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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 UPDATES

Affordable Care Act Implementation

Data Indicates 2.5 Million May Qualify for Marketplace Tax Credits

On October 4, the U.S. Department of Health and Human Services (DHHS) said in a press release that roughly 2.5 million individuals who currently do not purchase individual coverage on the Affordable Care Act (ACA) Marketplace may qualify for 2017 tax credits if they purchase coverage through the Marketplace. This represents a total of 36% of all off-Marketplace insurance consumers, with 1.1 million of the 2.5 million consumers having incomes below 250% of the Federal poverty level. The press release cited a recent Commonwealth Fund survey which found that only 52% of uninsured adults were aware that financial assistance was available to them through the Marketplace and thus DHHS intends to make sure consumers are informed of their options during the Open Enrollment period.

ACA Section 1557 Nondiscrimination Compliance Deadline

On May 18, the U.S. Department of Health and Human Services (HHS) issued its final rule concerning the Affordable Care Act (ACA) Section 1557 nondiscrimination policies, which prohibit discrimination by covered health programs on the basis of race, color, national origin, sex, age, and disability. Although the final rule became effective on July 18, the nondiscrimination notification requirements under the rule take effect on October 17.

The notification requirements provide that covered health care providers and payers must provide the following types of nondiscrimination communications to patients, insureds, and members of the public:

(1) Posting nondiscrimination notices in "significant publications and significant communications", in conspicuous physical locations where the entity interacts with the public, and in a conspicuous location on the entity's website. Among other requirements, nondiscrimination notices must contain a statement that the entity does not discriminate on the basis of race, color, national origin, sex, age, or disability; that it provides auxiliary aids and services; that it provides specified language assistance services; identification of, and contact information for, the designated Civil Rights Coordinator of the entity; and a statement of how to file a grievance with the entity and a discrimination complaint with the HHS Office for Civil Rights (OCR). A sample notice is provided in the appendices of the final rule.

(2) Posting nondiscrimination statements for "small-sized" significant publications and significant communications (postcards or tri-fold brochures, for example). Nondiscrimination statements must only contain a statement that the entity does not discriminate on the basis of race, color, national origin, sex, age, or disability and are not

required to contain the additional elements included in the nondiscrimination notices.

(3) Using taglines for both nondiscrimination notices and nondiscrimination statements, which are statements that alert non-English language speakers to the availability of language assistance services. For nondiscrimination notices, the taglines must be translated into the top 15 non-English languages spoken in the state in which an entity operates, in each of the language's native script. For nondiscrimination statements, taglines in the top two non-English languages spoken in the state must be included.

You can find the specific requirements of the nondiscrimination notices for the October 17 deadline in the final rule:

https://www.federalregister.gov/documents/2016/05/18/2016-11458/nondiscrimination-in-health-programs-and-activities

Other Federal Developments

OIG Says $744 Million Recovered in FY 2015 Medicaid Fraud Recovery Efforts

In a September 14 report, the U.S. Department of Health and Human Services Office of Inspector General (OIG) announced that $744 million in criminal and civil recoveries were reported by Medicaid Fraud Control Units (MFCUs) in FY 2015. OIG noted that expenditures on MFCUs totaled $251 million in FY 2015, yielding a $3 recovery average for every dollar spent of the total recoveries. $394 million was from civil recoveries and $350 million from criminal recoveries. OIG also noted that Texas accounted for over a quarter of the recoveries, totaling $210 million of the $744 million recovered. MFCUs reported 1,553 convictions in FY 2015, 235 more than reported in FY 2014 and the highest number of convictions in the last 5 years.

The report stated that 31% of the reported convictions were of personal care services attendants, 11% were of nurse aides, and another 11% were of licensed nurses, physician assistants, or nurse practitioners. 71% of all convictions involved fraud and 29% involved abuse or neglect. Drug diversion cases accounted for 8% of convictions.

OIG Issues MFCU Proposed Rule

On September 20, the U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) issued a proposed rule concerning updates to Medicaid Fraud Control Unit (MFCU) regulations. OIG proposed raising the Federal matching funds for MFCUs from 50% to 75% and also proposed giving MFCUs the discretionary option to investigate and prosecute patient abuse and neglect, even when the organization does not receive Medicaid payments. The rule would also require MFCUs to submit all convictions to OIG within 30 days of sentencing for program exclusion purposes. Furthermore, MFCUs will be required to report issues they do not have the authority or capability to pursue to the Federal government, and will be required to refer overpayment collections to state Medicaid programs when they opt not to pursue the collections themselves. The rule also expands the definition of fraud to civil matters, authorizing MFCUs to investigate them as well as criminal matters. The rule also includes certain staffing requirements, such as requiring MFCUs to employ directors, prohibiting MFCUs from outsourcing investigations, and requiring MFCUs to train professional employees on Medicaid fraud and abuse. Comments on the rule are due on November 21.

DHHS Issues Clinical Trial Information Final Rule

On September 21, the U.S. Department of Health and Human Services issued a final rule that

enhances clinical trial transparency by making the results of clinical trials more readily available to the public on ClinicalTrials.gov. The rule implements the Food and Drug Administration (FDA) Act of 2007 and details the new requirements for registering and submitting trial results with the FDA. Under the rule, clinical trials must be registered no later than 21 days after the first participant is enrolled. Registration will require descriptive, recruitment, location, contact, and administrative information to be disclosed to the FDA. The rule also requires summary data concerning key outcomes and adverse events to be submitted within one year of a clinical trial's completion, regardless of FDA end-product approval. The rule does not apply to phase 1 clinical trials of drugs and biological products or feasibility studies of device products. The rule is effective January 18, 2017, with a 90-day compliance window.

OCR Announces $400k Business Associate Agreement Settlement

On September 23, the U.S. Department of Health and Human Services (DHHS) Office for Civil Rights (OCR) announced that it had reached a settlement agreement with Care New England Health System (CNE) concerning potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. CNE will pay OCR $400,000 and enter into a comprehensive corrective action plan after an investigation into a data breach incident at one of CNE's client hospitals revealed that protected health information had been disclosed to CNE from the hospital under a business associate agreement that had not been updated to include requirements of the HIPAA Omnibus Final Rule.

ONC Issues EHR Contract Negotiation Guide and Health IT Playbook

On September 26, the U.S. Department of Health and Human Services (DHHS) Office of the National Coordinator for Health Information Technology (ONC) issued a guide to help providers through the process of acquiring an electronic health records (EHR) system. The guide, *EHR Contracts Untangled: Selecting Wisely, Negotiating Terms, and Understanding the Fine Print,* covers a wide variety of issues applicable to contracting with vendors, such as safety and security requirements, system performance, data rights, interoperability and integration, intellectual property, risk management, dispute resolution provisions, and changing EHR systems if necessary. The guide includes examples of contract language, and identifies terms and conditions that providers might want to include or avoid. At the same time, ONC also released a new *Health IT Playbook*, which is a web-based tool to help healthcare providers find information on specific topics pertinent to EHR.

DHHS Issues Opioid Treatment Medication Reporting Final Rule

On September 27, the U.S. Department of Health and Human Services (DHHS) issued a final rule concerning prescriber reporting requirements for qualified physicians who prescribe buprenorphine to treat opioid use disorder. The final rule, effective October 27, requires qualified physicians to provide annual patient caseload information reports by month to the Substance Abuse and Mental Health Services Administration (SAMHSA). That information includes monthly caseload, number of patients provided or referred to behavioral health services, and features of the practitioner's diversion control plan.

You can find the final rule here:

https://www.gpo.gov/fdsys/pkg/FR-2016-09-27/pdf/2016-23277.pdf#sthash.xH8KpLL9.dpuf

New CMS Rule Prohibits Arbitration Clauses in Contracts with Nursing Homes

On September 28, the Centers for Medicare and Medicaid Services (CMS) released a new rule that in part, prohibits nursing homes from including pre-dispute binding arbitration clauses in contracts with their residents or residents' representatives. According to the CMS press release, the rule affects approximately

15,000 long-term care (LTC) facilities and over 1.5 million nursing home residents across the country and is the first comprehensive update to the conditions of participation for LTCs in the Medicare and Medicaid programs since 1991. The purpose behind the prohibition of arbitration clauses was a recognition of the difference in bargaining power between residents and LTC facilities that come at a time in a resident's life that is often entering this type of facility for the first time and may have physical or mental impairments. According to CMS, "[G]iven the unique circumstances of LTC facilities, we have concluded that it is unconscionable for LTC facilities to demand, as a condition of admission, that residents or their representatives sign a pre-dispute agreement for binding arbitration that covers any type of disputes between the parties for the duration of the resident's entire stay, which could be for many years." The rule becomes effective on November 28, 2016.

The final rule may be found here:

https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities

OIG Issues Advisory Opinion on Manufacturer-Provided Discounts for Excluded Drugs

On June 27, 2016, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) published Advisory Opinion 16-07 regarding whether a drug manufacturer's issuance of a savings card for a drug excluded from coverage under Medicare Part D violates the Federal anti-kickback statute. Under the proposed arrangement, the manufacturer would provide savings cards to patients who are prescribed a particular erectile dysfunction medication that is excluded from coverage under Medicare Part D. The savings cards provide discounts to defray part of the out-of-pocket cost that the patients incur. OIG concluded that the arrangement would not violate the anti-kickback statute for two main reasons: (1) although the discount is likely to induce the purchase of the excluded drug, the manufacturer has mechanisms in place to prevent Federal reimbursement for any of the purchases of the drug, and in any event the drug is excluded from payment; and (2) the risk that Medicare beneficiaries will be induced to purchase other federally payable products manufactured, marketed, or distributed by the manufacturer is low, because the manufacturer certified that it will not use the arrangement as a vehicle to market its other products to Federal health care program beneficiaries.

You can read the opinion in its entirety on the OIG website:

https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-07.pdf

OIG Issues Advisory Opinion on Room & Board Payments Made by Hospice Providers to Nursing Facilities on Behalf of Dually-Eligible Hospice Patients

On July 27, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) published Advisory Opinion 16-08 regarding whether a hospice provider's payment to a nursing facility for the room and board of a dually-eligible hospice patient violates the Federal anti-kickback statute. Medicare provides a hospice benefit, but not a nursing facility benefit. However, state Medicaid programs are required to provide a nursing facility benefit. Accordingly, for dually-eligible hospice patients, hospice providers are reimbursed for hospice care through Medicare and nursing facilities are reimbursed for room and board through Medicaid. Under the proposed arrangement, managed care organizations (MCOs) participating in a state demonstration program provide the payments to nursing facilities under the state's Medicaid program, however because the payment for a dually-eligible hospice patient may only be 95% of the amount normally paid to nursing facilities, the hospice provider proposes providing a payment equal to

the remaining 5% in order to remove any disincentive for nursing facilities to accept dually-eligible hospice patients. OIG concluded that this arrangement would not violate the Federal anti-kickback statute or the guidelines provided in the OIG's 1998 Special Fraud Alert, because the supplemental payment would never result in a nursing facility receiving more for a dually-eligible hospice patient than it would for a patient not receiving hospice care.

You can read the opinion in its entirety on the OIG website:

https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-08.pdf

OIG Issues Advisory Opinion on Vaccine Storage System in Physician Offices

On September 23, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) published Advisory Opinion 16-09 regarding a proposal whereby a manufacturer of a vaccine storage system would provide free storage units to health care providers. Under the proposed arrangement, the manufacturer of the storage unit would provide the units to providers free of charge, so long as they agree to stock at least one vaccine made by a vaccine manufacturer participating in an agreement with the storage unit manufacturer. The vaccine manufacturers would pay a fee to the storage unit manufacturer for each unit of their vaccines that the participating providers administer from inventory stored within the storage unit. OIG concluded that the proposed arrangement is potentially problematic, because it would enable vaccine manufacturers to provide use of a valuable item – the storage unit – that will facilitate, and thus encourage, the use of its products by referral sources, the providers. However, OIG concluded that the arrangement would not violate the anti-kickback statute for a number of reasons, including because the arrangement only requires providers to stock one vaccine from a participating vaccine manufacturer, leaving providers to stock any other vaccines they wish, and because the per-dispense fee would go to the storage unit manufacturer, which would not be the party in a position to generate Federal health care program business. OIG also noted that such an arrangement might advance the Centers for Disease Control and Prevention's stated goal of increasing adult vaccination rates.

You can read the opinion in its entirety on the OIG website:

https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-09.pdf

OIG Issues Advisory on PCS Fraud and Patient Harm

On October 3, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued an investigative advisory warning the Centers for Medicare and Medicaid Services (CMS) that personal care services (PCS) programs are vulnerable to significant fraud, compliance, and patient harm issues. In *Medicaid Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement*, OIG recommended that CMS establish minimum Federal qualifications and screening standards for PCS workers (such as criminal background checks); require that states enroll or register all PCS attendants; require that all PCS claims identify dates of service and the PCS attendant who performed the service; and that CMS consider whether additional controls are needed to make sure that PCS is allowed under program rules and are actually being provided. OIG formulated these recommendations based on significant issues OIG continues to encounter since it released a Portfolio report in 2012 with similar concern about fraud and patient harm issues in PCS programs. OIG noted that since its 2012 Portfolio report, it has opened more than 200 federal criminal investigations in the PCS program.

CMS Announces Refinements in Medicare Advantage Value-Based Insurance Design Model

On October 3, the Centers for Medicare and Medicaid Services (CMS) announced changes to the Medicare Advantage (MA) Value-Based Insurance Design (VBID) model, slated to begin on January 1, 2017. The VBID model aims to structure enrollee cost sharing and other health plan elements to encourage enrollees to use high-value services have the greatest positive health impacts. In the first year, CMS will test the model in Arizona, Indiana, Iowa, Massachusetts, Oregon, Pennsylvania, and Tennessee, which were selected because they are generally representative of the national MA market. CMS announced it will add Alabama, Michigan, and Texas to the model in the second year, beginning January 1, 2018. CMS also announced that in the second year of the VBID it will open the model to new applicants; add rheumatoid arthritis and dementia to the clinical categories; make adjustments to existing clinical categories; and change the minimum enrollment size for some Medicare Advantage and Medicare Advantage Part D plan participants.

OIG Advises CMS on Medicare Claims Forms

In a September 30 memorandum, the U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) advised the Centers for Medicare and Medicaid Services (CMS) that it should include medical device-specific information on Medicare claims data forms. OIG found that without the specific data, CMS is unable to accurately track Medicare's total costs related to replacement of recalled or defective devices. OIG was prompted to advise CMS of this issue after it attempted to determine the total expenditures Medicare incurred on faulty or defective device replacement and found that CMS currently does not ask for device-specific information on its Medicare claims data forms. OIG recommended that CMS collaborate with the Accredited Standards Committee X12 to include the device identifier (DI) portion of the Unique Device Identifier (UDI) for implantable devices on the next version of the claim forms.

New Overtime Rules Effective December 1, 2016

Please see the attached summary of the new overtime rules under the Fair Labor Standards Act that go into effect on December 1, 2016.

STATE DEVELOPMENTS

NHDOT Receives Medicaid Assistance Grant

The U.S. Department of Transportation awarded the NH Department of Transportation (NHDOT) $182,900 to improve the system for Medicaid enrollees to get rides to doctor appointments. The Rides to Wellness grant will go to NHDOT's Bridge to Integration Project, which aims to help Medicaid enrollees, individuals with disabilities, and older individuals get to their healthcare appointments. In total, 16 states received a total of $7.3 million in grants.

Tufts Health Freedom Plan and Northeast Delta Dental Partnership Announced

On September 19 Tufts Health Freedom Plan and Northeast Delta Dental announced a partnership that is intended to recognize the link between oral health and overall health. Through this partnership, the Plans will provide additional preventative dental care to individuals who are at risk for dental disease that can exacerbate chronic conditions such as diabetes and heart disease. Employers enrolling in both Plans will receive premium discounts.

New Hampshire Selected to Continue Patient Safety Efforts Through Hospital Improvement Innovation Networks

As part of the American Hospital Association Health Research & Education Trust Hospital

Engagement Network, New Hampshire's Partnership for Patients initiative will receive an award to continue its efforts to improve patient safety though a contract with the Hospital Improvement Innovation Networks. The 16 organizations selected to receive the awards will work towards achieving a 20 percent decrease in patient harm and a 12 percent reduction in 30-day hospital readmissions. CMS will monitor the progress of the organization's activities to ensure they are demonstrating results and improving patient safety.

NH Board of Medicine Sanctions Two Physicians

The Board of Medicine took disciplinary action against two physicians in September. In one case the Board found that a patient's presentation of a urinary obstruction with hydronephrosis of a solitary kidney should have been treated as a urologic emergency warranting admission and that the failure to promptly place a stent resulted in acute renal failure. In the other, a physician who had a prior settlement agreement with the Board for an incident of gross negligence failed to properly diagnose a patient presenting with symptoms of Lyme disease. In both cases, the Board cited a violation of RSA 329:17, VI (c). This statute permits the Board to take disciplinary action in cases where the Board finds the physician "has displayed medical practice which is incompatible with the basic knowledge and competence expected of persons licensed to practice medicine or any particular aspect or specialty thereof." The Board did not make a specific finding that the physicians violation RSA 329:17(d) which permits the Board to take disciplinary action when a physician has "been grossly or repeatedly negligent. " These cases raise questions about exactly what level of negligence will subject a physician to disciplinary action and whether a single act of ordinary negligence (rather than gross or repeated negligence) is sufficient.

Open Enrollment for the NH Premium Assistance Program Starts November 1, 2016.

Open enrolment for those in the NH Premium Assistance Program runs from November 1 through December 15 at 4pm. There are five Qualified Health Plans for participants to choose from including Ambetter Balanced Care 8 (NH Healthy Families), Anthem Silver Pathway X Enhanced HMO (Anthem BlueCross Blue Shield), ElevateHealth Silver HMO (Harvard Pilgrim), NH Network Silver HMO Premium (Harvard Pilgrim) and MyDoc HMO Silver Assistance A (Minuteman Health). As previously reported, Maine Community Health Options announced it will no longer be offering a plan in New Hampshire after this year and, accordingly, those enrolled in that plan will have to choose among the remaining 5 plans.

New Leadership at the NH Bureau of Developmental Services

On September 14, Commissioner Jeffrey Meyers announced the appointment of Christine Santaniello to serve as Director of the Bureau of Developmental Services and the appointment of Sandy Hunt to serve as Deputy Director. Ms. Santaniello has worked in the developmental services system for more than 25 years serving for the past 10 years as the leader of Lakes Region Community Services. Ms. Hunt served on the Senior Management team of Life Share Management Group for 15 years before joining DHHS as the Interim Director of BDS in June 2015.

2016 Legislative Updates

NH Legislators Begin Submitting Bills for the 2017 Session

The NH House began accepting Legislative Service Requests from incumbent legislators on September 12, 2016. Of the 129 LSRs filed thus far, the following are related to health care. We will continue to update this list as new bills are submitted. At this point, only the brief description is available with the full text of the bills to follow at a later date.

2017-0007: relative to involuntary administration of medication to inmates with mental illnesses.

2017-0027: repealing the prospective repeal of the New Hampshire health protection program.

2017-0071: permitting qualifying patients to cultivate cannabis for their own therapeutic use.

2017-0115: adding opioid addiction to qualifying medical conditions under therapeutic use of cannabis.

2017-0116: adding fibromyalgia to qualifying medical conditions under therapeutic use of cannabis.

2017-0117: adding post-traumatic stress disorder to qualifying medical conditions under therapeutic use of cannabis.

2017-0118: relative to the definition of "qualifying medical condition" for the therapeutic use of marijuana.

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Cinde Warmington, Kara J. Dowal, S. Amy Spencer and Alexander W. Campbell contributed to this month's Legal Update.

BIOS

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The Fair Labor Standards Act: New Overtime Rules

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What is the Overtime Rule?
Unless specifically exempted, employees covered by the Fair Labor Standards Act (FLSA) must receive pay for hours worked in excess of 40 in a workweek at a rate not less than one and one-half their regular rates of pay. This is referred to as "overtime" pay.

What has changed?
As of December 1, 2016, the new rules **increase the standard salary level from $455 per week ($23,660 for a full-year worker) to $913 per week ($47,476 for a full-year worker)**

Do the changes affect my business?

- Generally, employees of enterprises that have an annual gross volume of sales made or business done of $500,000 or more are covered by FLSA. In addition, employees of certain entities are covered by the FLSA regardless of the amount of gross volume of sales or business done.
- Those entities include: hospitals; businesses providing medical or nursing care for residents; schools (whether operated for profit or not for profit); and public agencies.

Are your employees exempt? Exempt employees are generally:

- Salaried
- Paid more than a specified weekly salary level, which will be $913 per week as of December 1
- Primarily perform executive, administrative, or professional duties, as defined by the standard duties test

What are my options for responding to changes in the salary level?

- Review employee salaries and employment classifications
- Review timekeeping procedures and trainings
- Raise salaries
- Pay overtime
- Adjust work hours and schedules
- Adjust wages

Resource: https://www.dol.gov/featured/overtime Comprehensive website of the U.S. Department of Labor

For 35 years, Shaheen & Gordon, P.A. has earned a reputation of excellence for its exceptional legal services. With more than 40 lawyers handling cases in all practice areas, our firm is known for putting the needs of our clients first. Shaheen & Gordon, P.A. serves the personal and business needs of clients throughout Northern New England from office locations in Manchester, Dover, and Concord, NH and Saco, ME.