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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

IRS Releases Final Employer Reporting Rules

On March 10, the Treasury Department and IRS published final regulations implementing information reporting for employers with 50 or more full-time equivalent employees under the ACA. These requirements, which are designed to assist the IRS with enforcing the employer mandate and determining eligibility for premium tax credits, are scheduled to take effect in 2015 and will require annual reporting to both the IRS and individual employees, akin to the filing of Form W-2. (Employees can consent to receive the statements electronically.) The forms will be due to employees and the IRS on the same filing schedule as Form W-2, and the first such returns will be due in early 2016, covering calendar year 2015. Both employers that self-insure and employers that do not will be able to use a single consolidated reporting form.

Employers will make a separate return for each full-time employee, accompanied by a single transmittal form for all of the returns filed for a given calendar year. The employee forms will be known as Form 1095-C, and the transmittal as Form 1094-C. The use of substitute forms will also be permitted, and the employer is permitted to furnish employees a statement, prescribed by the IRS, in lieu of furnishing a copy of the Form 1095-C filed with the IRS. There are simplified reporting requirements for employers who provide "qualifying offers" of health insurance to employees. For more details, please see the article on our website, *IRS Releases Final Employer Reporting Rules Under the Affordable Care Act*.

Final Week of ACA Signup Nets Many New Enrollees

On April 1, President Obama announced that some 7.08 million Americans had signed up for health insurance through the marketplaces in the initial open enrollment period, which ended March 31. (This compares with 4.2 million people who had enrolled as of the end of February.) These figures do not include new enrollees who enrolled in health plans directly with insurers outside the marketplaces. The number of such new enrollees is estimated at several million, although there is a debate about precisely how many are new enrollees. (Those who enroll directly with insurers are not able to take advantage of premium tax credits or cost-sharing reductions, but are able to take advantage of such other ACA benefits, such as the prohibition on rating enrollees based upon health status or pre-existing conditions.) In addition, non-governmental analysts estimate that approximately four to six million other individuals have enrolled in Medicaid as a result of Medicaid expansion.

Open enrollment in New Hampshire, which uses the federal exchange, closed on March 31. (Enrollment in some states that use state exchanges has been extended.) The next open enrollment period is

scheduled to run from November 15, 2014 through February 15, 2015. Those who experience a qualifying life event such as the birth or adoption of a child, marriage, moving outside the insurer's coverage area, gaining citizenship, leaving incarceration, or the non-voluntary loss of other health coverage can enroll outside the open enrollment period for a period of 60 days following the qualifying event. Individuals who had difficulty enrolling in coverage due to an exceptional life circumstance, being the victim of fraud, or system errors can also qualify to enroll after the deadline. Medicaid enrollment will continue to remain available at any time.

New Hampshire ACA Enrollment Continues to Be Strong

As of March 1, the most recent date for which state-by-state data has been released, enrollment by New Hampshire residents in health insurance through the federal exchange was at 21,578, or 142% of the 15,200-person enrollment target originally set by the U.S. Department of Health and Human Services for enrollments from the state. New Hampshire's percentage of its target is the third highest of any state, the highest of any state using the federal exchange, and is almost twice the national average.

Challenges to ACA Subsidies for Enrollees on Federal Exchanges Continue to Percolate

On March 25, the U.S. Court of Appeals for the D.C. Circuit heard arguments in the latest case contending that the Affordable Care Act makes subsidies available only to those who purchase insurance on state marketplaces, and not on the federal marketplace serving 36 states. The plaintiffs contend that because key passages of the Affordable Care Act, including the passage defining who is eligible for a subsidy, make reference to the ACA's section dealing with state insurance marketplaces and do not also refer to the ACA's section that directs the federal government to establish insurance marketplaces in states that do not create them, that the subsidies should not be available to individuals who purchase insurance on the federal exchanges. The IRS, through regulations, made the subsidies available to eligible individuals who purchase insurance on either the state or federal regulations, and the plaintiffs are challenging the IRS interpretation as inconsistent with the statute. The Administration has responded, relying on a number of provisions, that it is clear that Congress intended to make the subsidies available on both the state and federal exchanges, and that the IRS's interpretation should be given deference.

Two out of the three judges hearing the appeal appeared to express skepticism of the Administration's position. Previously, lower federal courts in Virginia and the District of Columbia had agreed with the Administration's position in separate cases, including in the case now on appeal. Cases are pending in federal court in Indiana and Oklahoma, and the Virginia case is now on appeal at the U.S. Court of Appeals for the Fourth Circuit.

Substandard Health Plans May Continue for Two Years

On March 5, the Obama Administration announced that it would permit consumers to renew health insurance policies that do not comply with the Affordable Act Care for two additional years, meaning that non-compliant coverage will extend for some into 2017. These include policies that do not provide "essential health benefits," that charge women more than men, and that charge higher premiums based upon a person's health status. Estimates of the number of individuals in non-compliant plans range from 500,000 to 1.5 million.

Congress Passes Legislative Patch for Scheduled Medicare Physician Payment Reduction Containing Numerous Other Provisions

Congress Puts Off Cuts to Physician Reimbursement . . . Again

In late March, Congress acted to avert a cut to Medicare physician reimbursement scheduled to go into effect on April 1, 2014, with the enactment of the Protecting Access to Medicare Act of 2014. In late 2013 and earlier this year, beltway watchers had hopes for a more permanent fix to the reductions required by the Sustainable Growth Rate law, but continuing disagreements over how to offset the cost of such a proposal prevented a final bill from coming to fruition by the time the prior patch was scheduled to expire. This new law extends the patch through March 31, 2015 and extends the previously-implemented 0.5% physician fee increase through the end of 2014.

Congress Delays Implementation of ICD-10 Until 2015

The new law prohibits the Secretary of the Department of Health and Human Services from adopting ICD-10 code sets prior to October 1, 2015. Some sources estimate that the delay could cost as much as $6.6 billion in industry costs, including money already spent by providers to upgrade systems in advance of implementation. This delay has left some organizations wondering whether CMS will allow providers to make the switch to ICD-10 voluntarily or whether the agency will skip over ICD-10 entirely and move straight to ICD-11, which is slated for release in 2017. We will keep you updated on these developments.

Congress Further Delays Two-Midnight Rule

The law further delays full implementation of the "Two Midnight" Rule. With the latest extension, Medicare Recovery Audit Contractors ("RACs") will not be able to audit inpatient hospital claims for compliance with the two-midnight rule from October 1, 2013 through March 31, 2015. Under the Two-Midnight Rule, a patient's status as an admitted inpatient is generally presumed to be appropriate if the patient stays at the hospital for at least two midnights. The Recovery Auditors were set to begin enforcing the rule on October 1, 2013, but that deadline was previously delayed until March 31, 2014, then most recently to September 30, 2014. The passage of the law pushes this deadline out another six months, requiring Recovery Auditors to wait until March 31, 2015 to begin using the rule during audits.

Congress Makes Significant Changes to Clinical Laboratory Fee Schedule

The law will implement the most significant changes to the clinical laboratory fee schedule since its creation in 1984. Beginning in January 2017, the law will phase in an alignment of Medicare payment rates with market-based rates. Medicare payment for each test will eventually be based on the weighted median of private payors' payment rates.

Congress Makes Numerous Other Changes

Among other changes, the law establishes a new value-based purchasing program for skilled nursing providers based on performance on hospital readmissions, scheduled to take effect October 1, 2018. It creates new mental health grant programs. It delays from 2016 to 2017 the start of planned reductions in Medicaid disproportionate share hospital payments, but increases the amount of reductions that are scheduled to take place from 2017 through 2024. It repeals a provision of the Affordable Care Act limiting cost-sharing (deductibles) for employer-sponsored health plans.

The law will require providers to utilize "appropriateness criteria" in determining whether to order an advanced medical imaging procedure for a Medicare patient. According to the American College of Radiology, this is the first time Medicare is requiring providers to use "point of care, evidence-based

ordering" for any procedure.

The legislation also extends a number of existing provisions until March or April of 2015, including the geographic practice cost index floor, therapy cap exceptions process, add-on payments for ambulance services in rural areas, and the Medicare-Dependent Hospital program. It also makes other changes.

Federal Regulatory Update

CMS Pauses Recovery Audit Program

On February 18, CMS announced that it was winding down its current Recovery Audit program, so that the current contractors could complete outstanding claim reviews by the end date of their contracts, and so that CMS could focus on its procurement process for the next round of contracts and on "refin[ing] and improv[ing]" the Medicare Recovery Audit Program. In accordance with this winding down, CMS announced that February 21 is the last day a Recovery Auditor may send a postpayment "Additional Documentation Request"; February 28 is the last day a Medicare Administrative Contractor ("MAC") may send prepayment Additional Document Requests; and June 1 is the last day a Recovery Auditor may send improper payment files to the MACs for adjustment.

On March 7, CMS noted that Recovery Auditors would be continuing to complete reviews based upon Additional Document Requests sent prior to February 28, and that Recovery Auditors can continue to conduct automated reviews that do not require soliciting medical record documentation from providers through June 1.

HHS Releases Security Risk Assessment Tool for Small to Medium Providers

On March 28, the U.S. Department of Health and Human Services released a new security risk assessment tool ("SRA tool") to assist small-to-medium sized offices conduct HIPAA risk assessments of their organizations. The SRA tool is designed to help practices conduct and document their assessment of the potential risks and vulnerabilities to the confidentiality, integrity and availability of electronic protected health information. Conducting a security risk assessment is a key requirement of the HIPAA Security Rule and a core requirement for providers seeking payment through the Meaningful Use Program.

The SRA tool is designed to help practices conduct the risk assessment in a thorough, organized fashion at their own pace. It produces a report that the practice can later provide to auditors. The SRA tool is available for both Windows operating systems and iPads running iOS and it may be downloaded here: http://www.healthit.gov/providers-professionals/security-risk-assessment. Public comments on the SRA tool will be accepted until June 2, 2014.

A Detailed Risk Analysis Is Required for Those Running Windows XP After April 8, 2014

Microsoft recently announced that as of April 8, 2014, it will no longer provide security updates or technical support for the Windows XP operating system. According to Microsoft's announcement, "[b]usinesses that are governed by regulatory obligations such as HIPAA may find that they are no longer able to satisfy compliance requirements." However, many health care providers using Windows XP will not be instantly non-compliant as of April 8th because the HIPPA Security Rule does not specifically require the use of operating systems that are manufacturer-supported.

The U.S. Department of Health and Human Services provides the following question and answer on its website:

Does the Security Rule mandate minimum operating system requirements for the personal computer systems used by a covered entity?

Answer: No. The Security Rule was written to allow flexibility for covered entities to implement security measures that best fit their organizational needs. The Security Rule does not specify minimum requirements for personal computer operating systems, but it does mandate requirements for information systems that contain electronic protected health information (e-PHI). Therefore, as part of the information system, the security capabilities of the operating system may be used to comply with technical safeguards standards and implementation specifications such as audit controls, unique user identification, integrity, person or entity authentication, or transmission security. Additionally, any known security vulnerabilities of an operating system should be considered in the covered entity's risk analysis (e.g., does an operating system include known vulnerabilities for which a security patch is unavailable, e.g., because the operating system is no longer supported by its manufacturer).

While the HHS guidance suggests that running Windows XP without security updates will potentially make healthcare entities vulnerable to security risks, operating Windows XP past April 8 will not result in an automatic HIPAA violation so long as the covered entity engages in a detailed risk analysis which addresses the known vulnerabilities, the potential effects of such vulnerabilities, and includes a plan to address these issues. If the assessment reveals that the covered entity cannot address the risks associated with using an unsupported operating system, then the entity should consider upgrading its workstations to a new operating system.

OIG Issues Favorable Opinion Regarding the Use of "Preferred Hospital" Networks as Part of Medigap Policies

On February 12, OIG issued Advisory Opinion No. 14-02, concerning the use of preferred hospital networks as part of certain Medicare Supplemental Health Insurance (Medigap) policies offered 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 a $100 premium credit to policyholders who use a network hospital for an inpatient stay.

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.

HHS Issues Additional Guidance in Light of Supreme Court Decision on Same-Sex Marriage

In March, the Department of Health and Human Services released new guidance offering protections to same-sex couples purchasing insurance coverage, including through the Marketplaces established by the Affordable Care Act. In the guidance HHS clarified that, starting in 2015, if an insurance company offers

coverage to opposite-sex spouses, then it cannot choose to deny that coverage to same-sex spouses. Coverage for same-sex spouses must be offered regardless of the state where the couple lives, or where the policy is issued, so long as the couple is legally married.

More recently, on April 3, HHS announced that the Social Security Administration is now able to process requests for Medicare Part A and Part B Special Enrollment Periods for participants to make changes to their Medicare Advantage and Medicare prescription drug coverage, and reductions in Part B and premium Part A late-enrollment penalties for certain eligible people in same-sex marriages. According to a HHS media release, this decision was in response to the June 2013 decision of the U.S. Supreme Court in *United States v. Windsor*, which ruled that Section 3 of the Defense of Marriage Act is unconstitutional. As a result, Medicare is no longer prevented by the Act from recognizing same-sex marriages for determining entitlement to, or eligibility for, Medicare.

HHS Issues Guidance on Sharing Information Related to Mental Health

In February, the Department of Health and Human Services' Office for Civil Rights ("OCR") released guidance about the use and disclosure of mental health information. The guidance, entitled "HIPAA Privacy Rule and Sharing Information Related to Mental Health," addresses some of the more frequently asked questions about when it is appropriate under the Privacy Rule for a health care provider to share the protected health information of a patient who is being treated for a mental health condition. The guidance clarifies when HIPAA permits health care providers to:

- Communicate with a patient's family members, friends, or others involved in the patient's care;
- Communicate with family members when the patient is an adult;
- Communicate with the parent of a patient who is a minor;
- Consider the patient's capacity to agree or object to the sharing of their information;
- Involve a patient's family members, friends, or others in dealing with patient failures to adhere to medication or other therapy;
- Listen to family members about their loved ones receiving mental health treatment;
- Communicate with family members, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others; and
- Communicate to law enforcement about the release of a patient brought in for an emergency psychiatric hold.

In addition, the guidance provides relevant reminders about related issues, such as the heightened protections afforded to psychotherapy notes by the Privacy Rule, a parent's right to access the protected health information of a minor child as the child's personal representative, and the potential applicability of Federal alcohol and drug abuse confidentiality regulations or state laws that may provide more stringent protections for information than HIPAA.

HHS Prepares to Resume HIPAA Compliance Audit Program

On February 24, OCR announced its plans to conduct a pre-audit HIPAA compliance survey of 800 covered entities and 400 business associates. The purpose of this pre-audit survey is to gather information about survey respondents to enable OCR to identify candidates for audit under the OCR HIPAA Audit Program. The survey will collect information related to recent data about the number of patient visits or insured lives, use of electronic information, revenue and business locations. OCR estimates that the covered entities or business associates selected to participate in the pre-audit survey will spend 30 to 60 hours responding to the survey. HHS is accepting comments regarding the pre-audit survey until April 25, 2014.

CMS Publishes Interim Final Rule Increasing Payments to Low-Volume and Medicare Dependent Hospitals

On March 18, CMS published an interim final rule increasing Medicare payments to low-volume and Medicare-dependent hospitals under the hospital inpatient prospective payment system. Low-volume hospitals are those located 15 miles or greater from the nearest like hospital with fewer than 1,600 Medicare discharges. Medicare-Dependent Hospitals are rural hospitals with 100 or fewer beds for which Medicare Part A patients make up at least 60% of hospital inpatient days or discharges and that are not also classified as a "sole community hospital." (Critical Access Hospitals, which do not participate in the hospital inpatient prospective payment system, are not affected by this rule.)

CMS Begins Collecting Data Under the Physician Payments Sunshine Act

On February 18, CMS began the first of two phases of data collection under the Physician Payments Sunshine Act (section 6002 of the Affordable Care Act), which requires manufacturers of drugs, devices, and other medical supplies, as well as group purchasing organizations, to report data to CMS on payments or transfers of value made to health care providers, including gifts, consulting fees, and research activities. The first phase will involve the creation of online profiles and the submission of aggregate 2013 payment data. The second phase, which will begin in May, will require the submission of detailed 2013 payment data. Data submission is expected to be complete by August 1, at which point health care providers and manufacturers will be able to review the data for accuracy. CMS expects to post the data on its website by the end of September.

Federal Trade Commission Issues Policy Paper Regarding Scope of Practice for Advanced Practice Registered Nurses

On March 7, the FTC issued a policy paper urging state legislatures and policymakers considering proposed changes to the scope of practice for APRNs "to view competition and consumer safety as complementary objectives, and to integrate consideration of competition into their deliberations." The FTC pointed out that while patient health and safety remains paramount, physician supervision requirements enable "one group of health care professionals to restrict access to the market by another, competing group of health care professionals," and therefore must be viewed critically. APRNs, the FTC report noted, "play a critical role in alleviating provider shortages and in expanding access to health care services for medically underserved populations." According to the report, "[b]ased on substantial evidence and experience, expert bodies have concluded that APRNs are safe and effective as independent providers of many health care services within the scope of their training, licensure, certification, and current practice." In addition, the FTC pointed out, APRNs typically collaborate with other health care providers in a variety of ways, and requiring physician supervision is not the only means of ensuring effective collaboration.

NEW HAMPSHIRE DEVELOPMENTS

Governor Hassan Signs Medicaid Expansion Into Law

Last week, Governor Hassan signed a law expanding Medicaid in New Hampshire. The law is expected to make some 50,000 poor adults in New Hampshire eligible for federal subsidies under the Affordable Care Act. The law will rely on federal funds—some $340 million dollars per year once the program is up and running—to buy private health insurance for adults making less than 138% of the federal poverty level.

Transition to Medicaid Managed Care for Individuals with Developmental Disabilities Will Be Delayed

On April 3, New Hampshire Governor Maggie Hassan announced that the transition to Medicaid Managed Care for individuals with developmental disabilities, which was originally scheduled to take place on December 1 of this year, will be delayed. Rather, Governor Hassan said that the state needs to focus its resources on the start of expanded Medicaid rather than the transition to managed care. About 12,000 developmentally disabled individuals receive services from New Hampshire Medicaid.

Summary Legislative Update

The current legislative session is halfway over and several bills that we have been tracking have passed their respective chambers and have crossed over to the other body for another round of committee hearings and votes. Here is a brief overview of those bills:

- **SB 308, *relative to innovation in the delivery of health care***. Under the bill, entitled the Health Care Delivery Innovation Through Cooperation Act, the attorney general may issue certificates for cooperative agreements among health care providers and entities governing the sharing of personnel, facilities, and other assets. Under the proposed law, health care providers are not required to enter into cooperative agreements or to request approval of a cooperative agreement from the attorney general. However, parties to a cooperative agreement approved by the attorney general will be entitled to state action immunity under federal antitrust laws.

- **HB 1434, *allowing a mentally competent adult to make medical decisions for an adult who lacks health care decision making capacity***. This bill would allow a person's next of kin to make health care decisions without involving court action when there is no advance directive.

- **SB 340, *requiring the insurance department to hold public hearings before approval of products to be sold on the health exchange***. This bill would require the N.H. Insurance Department to hold at least two public information sessions concerning the proposed provider networks of insurance products proposed to be sold on the Health Benefits Marketplace, including information on the proposed network of hospitals and essential community providers to be made available to the public at or before the information sessions.

- **HB 1613 and SB 369, *relative to payment of the Medicaid enhancement tax***. These bills change payments of the Medicaid enhancement tax to quarterly. The bill was requested by the Medicaid enhancement tax study commission.

- **HB 597, *relative to mandatory drug testing for certain health care workers***. This bill would require health facilities to develop policies for a drug-free workplace that includes procedures for drug

testing when reasonable suspicion exists.

- **HB 658, *relative to registration for medical technicians***. This bill establishes the Board of Registration of Medical Technicians thereby requiring individuals employed as medical technicians to register with the Board.

EMPLOYMENT LAW UPDATE

FLSA Overtime Regulations Expected to Exempt Fewer Employees from Overtime in the Future

On March 13, 2014, President Obama issued a presidential memorandum on the subject of "Updating and Modernizing Overtime Regulations." This memorandum stems from the President's view that the existing overtime regulations are outdated and improperly exempt millions of Americans from the protections of overtime or the minimum wage. In particular, the President noted, existing "regulations regarding exemptions from the Act's overtime requirement, particularly for executive, administrative, and professional employees (often referred to as 'white collar' exemptions) have not kept up with our modern economy."

Accordingly, the memorandum directs the Secretary of Labor to update Fair Labor Standards Act (FLSA) regulations to "modernize and streamline the existing overtime regulations," so that the Act will continue to protect those employees that it is intended to protect. While the revision process is likely to be a lengthy one, employers should nonetheless prepare for changes and, as always, carefully analyze and classify employees as either exempt or nonexempt in accordance with FLSA requirements.

Hospital Settles Case Involving Need for Modified Work Schedule to Accommodate Employee's Disability

A Florida hospital system recently agreed to pay $215,000, in addition to other terms, in order to settle a disability discrimination suit brought by the U.S. Equal Employment Opportunity Commission (EEOC), according to an EEOC press release issued on February 21, 2014. The suit resulted from the hospital system's termination of an epileptic general practitioner after reversing its decision to provide a reasonable accommodation for her epilepsy. According to the press release, the hospital system initially agreed to provide the doctor with a reasonable accommodation, specifically by limiting her workday to eight hours. However, as set forth by the EEOC, the hospital system later reversed its decision and fired her because of her disability. The hospital system ultimately settled the matter, agreeing to pay $215,000 in back pay and compensatory damages, as well as agreeing to several nonmonetary terms, including providing specific live training in the area of disability discrimination (including for managers, human resources personnel, and recruiters), internal complaint reporting and monitoring by EEOC, and posting a public notice about the lawsuit. This substantial—and public—settlement serves as an important reminder that if a reasonable accommodation for disability can be provided without undue hardship, which may include a modified work schedule, the employer must provide it. Healthcare employers should take particular note of a statement by EEOC's Miami District director, Malcolm Medley included in the press release: "A health care facility should especially understand the importance of non-discrimination regardless of disabilities. We will combat job discrimination against people with disabilities wherever we find it, however unlikely the place where it occurs." Healthcare employers should ensure their discrimination policies and training are up to date and should consult with counsel when facing difficult reasonable accommodation requests.

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

BIOS

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