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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

Health Insurance Marketplaces Open

The individual health insurance marketplaces (also known as "exchanges") became open for business on October 1, 2013, for coverage beginning January 1, 2014. The small business health insurance marketplace was supposed to open the same day, but the opening has been delayed until November.

The day before the marketplace opened, the federal government announced that in addition to the health plans offered by Anthem Blue Cross and Blue Shield and the dental plans offered by Northeast Delta Dental, a "multistate insurance plan" pursuant to a contact between the federal government and the Blue Cross and Blue Shield Association would be available in the New Hampshire marketplace and in 29 other states. In New Hampshire, this plan is issued through Anthem and is known as "Anthem Blue Cross and Blue Shield Gold (or Silver) DirectAccess, a Multi-State Plan." Premiums on the Silver Multi-State Plan are very close to those on other Silver plans, while those on the Gold Multi-State Plan are more than those on the other Gold plans.

The October 1 opening was marred by technical glitches over the first days of operation. Far more visitors than the administration anticipated flocked to the federal exchange website, healthcare.gov, which serves New Hampshire and 33 other states. As of this writing, online access remains difficult, but it is expected that it will become easier as technical glitches are repaired and the peak of initial interest dissipates. Open enrollment runs through March 31, 2014, and individuals have until December 15, 2013, to sign up for coverage beginning January 1, 2014. The marketplace is available online at www.healthcare.gov. Individuals who need assistance in accessing the marketplace may call a federally-run call center at (800) 318-2596.

Appointments for enrollment assistance with Planned Parenthood of Northern New England, one of two navigators who received grants from the federal government to assist with enrollment in New Hampshire, can be made at ppnne.org, via email to getcoverednh@ppnne.org, or by phone at (866) 476-1321.

The monthly cost of coverage on the individual health insurance marketplace appears on the next page. These premiums, before taking income-based subsidies into account, are 25 percent lower than Anthem's previous individual offering.

For small businesses in New Hampshire, purchasing coverage through the marketplace when it becomes available next month will cost

the same as purchasing an Anthem small group plan outside the marketplace. (These plans will also pay providers at Anthem's ordinary market rates rather than at the lower Medicare-based rates paid by the individual plans.) However, the small business marketplace-based plans will use the same "narrow" network as the individual plans. Accordingly, it appears that the only small businesses for which purchasing coverage through the marketplace will be advantageous are those that want to take advantage of the small business tax credit, which is only available for plans purchased through the marketplace.

The cost of coverage purchased on the Individual Health Insurance Marketplace, based on non-tobacco rates and the 2013 federal poverty guidelines, and for family plans, assuming identically-aged adults and two children under the age of 21, is as follows:

Unsubsidized Premium Rates, Singles

Type of Plan	Deductible/Coinsurance	21 year old	40 year old	60 year old
Bronze	$5,750/10%	$177	$227	$482
Silver	$2,500/10%	$226	$288	$612
Gold	$1,000/10%	$268	$342	$727

Unsubsidized Premium Rates, Family of 4

Type of Plan	Deductible/Coinsurance	21 year olds	40 year olds	60 year olds
Bronze	$11,500/10%	$580	$679	$1,188
Silver	$5,000/10%	$738	$863	$1,511
Gold	$2,000/10%	$876	$1,025	$1,794

Subsidized Premium Rates (Tax Credit/Cost Sharing), Singles, Income $11,490 (100% FPL)

Type of Plan	Deductible/Coinsurance	21 year old	40 year old	60 year old
Bronze	$5,750/10%	$0	$0	$0
Silver	$500/0%	$18	$18	$17
Gold	$1,000/10%	$61	$72	$132

Subsidized Premium Rates (Tax Credit/Cost Sharing), Family of 4, Income $23,550 (100% FPL)

Type of Plan	Deductible/Coinsurance	21 year olds	40 year olds	60 year olds
Bronze	$11,500/10%	$0	$0	$0
Silver	$1,000/0%	$37	$36	$34
Gold	$2,000/10%	$175	$198	$317

Subsidized Premium Rates (Tax Credit), Singles, Income $34,470 (300% FPL)

Type of Plan	Deductible/Coinsurance	21 year old	40 year old	60 year old
Bronze	$5,750/10%	$177	$210	$140
Silver	$2,500/10%	$226	$272	$271
Gold	$1,000/10%	$268	$326	$385

Subsidized Premium Rates (Tax Credit), Family of 4, Income $70,650 (300% FPL)

Type of Plan	Deductible/Coinsurance	21 year olds	40 year olds	60 year olds
Bronze	$11,500/10%	$399	$372	$232
Silver	$5,000/10%	$557	$557	$554
Gold	$2,000/10%	$695	$718	$837

Employer Reporting

On September 9, the Treasury Department and IRS published proposed regulations regarding the reporting requirements for providers of minimum essential health coverage under section 6055 of the Tax Code (section 1502(a) of the Affordable Care Act). (Minimum essential health coverage is the type of coverage that an individual needs to meet the individual responsibility requirement under the Affordable Care Act.) The Affordable Care Act requires providers of coverage to report to the IRS and covered individuals information about the type and period of coverage each individual had during the calendar year.

The proposed regulations provide that for fully-insured coverage provided by an employer, reporting will be performed by the health insurance issuer rather than by the employer. On the other hand, sponsors of self-insured group health plans established or maintained by a single employer will need to report themselves. The proposed regulations also set forth rules governing reporting by self-insured group health plans or arrangements covering employees of multiple employers; typically, in such a situation, each employer must report for its own employees, but one member of a group of related corporations can assist the other members by filing returns and furnishing statements on behalf of all members.

Although reporting was originally supposed to become mandatory in 2014, the IRS announced this summer that information reporting would be optional (but encouraged) for 2014. Accordingly, the first reports will not be due until February 28, 2016 (March 31, 2016 if filed electronically) for calendar year 2015.

The IRS is considering whether employers will be permitted to combine reporting under section 6055 with reporting under section 6056 of the Tax Code (section 1514(a) of the Affordable Care Act). Section 6056 requires those employers subject to the employer mandate (generally, those with 50 or more full-time equivalent employees) to report information about the coverage that they offer to full-time employees and to furnish related statements to employees.

The IRS recently announced that that final rules on the employer shared responsibility payments under section 4980H of the Tax Code (section 1513 of the Affordable Care Act), as well as reporting rules under sections 6055 and 6056, will be finalized by early December. New guidance on transition rules under section 4980H is expected to be released in mid to late October.

Notice of Coverage to Employees

Starting October 1, 2013, the Affordable Care Act requires that employers provide employees with a notice of their coverage options. Employers are obligated to provide notice whether or not they offer a health plan. However, there is no penalty or fine for failing to provide the notice.

The Department of Labor has created model notices, available online at http://www.dol.gov/ebsa/healthreform/.

Basic Health Program

On September 20, CMS issued a proposed rule establishing eligibility and enrollment standards for the "Basic Health Program" under section 1331 of the Affordable Care Act, which gives states an option to establish a state-operated health benefits program for adults between the ages of 19 to 64 with modified adjusted gross incomes between 138% and 200% of the poverty level who don't qualify for Medicaid, any

other government provided health care program, or affordable minimum essential coverage offered by their employer. States need to opt into this plan, which serves as a sort of "bridge" between Medicaid and the health insurance marketplace. Under the proposed rule, open enrollment would take place beginning October 2014. The federal government would provide funding equal to 95% of the premium tax credits and cost sharing reductions that would otherwise have been provided to (or on behalf of) eligible people if they enrolled in a qualified health plan through the marketplace. Noncitizens (who are not eligible for Medicaid) with incomes less than 133% of the poverty level would also be eligible to enroll.

OCR Releases Guidance in Anticipation of September 23 HIPAA Omnibus Rule Compliance Deadline

Days before the September 23, 2013 compliance date for the HIPAA Omnibus Final Rule, the Department of Health and Human Services' Office for Civil Rights published several new guidance tools and documents. These are summarized below.

Model Notices of Privacy Practices (NPPs)

HHS published a number of model NPPs, for both health care providers and health plan covered entities in editable .pdf and text formats. The notices are in plain language and can be tailored to a particular entity, while also ensuring compliance with the requirements of the Privacy Rule. HHS recommends that the NPPs be published in color and booklet form, but the models come in a variety of formats. HHS also published summary documents that can be used for layered notices. While covered entities can use the NPPs to comply with the new requirements of the HIPAA Rules, providers and health plans should consider applicable state law and their particular operations.

Delay in Enforcement of NPP Requirement for Certain CLIA and CLIA-Exempt Labs

On September 19, HHS announced that it would delay enforcement of the requirement that certain HIPAA-covered laboratories revise their Notices of Privacy Practices to comply with the Omnibus Rule. The enforcement delay applies to laboratories that are certified or exempt from certification under CLIA (the Clinical Laboratories Improvement Amendments of 1988), and that are not required to provide individuals direct access to their laboratory reports. HHS issued the enforcement delay because it anticipates publishing an amendment to the HIPAA Privacy Rule and the CLIA regulations regarding the right of individuals to receive their test results directly from CLIA and CLIA-exempt labs. The delay will relieve CLIA and CLIA-exempt labs of the possible burden and expense of having to revise their NPPs twice in a short period of time. OCR will issue a notice at least 30 days in advance to advise the public when the enforcement day will end. The enforcement delay does not apply to laboratories that do not have their own laboratory-specific NPPs, such as laboratories that are part of a hospital.

Guidance on Decedents and Student Immunizations

On September 19, OCR released guidance regarding decedents and student immunizations. In addition to the guidance, OCR published FAQs addressing both topics.
First, the Omnibus Rule made two changes affecting deceased persons. One was to allow covered entities to disclose health information to family members and others involved in an individual's care, protected health information that is relevant to that involvement. The other was to lift the HIPAA protection on health information altogether 50 years following the death of the individual. HHS states that this is intended to balance the privacy interests of surviving relatives with the need for others to access old records for historical purposes. The guidance also summarizes the existing privacy exceptions that apply only to deceased persons, such as providing information to coroners, funeral directors and organ procurement agencies.

In addition, covered entities may now disclose proof of student immunizations directly to a school that is required by state or other law to have proof of required immunizations before admitting the student. Health care providers are not required to obtain a formal written consent or authorization in order to release immunization records, but must have agreement from a parent, guardian or the emancipated minor to make the disclosure and the agreement must be documented. HHS notes that this disclosure is permitted in the interest of public health and safety, as schools play an important role in preventing the spread of communicable diseases among students. The new guidance and FAQs address what documentation is suitable and other issues that may arise.

Clarification on Prescription Drug Refill Reminder Programs

Also on September 19, OCR published guidance on when refill reminders and other communications about drugs currently being prescribed for an individual do not constitute "marketing," and thus do not require prior patient authorization under the Privacy Rule. The guidance sets forth a two-part test in determining whether a communication falls within the refill reminder exception. The first is whether the communication is about a "currently prescribed drug or biologic." That means refill reminders, communications about generic equivalents of a prescribed drug, communications about a recently lapsed prescription, and adherence communications encouraging individuals to take prescribed medicines as directed would fall within the exception. The second part is whether the communication involves financial remuneration to the entity issuing the reminder, and if it does, whether the financial remuneration is "reasonably related to the covered entity's cost of making the communication." If a covered entity receives payment, the payment must be limited to the reasonable direct or indirect costs related to the labor, materials, supply, and capital and overhead costs of making the communication. If a business associate receives payment, the payment is limited to the fair market value of its services in making the communication. Communications for which a covered entity received remuneration that do not fall within the exception require a patient's written authorization. HHS will not enforce the restrictions on remunerated refill reminders and other communications until November 7, 2013.

A Guide for Law Enforcement

On September 20, OCR announced the released of its guidance, "Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement." The guide is designed to assist law enforcement agencies and emergency planners when addressing information-sharing situations where the HIPAA Privacy Rule may be at issue. The guide describes the Privacy Rule and identifies entities that must comply with tis requirements. The guide also outlines the manner in which the Privacy Rule allows the disclosure of protected health information in common situations involving law enforcement, such as making a report to prevent or lessen a serious and imminent threat to the health or safety of an individual or the public.

Federal Government Shutdown Persists

On October 1, the federal government began a new fiscal year without spending authority in place, and was forced to shut down most programs except those that do not rely on annual appropriations or involve the safety of human life or the protection of property. Many federal employers were furloughed, and many others are working without pay. The shutdown will last until Congress passes, and the President signs, legislation funding government operations.

Of particular interest to health care providers, the U.S. Department of Health and Services (HHS) has furloughed 52% of its employees. Grant-making and employee-intensive agencies have furloughed the vast majority of their staff, while agencies with a substantial direct component have retained most of

their staff. Programs of significance to providers that are continuing include:

- Medicare, at least for the short-term, but disruptions in Medicare claims processing could occur if the shutdown persists;
- Medicaid and the Children's Health Insurance Program;
- CMS activities implementing the Affordable Care Act, including coordination between Medicaid and the Marketplace;
- Exchanges under the Affordable Care Act, though the shutdown could have harmful effects if it persists;
- National Institutes of Health patient care for current patients;
- HRSA funding for Community Health Centers and the National Practitioner Databanks; and
- Phone helplines run by the Substance Abuse and Mental Health Services Administration, at least until grants run out.

Operations that are being significantly curtailed include:

- Centers for Disease Control, including much infectious disease surveillance and outbreak detection, and support for the seasonal influenza program. CDC will have a significantly reduced capacity to respond to emergencies and outbreaks;
- Food and Drug Administration food safety, nutrition, and cosmetics activities, except for select vital activities;
- Social services grants to states, including grants that fund Temporary Assistance for Needy Families, Child Care, Social Services Block Grant, Refugee Programs, Child Welfare Services, and the Community Service Block Grant Programs;
- Administration for Community Living programs designed to prevent elder abuse and neglect and residents of long-term care facilities or those with developmental disabilities;
- CMS fraud and abuse strike teams;
- CMS provider recertification and initial surveys, which will be significantly scaled back;
- Admission of new patients to the National Institutes of Health, actions on grant applications or awards, or the release of new funding; and
- Publication of regulations or sub-regulatory guidance, unless related to "imminent threats to the safety of human life or protection of property."

Stage 2 Meaningful Use Guide Published

Recently, CMS published "An Eligible Professional's Guide" to the Stage 2 Meaningful Use criteria for the Electronic Health Record (EHR) incentive programs. The guide may be accessed online at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2_Guide_EPs_9_23_13.pdf

The Stage 2 criteria will go into effect in 2014 for those providers who demonstrated meaningful use in 2011, 2012, and 2013, or in 2012 and 2013. Other providers will need to meet two years of meaningful use under the stage 1 criteria before advancing to the stage 2 criteria in their third year.

In 2013 and years after 2014, providers must demonstrate meaningful use for a 90-day EHR reporting period in their first year of participation, and for a full calendar year reporting period in subsequent years. For 2014 only, all providers, regardless of their stage of meaningful use, are only required to demonstrate meaningful use for a 3-month EHR reporting period. For Medicare providers, this period is fixed to the quarter of the calendar year to align with the Physician Quality Reporting System.

CMS Gives Hospitals Three Months to Comply with New Inpatient Review Policy

On September 26, CMS announced during its Open Door Forum that, for a period of 90 days, it would delay enforcement of the agency's "Admission and Medical Review Criteria for Hospital Inpatient Services" provision (known as the "2-Midnight Rule) that was finalized as part of the FY14 Inpatient Prospective System rule. Under the 2-Midnight Rule, inpatient admissions must cross at least two midnights to qualify for reimbursement. In an effort to provide guidance and education to hospitals about the new 2-Midnight Rule, CMS will instruct the Medicare Administrative Contractors (MACs) to review a sample of 10-25 inpatient claims per hospital, spanning less than two midnights after admission with dates of admission between October 1, 2013 and December 31, 2013. These reviews will determine whether the medical necessity of the patient status complied with the 2-Midnight Rule. If the MAC identifies issues from its review of a hospital's inpatient admission claims, the MAC will conduct education for that hospital, as well as any additional follow up.

Federally Qualified Health Center Prospective Payment System To Be Implemented

On September 20, CMS issued a proposed rule that would establish methodology and payment rates for a Medicare prospective payment system (PPS) for federally qualified health center (FQHC) services (including FQHC "look-alikes" enrolled in Medicare as FQHCs) under Medicare Part B. The system would go into effect beginning October 1, 2014, and FQHCs would transition into the PPS based on their cost reporting periods beginning on or after that date.

CMS proposes to establish a national, encounter-based rate for all FQHCs, for professional services furnished per beneficiary per day. The rate would be calculated based on an average cost per visit using Medicare cost report and claims data. CMS asserts that using an encounter-based payment rate will give FQHCs the flexibility to implement efficiencies to reduce over-utilization of services, and would be similar to the payment system already in effect for services furnished to Medicaid recipients. The rate would be adjusted for geographic differences in a similar manner to adjustments performed under the Medicare Physician Fee Schedule. The rate would also be adjusted when a FQHC furnishes care to a patient for the first time or to a patient receiving a "Welcome to Medicare" visit. Payment exceptions that currently allow FQHCs to bill for multiple visits on one day in limited circumstances would be eliminated, but CMS is seeking comments (due November 18) on whether this will have an adverse impact on beneficiaries' access to services, particularly mental health services. Coinsurance would be 20 percent of the lesser of the actual charge or the PPS rate, except for eligible preventive services, for which coinsurance would continue to be waived. A proportional amount of coinsurance will be waived for claims that include a mix of preventive and non-preventive services. Medicare beneficiaries receiving services at a FQHC are not subject to the annual Medicare deductible.

The proposed FQHC PPS is estimated to have an overall impact of increasing total Medicare payments to FQHCs by approximately 30%.

CMS Issues Final and Interim Final Medicare DSH Rule

On September 18, CMS published a final rule implementing reductions required by the Affordable Care Act for the disproportionate share hospital (DSH) program. The ACA required a cut in federal DSH funding based on an expected reduction in uncompensated care costs resulting from expansion of coverage through increased access to health insurance through Health Insurance Exchanges and the expansion of Medicaid. The final rule sets forth the methodology to implement the annual reductions for fiscal years 2014 and 2015, and it includes additional DSH reporting requirements for use in implementing

the DSH health reform methodology. However, because some states have elected not to expand their Medicaid programs, CMS noted that they intend to account for the different circumstances among states in the DSH funding formula in future rulemaking, when additional data is available. However, for fiscal years 2014 and 2015, the DSH funding formula does not account for differential Medicaid coverage expansions.

Then, on October 1, CMS released an interim final rule that modifies the process for how DSH payments will be made for DSH-eligible hospitals with cost-reporting periods that span more than one federal fiscal year. According to the rule, CMS will align final Medicare DSH payments with each individual hospital's cost reporting period instead of issuing payments only on the government's fiscal year. In the interim final rule, CMS also changed the data to be used in the uncompensated care payment calculation to ensure that Indian Health Service hospitals are included in certain factors of the calculation. CMS will accept comments on the interim final rule through November 29, 2013.

NEW HAMPSHIRE DEVELOPMENTS

Medicaid Expansion Update

As explained in the September Update, the New Hampshire Commission to Study the Expansion of Medicaid Eligibility continues to meet and faces an October 15 deadline to issue its recommendations. On October 2, the nine-member commission met to debate a plan proposed by Representative Tom Sherman. The commission unanimously endorsed the principle that New Hampshire residents, ages 19 to 64, with income up to 138 percent of the federal poverty level, would be covered. In addition, under Sherman's plan, the state would expand the existing Health Insurance Premium Program to pay premiums for employer-provided health insurance when it is available. The plan would also give residents the option of buying insurance on their own, including the plans available on the new marketplace. If the federal government fails to fund the expansion's costs, the Legislature would have six months to reauthorize the expanded program before it would end automatically. The commission meets again on October 8 to discuss Sherman's proposal.

Legislative Update

At the end of the legislative session that ended in June, several bills impacting health care were retained in various committees. Those committees will make recommendations at the beginning of the next legislative session in January 2014 as to whether those bills should be recommended for future legislation. Some of these have been discussed in prior Legal Updates. Here is a list of bills we will watch:

Executive Departments of Administration

HB 326, *relative to licensure of polysomnographers by the board of respiratory care practitioners.* This bill requires persons practicing polysomnography to be licensed by the board of respiratory care practitioners.

HB 469, *relative to time limits for regulatory boards and commissions to hold disciplinary proceedings.* This bill provides that occupational and professional boards will lose jurisdiction over a disciplinary matter when statutory time limits for holding hearings on disciplinary actions are not met.

HB 658, *relative to registration for medical technicians.* This bill establishes the medical technician registration board. This bill requires persons employed as medical technicians who are not licensed or certified in this state to register with the board within 5 days of receiving employment in New Hampshire. The bill also requires licensed health care facilities employing such technicians to ensure that they are registered in accordance with this chapter. The Executive Departments and Administration Committee will make a recommendation at the start of next season whether the bill should be recommended for future legislation.

Health, Human Services and Elderly Affairs

HB 329, *requiring purchasers of medical equipment to be notified of the actual cost of such equipment at the time of sale.* This bill requires the provider of medical equipment to disclose to the consumer, in writing, the total charge of the medical equipment at the time of sale.

HB 476, *relative to medical care price disclosure and transparency.* This will requires health care professionals and health care facilities to provide the expected direct care price for medical services upon the request of an uninsured patient or a prospective patient.

HB 584, *relative to covered prescription drugs.* This bill requires insurers to allow covered persons to purchase their 90-day supply of covered prescription drugs at the pharmacy of their choice.

HB 597, ***relative to mandatory drug testing for certain health care workers.*** This bill requires the commissioner of the department of health and human services to establish a program requiring facilities licensed under RSA 151 to perform mandatory drug testing on health care workers employed in such facilities.

Criminal Justice and Public Safety

HB 217, *imposing an extended term of imprisonment for assault against a health care provider.*

Judiciary

HB 582, *repealing early offers for medical injury claims.* This bill repeals a system of early offers for medical injury claims as an alternative to litigation or screening panels under RSA 519-B.

HB 583, *relative to proceedings of medical injury claims screening panels*. This bill modifies procedures for screening panels for medical injury claims.

Labor, Industrial and Rehabilitative Services

HB 255, *relative to the workers' compensation law*. This bill makes certain changes in the workers' compensation law, including allowing an employer or the employer's insurance carrier or self-insurer to select a health care provider during the first 10 days of an employee's injury; requiring pharmacies to substitute generic drugs unless the prescribing physician indicates that the

brand name drug is medically necessary; establishing a three-year pilot program in certain counties for a 90-day preferred provider network; and allowing an employer or employer's insurance carrier or self-insurer to provide a pharmacy benefits management program.

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

BIOS

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