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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

CMS Finalizes Rule for Automatic Re-Enrollment in Marketplace Coverage

On September 5, CMS published a final rule that will allow consumers in the Affordable Care Act health insurance marketplace operated by the federal government to automatically re-enroll in coverage for 2015. Consumers in federally facilitated marketplaces, including New Hampshire's marketplace, will receive notices shortly before open enrollment begins for 2015. The notices will explain the auto-enrollment process, and how consumers can see if they qualify for additional financial assistance and shop for plans. Consumers will also receive notices from their insurance company about 2015 premiums and how much they may save with premium tax credits. If consumers do nothing, they will be automatically enrolled in the same plan with the same premium tax credits and other financial assistance, if applicable, as they had in the 2014 plan year. The rule is effective October 6. Open enrollment begins November 15.

Administration Predicts Twenty-Five Percent Increase in Number of Insurers Participating in Marketplaces, with Largest Rise in New Hampshire

On September 23, the Administration released preliminary data on participation in the health insurance marketplaces in 2015. Nationally, the number of insurers has increased to 315 for next year, from 252 this year. (If a single insurer participates in multiple states, it is counted separately for each state in which it participates.)

In New Hampshire, the number of participating insurers is expected to increase from one to five, the greatest increase on a percentage basis of any state, for a total of over 70 marketplace plans. All twenty-six hospitals will participate with at least three of the five insurers next year. In addition to Anthem Blue Cross Blue Shield, the sole participant in 2014, the following insurers will participate in the health insurance marketplace: Assurant Health, Harvard Pilgrim Health Care of New England, Minuteman Health, and Maine Community Health. It is expected that the exchange will feature both narrow networks, with lower premiums, and broad networks, with higher premiums.

OIG Finds Personal Data Vulnerable in Insurance Exchanges

On September 23, the OIG released a report, "Health Insurance Marketplaces Generally Protected Personally Identifiable Information But Could Improve Certain Information Security Controls," in which it concluded that some state health insurance exchanges are still vulnerable to attack, putting personally identifiable information at risk. The OIG examined the website and databases of the federal insurance exchange, as well as the state exchanges in Kentucky and New Mexico. The OIG found that the data in all three exchanges were protected, but there were opportunities to

improve database access and security controls to adhere more strictly to federal requirements. Specifically, the OIG found a "critical vulnerability" in the federal exchange operated through the HealthCare.gov website, which might allow an attacker to execute commands on the server, or retrieve and modify information. The OIG recommended that CMS management address the findings it identified to ensure that consumer personally identifiable information entered on Healthcare.gov is secure and protected.

HHS Reports Hospital Uncompensated Care Costs Will Drop $5.7 Billion in 2014

On September 24, HHS released a report in which it concluded that hospitals will save $5.7 billion this year in uncompensated care costs as a result of expanded health insurance coverage provided under the Affordable Care Act. The report said that hospitals in the twenty-seven states that have expanded Medicaid are projected to save up to $4.2 billion, or about three-quarters of the total savings. Hospitals in the twenty-three states that have opted not to expand Medicaid are projected to save up to $1.5 billion this year, or about one-quarter of the total savings nationally, it added.

Other Federal Developments

DEA Expands Drug Take-Back Program to Hospitals and Clinics

On September 9, the U.S. Drug Enforcement Administration ("DEA") issued a final rule implementing the Secure and Responsible Drug Disposal Act of 2010. The final rule allows manufacturers, retail pharmacies, hospitals and clinics with an on-site pharmacy and other authorized entities to institute prescription take-back programs where patients can turn over unused pharmaceuticals either by mail or by dropping them off with the collecting entity. It also provides guidance on how collected drugs must be destroyed. Entities are not required to implement such take-back programs, and patients are not obligated to participate in any program in order to dispose of prescription drugs. The rule goes into effect October 9.

HHS Provides Additional Flexibility for Certification of Electronic Health Record

On September 10, HHS issued a final rule that adds flexibility as well as clarity and improvements to the current 2014 Edition electronic health record ("EHR") certification criteria and the Office of the National Coordinator for Health IT ("ONC") Certification Program through a new release of optional and revised criteria. The certification criteria and program updates included in the final rule were proposed earlier this year. In consideration of public comment received on the proposed rule, the final rule provides alternative certification criteria and approaches for the voluntary certification of heath IT. The rule can be found online at https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-21633.pdf.

OIG Report Reveals Twelve Percent of Rural Health Clinics ("RHCs") Do Not Meet RHC Certification Requirements

On September 12, the OIG released a report regarding CMS's enforcement of the statutory provisions governing RHCs. RHCs must meet two location requirements to receive enhanced Medicare and Medicaid payment for most services: (1) they must be located in rural areas and (2) they must be located in areas that have a shortage of health care workers. In its report, the OIG found that approximately twelve percent (12%) of RHCs no longer meet the RHC location requirements in 2013, but are still receiving enhanced Medicare reimbursement. According to the OIG, these RHCs received $132 million from Medicare beneficiaries in 2012.

Pursuant to the Balanced Budget Act of 1997, these RHCs should only continue to qualify as RHCs if they are determined to be "essential providers." However, CMS has yet to issue final regulations that would allow RHCs that do not meet the location requirements to qualify as essential-provider RHCs. The OIG

recommends that CMS issue regulations to ensure that RHCs determined to be essential providers remain certified as RHCs. In response to the OIG's report, CMS thanked OIG "for their efforts on this issue" and provided no further comment.

OCR Issues Guidance on HIPAA and Same-Sex Marriage

On September 17, the U.S. Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") released guidance to assist covered entities in understanding how the U.S. Supreme Court's decision in *United States v. Windsor* may affect certain of their Privacy Rule obligations. In *Windsor*, the Supreme Court ruled that Section 3 of the Defense of Marriage Act ("DOMA"), which provided that federal law would recognize only opposite-sex marriages, was unconstitutional.

OCR's guidance clarifies that, under the Privacy Rule, the term "spouse" includes both same-sex and opposite-sex individuals who are legally married. In addition, the term "marriage" extends to same-sex and opposite sex-marriages, and "family member" includes dependents of those marriages. All of these terms apply to individuals who are legally married, whether or not they live or receive services in a jurisdiction that recognizes their marriage.

The HIPAA Privacy Rule provides some protections to family members, including spouses, of patients. For example, under certain circumstances, covered entities are permitted to share an individual's protected health information with a family member of the individual. In additions, the protections against the use of an individual's genetic information for underwriting purposes under the Genetic Information Nondiscrimination Act extend to certain information about family members. OCR indicated that it intends to issue additional clarifications through guidance or to initiate rulemaking to address same-sex spouses as personal representatives under the Privacy Rule.

Obama Administration Takes Actions to Combat Antibiotic-Resistant Bacteria

On September 18, President Obama signed an Executive Order directing key Federal departments and agencies to take action to combat the rise of antibiotic-resistant bacteria. The Administration also released its "National Strategy for Combating Antibiotic-Resistant Bacteria," which provides a five-year plan for enhancing domestic and international capacity to: prevent and contain outbreaks of antibiotic-resistant infections; maintain the efficacy of current and new antibiotics; and develop and deploy next-generation diagnostics, antibiotics, vaccines, and other therapeutics. In addition, the President's Council on Advisors on Science and Technology released a related report on combating antibiotic resistance. The Administration also announced a $20 million prize, co-sponsored by the National Institutes of Health and the Biomedical Advanced Research and Development Authority, to facilitate the development of rapid, point-of-care diagnostic tests for healthcare providers to identify highly resistant bacterial infections. The Administration took these steps because, according to the Centers for Disease Control and Prevention, antibiotic-resistant infections are associated with 23,000 deaths and 2 million illnesses in the United States each year, and may cost as much as $20 billion in excess direct health care costs.

OIG Issues Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons

On September 19, the OIG issued a Special Advisory Bulletin on Pharmaceutical Manufacturer Coupons (the "Advisory Bulletin") warning pharmaceutical manufacturers that they risk sanctions under the federal anti-kickback statute if they fail to take appropriate steps to ensure their copayment coupons do not induce the purchase of drugs paid for by federal health care programs, specifically Medicare Part D. Copayment coupons are intended to help patients defray the cost of their copays for specific brand-name drugs. Coupons come in several forms, including printed coupons, electronic coupons, a debit card or direct

payments from the manufacturer to the patient. The OIG found that the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available.

Concurrent with the Advisory Bulletin, the OIG issued a report, "Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs," in which it concluded that the safeguards pharmaceutical manufacturers currently use to prevent their copayment coupons from being used by Medicare Part D beneficiaries may not prevent all copayment coupons from being used for drugs paid for by Part D. The OIG recommends that CMS "cooperate with industry stakeholder efforts to improve the reliability of pharmacy claims edits and make coupons transparent." To further this goal, the OIG stated that CMS should take several steps, including: looking at options to verify a patient's Medicare Part D enrollment prior to a copayment coupon being processed; changing the Medicare Part D program to improve enrollment verification; and working with stakeholders to identify and make transparent the use of copayment coupons. CMS agreed with the OIG recommendation.

Lawmakers Call on HHS to Clarify Mobile Medical App Regulation

On September 25, Reps. Tom Marino (R-Pa.) and Peter DeFazio (D-Ore.) sent a letter to HHS Secretary Sylvia Mathews Burwell urging the agency to clarify and update HIPAA regulations for mobile application developers. In the letter, the representatives explained that vendors wish to comply with regulations but are unable to do so and "regulatory guidance should be routinely updated to reflect modern technologies being used in the health field." Reps. Marino and DeFazio suggested that federal officials:

- Clarify HIPAA obligations for services storing data on the cloud;
- Offer implementation standards through HHS's Office for Civil Rights;
- Update the steps vendors must take to comply with HIPAA; and
- Recruit employees who can work with startups to produce HIPAA-compliant products.

OIG Report Finds Better Oversight Needed of State Requirements for Medicaid Physician Access

On September 29, the OIG published a report titled, "State Standards for Access to Care in Medicaid Managed Care," in which it found that state standards for access to care vary widely and are rarely enforced by CMS. For example, the OIG found that standards range from requiring one primary care provider for every 100 enrollees to one primary care provider for every 2,500 enrollees. In addition, standards are often not specific to certain types of providers or to areas of the state. The OIG found that while CMS uses a checklist to confirm that states have access standards, the agency does not assess whether these standards are adequate to ensure access to care.

The OIG recommends that CMS strengthen its oversight of state standards and ensure that states develop standards for critical providers. In addition, the report said that CMS should strengthen its oversight of states' methods to assess plan compliance and improve states' efforts to identify and address violations of access standards. Further, the OIG recommended that CMS improve states' efforts to identify and address violations of access standards and provide technical assistance and share effective practices. CMS concurred with all of the OIG's recommendations. CMS said it will engage collaboratively with states to identify best practices for testing plan compliance, rather than endorse a particular method.

CMS Releases Open Payments Database to the Public

On September 30, CMS released the first round of Open Payments data to the public. The data, which contained 4.4 million payments totaling roughly $3.5 billion, covered financial transactions between drug and device manufacturers and physicians and teaching hospitals that took place in the last five months of 2013. The database shows 7,100 payments made to New Hampshire physicians, totaling $1.57 million. The data is attributable to 546,000 individual physicians and almost 1,360 teaching hospitals. About 40 percent of the records published do not include the name of the physicians and teaching hospitals receiving the payments due to technical issues. In addition, commentators have criticized the website, created by the same lead contractor as healthcare.gov, as difficult to use. Future releases of Open Payments data will be published annually and will include a full 12 months of payment data, beginning in June 2015.

CMS published the information after receiving a letter from three associations representing drug and device manufacturers urging CMS to include more context and background on Open Payments data. The letter, signed by the presidents and chief executive officers of the Advanced Medical Technology Association, the Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America also asked CMS to explain why it removed one-third of payment data from the Open Payments database in mid-August. The American Medical Association ("AMA") also issued a statement in advance of the public release of the Open Payments data, reinforcing its position that the data lack sufficient context and may contain inaccuracies. The AMA also expressed concern over the handling of records that were removed from the Open Payments data.

CMS Requests Comments on Data Matching Program for Reducing Improper Payments

CMS is requesting comments on a forthcoming computer matching program ("CMP") that will use data from the Department of the Treasury to reduce improper payments. Under the CMP, the Treasury's Bureau of Fiscal Service will provide CMS with data on individuals and organizations that have been blocked from receiving payments, contracts or other benefits from the federal government, and the CMS will match the data against records maintained in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). CMS began a similar matching program in 2013, in which the Social Security Administration provided CMS with data to verify individual eligibility for the Affordable Care Act's insurance exchanges. Comments are due October 8.

OIG Publishes Another Advisory Opinion on Use of "Preferred Hospital" Network as Part of Medigap Policy

On September 24, the OIG published Advisory Opinion No. 14-08, in which it concluded that a proposed arrangement in which a medigap plan would contract with a preferred hospital network in return for deductible discounts would not result in administrative sanctions. This Advisory Opinion closely mirrors several other recent Advisory Opinions published by the OIG.

HHS Announces Second Round of HIPAA Audits Will Be Used as an "Enforcement Tool"

On September 24, a senior HHS official told a joint conference with the National Institute of Standards and Technology that the next round of HIPAA audits will become a mechanism for launching investigations into whether healthcare organizations and their contractors are complying with HIPAA Privacy and Security Rules. The audits will include covered entities as well as their business associates. In addition to announcing the second phase of HIPAA audits, OCR is working on additional guidance for covered entities and business associates on a variety of topics, including: breach notification safe harbors; a breach risk assessment tool; HIPAA minimum necessary requirements; and HIPAA marketing rules.

CMS Reports Recovery Audit Contractors ("RACs") Collected $3.65 Billion in Medicare Overpayments in FY 2013

According to a recent CMS report, RACs collected $3.65 billion in Medicare overpayments during fiscal year 2013, in addition to blocking $22 million in improper payments from being made through prepayment review. The report also found that RACs received high accuracy scores from the Recovery Audit Validation Contractor, an independent contractor tasked with reviewing random samples of claims denied by RACs. For FY 2013, RACs had cumulative accuracy scores of 92 percent or higher, the report said.

DHHS OIG Issues Proposed Rule to Amend Safe Harbors of the Anti-kickback Statute

The Department of Health and Human Services Office of the Inspector General issued a proposed rule on October 2 that would add new safe harbors to the anti-kickback statute and exempt certain conduct from civil money penalties. The new safe-harbor provisions would address a number of behaviors, including:

- Pharmacy cost-sharing waivers for financially needy Medicare Part B beneficiaries;
- Cost sharing waivers for emergency ambulance services provided by state or municipality-owned ambulance services;
- Manufacturer discounts on drugs furnished to beneficiaries under the Medicare Coverage Gap Program;
- Certain transactions between Medicare Advantage organizations and Federally Qualified Health Centers; and
- Free or discounted local transportation services that meet certain criteria.

The CMP exceptions would include co-payment reductions for some outpatient services, copayment waivers for certain generic drugs and coupons and other reward programs that meet specific criteria.

STATE DEVELOPMENTS

More than 18,000 Enroll in Expanded Medicaid

The N.H. Department of Health and Human Services says 18,500 people have signed up for health care coverage under the State's expanded Medicaid program since July 1. This is more than a third of the estimated 50,000 adults who are eligible to enroll. Officials had previously predicted that 30,000 to 40,000 people would enroll in the first year.

Court Dismisses Claim Against Staffing Agency in Exeter Hospital Hepatitis C Outbreak Case

The U.S. District Court for the District of New Hampshire recently dismissed Exeter Hospital's claims against a medical staffing agency that formerly employed David Kwiatkowski, the cardiac catheterization technician responsible for infecting numerous hospital patients with hepatitis C. Exeter Hospital had previously settled with several patients and filed a complaint against Maxim Healthcare Services, Inc., the staffing agency that employed Kwiakowski, and the American Registry of Radiologic Technologists ("ARRT"), arguing that they should help pay for its settlements. The court found that Maxim did not owe

Exeter Hospital or its patients a duty to report Kwiatkowski's conduct. The court, however, refused to dismiss Exeter Hospital's claims against ARRT, finding that the agency may have "assumed a broader range of duties" than Maxim.

MapNH Health Highlights State's Future Health and Healthcare Needs

The New Hampshire Citizens Health Initiative recently launched MapNH Health, which charts a host of indicators of the State's well-being through 2030. According to the Citizens Health Initiative, the ratio of people younger than 20 and older than 64 to the working-age population is projected to rise from just more than 60 percent in 2010 to just less than 90 percent in 2030. Birth rates over the same period are projected to remain steady statewide, but in some parts of the State – including Merrimack County – they will decline slightly. Statewide obesity levels are predicted to rise from 25.6 percent in 2010 to between 33.9 percent and 43.4 percent in 2030, while the rates of cardiovascular disease, Alzheimer's disease, cancer and diabetes are also expected to rise through 2030. MapNH Health also predicts that the demand for primary care will rise across the State over the next two decades. The complete findings can be found online at mapnhhealth.org.

New Hampshire Board of Pharmacy Implements Emergency Rule in Response to DEA Reclassification of Hydrocodone-Containing Products

Effective October 6, the DEA will reclassify all Hydrocodone Containing Products ("HCPs"), including Vicodin, as Schedule II drugs. The DEA provided a 6 month period during which refills could be filled. However, on September 10, the New Hampshire Board of Pharmacy voted to implement emergency rules which will not allow such refills. Accordingly, all prescriptions written for HCPs with refills were null and void as of October 6.

Law Governing the Exchange of PHI Through the New Hampshire Health Information Organization ("NHHIO") Goes Into Effect

On September 9, Senate Bill 229, a bill that expands the availability of the NHHIO network to a larger group of healthcare providers became effective. The NHHIO operates a network which acts as a conduit in the secure transmission of protected health information between provider organizations. The amended statute now adds APRNs, physician assistants, care coordinators, managed care providers and the Department of Health and Human Services to the list of those who can transmit PHI through the NHHIO.

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

BIOS

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