurance Department Denies Patient Request to Include Frisbie Memorial Hospital in the Provider Network

On September 3, the New Hampshire Insurance Department denied a woman's request to include her doctor and others affiliated with Frisbie Memorial Hospital in the new provider network for individuals under the Affordable Care Act. The patient had argued before the Department that she was harmed by the Department's approval of Anthem Blue Cross Blue Shields Pathway network, which excludes 10 of the state's 26 hospitals. In denying her request to include Frisbie Memorial Hospital in the network, the Commission found that the patient's case consisted only of speculation and that she did not show that the network is inadequate.

N.H. Insurance Department Releases 2015 Marketplace Plan Preview

On August 25, the New Hampshire Insurance Department updated its 2015 New Hampshire Marketplace preview. While the information does not represent the final networks as they may appear on the health insurance marketplace in 2015, it is based on insurance carrier applications received through August 18. Based upon the current applications, the Insurance Department expects New Hampshire's insurance market to experience increased competition and selection in 2015. While in 2014, there was one insurance provider, Anthem Blue Cross Blue Shield, on the marketplace, in 2015 the Insurance Department expects there to be five. In 2014, there were 14 medical plans available, and in 2015 the Insurance Department expects there to be 61. Similarly, in 2014, only 16 of the state's 26 hospitals were covered, while in 2015 the Insurance Department expects every hospital in the state will be included in at least three insurance company networks.

All insurance plans still need final approval from both state and federal regulators. The New Hampshire Marketplace will open to the public for the purchase of 2015 plans starting on November 15.

Governor Hassan Signs Medicaid Enhancement Tax Bill Into Law

On June 30, Governor Hassan signed SB 369, which restructures the Medicaid Enhancement Tax. As we explained in a previous update, under the new law, 25 of the state's 26 hospitals agreed to drop the lawsuit that they had brought over the tax. Under the agreement, critical access hospitals will get back 75 percent of uncompensated care costs, and all other hospitals will get back 50 percent of uncompensated care costs in 2016 and 2017, and 55 percent of such costs starting in 2018. The law assumes that uncompensated care will decrease over time as more people buy health insurance, but contains protections for the state such that if revenue from the tax drops below a certain threshold, the state will lower its payments back to the hospitals.

EMPLOYMENT LAW UPDATES

Equal Employment Opportunity Commission Approves New Guidance Addressing Pregnancy Discrimination

On July 14, the Equal Employment Opportunity Commission ("EEOC") approved new guidance addressing the Pregnancy Discrimination Act ("PDA"). The PDA is a part of Title VII of the Civil Rights Act of 1964, which prohibits discrimination on the basis of sex, among other categories. The new guidance, "Enforcement Guidance: Pregnancy Discrimination and Related Issues," supersedes the 1983 EEOC Compliance Manual Section 626, making this the first update on this subject issued in decades. The guidance applies to pregnant workers, past-pregnant workers, potentially-pregnant workers, and those who care for infants. In addition to discussing the rights and obligations set forth by the PDA, the guidance also discusses application of the Americans with Disabilities Act to pregnancy related disabilities. Among other requirements, the guidance requires that employers who offer light duty work to certain categories of non-pregnant workers must also make light duty work available to pregnant workers.

The guidance also asserts some level of protection for workers using contraception by providing that an employer cannot discharge a worker for using or failing to use contraception. Apparently taking aim at the well-publicized Supreme Court ruling in *Burwell v. Hobby Lobby Stores*, the EEOC guidance provides that "[e]mployers can violate Title VII by providing health insurance that excludes coverage of prescription contraceptives, whether the contraceptives are prescribed for birth control or for medical purposes." Not surprising in light of prior guidance and Title VII law, the EEOC concludes that "[t]o comply with Title VII, an employer's health insurance plan must cover prescription contraceptives on the same basis as prescription drugs, devices, and services that are used to prevent the occurrence of medical conditions other than pregnancy. For example, if an employer's health insurance plan covers preventive care for medical conditions other than pregnancy, such as vaccinations, physical examinations, prescription drugs that prevent high blood pressure or to lower cholesterol levels, and/or preventive dental care, then prescription contraceptives also must be covered."

Notably, this guidance was approved in advance of the United States Supreme Court's decision in *Young v. United Parcel Service Inc.*, which the Court accepted for review on July 1. *Young* will address whether employers are required to offer light duty to pregnant workers when light duty is available for certain non-pregnant employees and therefore may impact the recently-issued guidance. The guidance also precedes congressional action on the proposed Pregnant Workers Fairness Act, which, if passed, would amend the PDA to require reasonable accommodations for pregnant workers.

YOUR REWARD FOR MAKING IT TO THE END

Healthcaredive.com Compiles a List of 16 Most Absurd ICD-10 Codes

There are 68,000 billing codes under the new ICD-10 system, as opposed to the 13,000 under the current ICD-9. According to Healthcaredive.com, these are the 16 most absurd codes in the ICD-10 set:

16. V97.33XD: Sucked into jet engine, subsequent encounter.

15. W51.XXXA: Accidental striking against or bumped into by another person, sequela.

14. V00.01XD: Pedestrian on foot injured in collision with roller-skater, subsequent encounter.

13. Y93.D: Activities involved arts and handcrafts.

12.Z99.89: Dependence on enabling machines and devices, not elsewhere classified.

11. Y92.146: Swimming-pool of prison as the place of occurrence of the external cause.

10. S10.87XA: Other superficial bite of other specified part of neck, initial encounter.

9. W55.41XA: Bitten by pig, initial encounter.

8. W61.62XD: Struck by duck, subsequent encounter.

7. Z63.1: Problems in relationship with in-laws.

6. W220.2XD: Walked into lamppost, subsequent encounter.

5. Y93.D: V91.07XD: Burn due to water-skis on fire, subsequent encounter.

4. W55.29XA: Other contact with cow, subsequent encounter.

3. W22.02XD: V95.43XS: Spacecraft collision injuring occupant, sequela.

2. W61.12XA: Struck by macaw, initial encounter.

1. R46.1: Bizarre personal appearance.

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Cinde Warmington, Clara Dietel, Benjamin Siracusa Hillman, and Jeanine Kilgallen contributed to this month's Legal Update.

BIOS

CINDE WARMINGTON
Cinde, a partner at Shaheen & Gordon, leads the Health Care Practice Group and focuses her practice entirely on representing health care clients. Her prior clinical and administrative experience makes her uniquely qualified to assist providers in facing a rapidly changing regulatory environment.

CLARA DIETEL
Clara advises health care providers on a variety of health related regulatory issues, with a focus on HIPAA compliance. She also practices in the area of civil litigation, representing heath care providers in state and federal court.

BENJAMIN SIRACUSA HILLMAN
Ben assists individual practitioners, group practices, and hospitals with a variety of health related business, regulatory, and litigation issues, and advises small businesses on compliance with the Affordable Care Act. Ben also practices in the areas of civil litigation, elder law, estate planning and probate.

JEANINE KILGALLEN
Jeanine advises employers on a variety of regulatory and compliance issues, and defends employers in federal and state court and before administrative agencies. She also practices in the areas of civil litigation and criminal defense.