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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

Open Enrollment Marketplace Plan Selections Surpass Last Year

On November 30, 2016, the Centers for Medicare & Medicaid Services (CMS) released their Biweekly Enrollment Snapshot. The snapshot includes national and state-by-state Open Enrollment data providing point-in-time estimates of bi-weekly plan selections, call center activity, and visits to the open enrollment websites. More than 2.1 million people have visited the HealthCare.gov platform to select their health insurance plans in the first four weeks—an 8% increase over last year at this time. More than 500,000 were new customers and 1.6 million were renewals; New Hampshire has enrolled over 10,000 Marketplace participants. Additional detailed reports will be available later in the Open Enrollment period. Open enrollment ends on December 15, 2016 for coverage starting January 1, 2017.

New Rule for Exchanges, Medicaid, and CHIP Eligibility and Appeals Effective January 20th

On November 30, 2016, the Centers for Medicare & Medicaid Services (CMS) published a final rule that implements provisions of the Affordable Care Act (ACA) that improve state coordination of Medicaid and the Children's Health Insurance Program (CHIP) eligibility, appeals, and enrollment. This rule finalizes the remaining provisions of CMS's January 22, 2013 proposed rule that were not finalized in the July 15, 2013 final rule. The rule requires states to develop systems and establish procedures that help consumers determine eligibility for Medicaid or for a tax credit to purchase insurance through the exchanges, receive coordinated communication on eligibility determinations, and allow applicants and beneficiaries to easily submit a fair hearing request. The final rule goes into effect on January 20, 2017.

The final rule does not address all the points introduced in the original proposed rule. Specifically, it does not finalize a definition for "lawfully present," as that term is used in determining participant eligibility, or clarify provisions on the state's options to cover lawfully residing children and pregnant women in Medicaid and CHIP under Section 214 of the CHIP Reauthorization Act. Nor does it finalize the provision relating to benefits for those individuals who are non-citizens.

CMS issued a complementary proposed rule "to promote modernization and coordination of Medicaid appeals processes" with other ACA programs by requiring states to make all modalities available effective six months "from the date of a Federal Register notice alerting them to the effectiveness of the requirement." For example, the same modalities currently available in the Medicaid appeals process would need to be available for individuals to request a review of CHIP determinations and would require that the agency provide written confirmation within five

business days of receiving a Medicaid or CHIP fair hearing request.

The final rule was published at 81 Fed. Reg. 86382 and can be found here:

https://www.gpo.gov/fdsys/pkg/FR-2016-11-30/pdf/2016-27844.pdf

CMS's proposed rule on Medicaid appeals can be found here:

https://www.gpo.gov/fdsys/pkg/FR-2016-11-30/pdf/2016-27848.pdf

No Risk Corridors Payments for 2015

On November 18, the Centers for Medicare & Medicaid Services (CMS) confirmed that all collections from the risk corridors program in 2015 will go to make up the 2014 shortfall. Temporary risk corridors programs were established by Section 1342 of the Affordable Care Act and managed by the Secretary of the Department of Health and Human Services (HHS) to provide issuers of qualified health plans in the individual and small group markets protection against uncertainty during the first three years of the Marketplace. A number of insurer lawsuits over the temporary risk-corridors program have been filed against the government. In one, Land of Lincoln Mutual Health Ins. Co. v. United States, the U.S. Court of Federal Claims ruled that the government is not obligated by statute or by contract to make full risk corridors payments annually.

The risk corridor payments for the 2014 benefit year exceeded the risk corridors collections for that year; therefore, the 2014 payments were reduced pro rata to reflect the shortfall. This amounted to HHS paying only 12.6% of the requested $2.87 billion in risk corridors payments for 2014. HHS began collecting 2015 risk corridor charges in November 2016, and will begin remitting risk corridors payments to issuers in December 2016 as collections are received.

The CMS memo can be found here:

https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2015-RC-Issuer-level-Report-11-18-16-FINAL-v2.pdf

IRS Extends Employer ACA Reporting Due Date to March 2, 2017

The Internal Revenue Service (IRS) is extending the upcoming deadline for insurers, self-insuring employers, and employers with 50 or more employees to comply with Affordable Care Act (ACA) reporting requirements. IRS Notice 2016-70 extends the deadline for providing individuals the 2016 Form 1095-B, *Health Coverage* and the 2016 Form 1095-C, *Employer-Provided Health Insurance Offer and Coverage*. The deadline has been extended by 30 days from January 31, 2017 to March 2, 2017. The notice also provides good-faith transition relief for entities that make a good-faith effort to comply with the regulations but nonetheless fail to fully comply. Those that do not make a good-faith effort or that fail to furnish a statement or file an information return are subject to penalty.

Because of this extension, taxpayers may not receive their form in time to file their 2016 tax return and may rely on other information provided by their employer.

The notice does not extend the deadline to file with the IRS the 2016 Forms 1094-B, 1095-B, 1094-C, and 1095-C. That deadline remains February 28, 2017, if not filing electronically, or March 31, 2017, if filing

electronically.

IRS Notice 2016-70 can be found here:

https://www.irs.gov/pub/irs-drop/n-16-70.pdf

Other Federal Developments

ONC Progress Report to Congress: "Examining the HITECH Era and the Future of Health IT"

In November 2016, The Office of National Coordinator for Health Information Technology (ONC) and the U.S. Department of Health and Human Services (HHS) submitted their annual progress report to Congress on the implementation of health IT. The report notes that 96% of hospitals and 78% of physician's offices currently use certified electronic health records. The report further describes HHS's three priority areas: (1) promoting common, federally-recognized standards; (2) building the business case for interoperability; and (3) changing the culture around access to information. The report discusses actions HHS has already taken towards achieving these priorities, such as publishing the Interoperability Standards Advisory (ISA) – a single resource for those looking for federally-recognized, national interoperability standards and guidance – creating implementation guides and resources to help providers realize the advantages of health IT, and supporting patients' rights to access their EHR. To continue to build upon this early success, ONC has requested additional budget authorities in the President's 2017 budget to combat information blocking, enhance transparency, establish rules for the electronic exchange of health information, and establish a Health IT Safety Collaborative.

The full report may be found at:

https://dashboard.healthit.gov/report-to-congress/2016-report-congress-examining-hitech-era-future-health-information-technology.php.

CMS launches Application Program Interface: an Online Tool for Sharing Medicare Quality Payment Program Data

On November 17, 2016, the Centers for Medicare & Medicaid Services (CMS) released the Application Program Interface (API), a tool to automatically share electronic data for the Medicare Quality Payment Program. The release is part of CMS's collaborative innovation efforts to create customizable tools that support clinicians by reducing the administrative burdens of participating in quality reporting programs. API builds on the Quality Payment Program website by providing easier access to the program's measures and allowing clinician practices to customize its applications through its Explore Measurers tool. The Quality Payment Program modernizes Medicare through streamlined policy and improved technology and operations by reducing reporting burdens and providing useful information to clinician practices. CMS hopes that these innovations will reduce the burden on clinicians by allowing clinicians to focus on their patients, and at the same time improve quality.

For more information, and to access the API, visit: https://qpp.cms.gov/education.

OIG Expects to Recover $5.66 Billion in FY2016

In its Semiannual Report to Congress, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) stated it expects to recover more than $5.66 billion for fiscal year (FY) 2016, including nearly $1.2 billion in audit receivables and nearly $4.46 billion in investigative receivables. In FY

2016, OIG pursued 844 criminal actions against individuals or entities and 708 civil actions. Additionally, "3,635 individuals and entities were excluded from participation in federal health care programs in FY 2016," OIG said. The work of the Health Care Strike Force gave rise to charges against 255 individuals or entities, 207 criminal actions, and $321 million in investigative receivables.

During its reporting period for the second half of FY 2016, OIG expanded its focus on the quality and safety of care in non-institutional settings, identifying "gaps in policies and controls to protect patients." The report discusses OIG's work to identify significant problems, abuses, deficiencies, remedies, and investigative outcomes for the administration of HHS programs and operations.

OIG's Semiannual Report to Congress can be found here:

https://oig.hhs.gov/reports-and-publications/archives/semiannual/2016/sar-fall-2016.pdf#sthash.6Nm1vsss.dpuf

UMass Amherst to Pay $650,000 HIPAA Settlement

On November 22, the Department of Health and Human Services Office for Civil Rights (OCR) announced that the University of Massachusetts Amherst (UMass) agreed to a $650,000 settlement of potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. The settlement stemmed from UMass's report to OCR on June 18, 2013 that the electronic protected health information (ePHI) of 1,670 individuals was impermissibly disclosed when a malware program infected one of the workstations in its Center for Language, Speech, and Hearing (Center). The OCR investigation of the event revealed several potential violations of the HIPAA Rules, including failing to designate all of its healthcare components when hybridizing, failing to implement technical security measures at the Center to guard against unauthorized access to ePHI information, and failing to conduct a precise risk analysis until September 2015. UMass also failed to implement policies and procedures at the Center to ensure compliance with the HIPAA Privacy and Security Rules. UMass agreed to a corrective action plan requiring it to conduct an enterprise-wide risk assessment and to develop and implement a risk management plan, including revising its policies, procedures, and staff training.

Regulation of Lab Developed Tests Not Finalized by FDA

On November 18, 2016, the Food and Drug Administration (FDA) announced it will not finalize guidance on regulating oversight of Lab Developed Tests (LDTs) by year-end. LDTs are tests that are designed, manufactured, and used within a particular laboratory and not distributed or sold to other labs. The FDA issued the draft guidance in 2014 (79 Fed. Reg. 59776) that would provide regulatory oversight of LDTs based on changes in the complexity and use of LDTs and the associated increased risks, stating that "its previous policy of general enforcement discretion towards LDTs is no longer appropriate." The draft guidance was opposed by laboratory industry representatives who assert that LDTs are not medical devices subject to FDA oversight. The FDA's inaction leaves further decision-making on this issue in the hands of the incoming president and Congress.

CMPs and Anti-Kickback Safe Harbors Revised by OIG

On December 7, 2016, the Department of Health and Human Services Office of Inspector General (OIG) codified changes made by the Affordable Care Act (ACA) by issuing two final rules that amend civil monetary penalty (CMP) provisions and create new Anti-Kickback safe harbors.

The first final rule, 81 Fed. Reg. 88334, ratified ACA changes related to Medicare Advantage and

Part D contractors. The rule amends the CMP rules by incorporating new CMP authorities, clarifying existing authorities, and reorganizing CMP regulations, assessments, and exclusions. The final rule establishes new CMPs for the following infractions:

- Failure to grant OIG timely access to records;
- Ordering or prescribing while excluded;
- Making false statements, omissions, or misrepresentations in an enrollment application;
- Failure to report and return an overpayment; and
- Making or using a false record or statement that is material to a false or fraudulent claim.

The final rule revising the CMP regulations can be found here:

https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28293.pdf

The second final rule, 81 Fed. Reg. 88368, updates the existing safe harbor regulations by adding protections for specific cost-sharing waivers, including a pharmacy waiver for businesses assisting low-income Medicare Part D beneficiaries and an emergency ambulance waiver for government-owned ambulance services. Additionally, new safe harbors have been created for the following:

- Certain remuneration between Medicare Advantage organizations and federally qualified health centers;
- Discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program; and
- Free or discounted local transportation services that meet specified criteria.

Finally, the rule codifies CMP regulations by revising the definition of "remuneration" and incorporating the following exceptions:

- Copayment reductions for certain hospital outpatient services;
- Certain remuneration that promotes access to care and poses a low risk of harm;
- Coupons, rebates, or other retailer reward programs that meet specified requirements;
- Certain remuneration to low-income individuals; and
- Copayment waivers for the first fill of generic drugs.

The final rule amending the anti-kickback safe harbors can be found here:

https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28297.pdf

The final rules go into effect January 6, 2017.

D.C. Court Compels Medicare Appeals Backlog Cleared by 2021

On December 5, 2016, the U.S. District Court for the District of Columbia issued an order requiring the Department of Health and Human Services (HHS) to clear its Medicare appeals backlog by 2021. The lawsuit was initiated by the American Hospital Association (AHA) and affiliated entities in May 2014 and sought to compel HHS to meet statutory deadlines for Medicare appeals review. The order requires HHS to reduce the current backlog on the following reduction timeline: by 30% at the end of 2017, by 60% at the end of 2018, by 90% at the end of 2019, and in full by December 31, 2020. It also requires the Secretary to provide quarterly status updates on the reductions. If HHS fails to meet the mandatory deadlines, plaintiffs

may seek further legal remedy.

To read the full court order, please see *American Hosp. Ass'n v. Burwell*, No. 14-851 (JEB) (D.D.C. Dec. 5, 2016), available here:

https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2014cv0851-48

Lab's Offer of Free Labeling Services to Dialysis Facilities Blocked by OIG—Again

On December 5, 2016, the Department of Health and Human Services Office of Inspector General (OIG) issued an advisory opinion (*Advisory Opinion 16-12*) expressing anti-kickback concern over a laboratory's renewed proposal to offer free labeling services to dialysis facilities when necessary to retain or obtain business. "In these circumstances, an inference arises that the free labeling services would be intended to influence the dialysis facilities' selection of a laboratory." OIG said it could not rule out administrative sanctions related to the current proposal.

The lab made an identical proposal in 2008 when Medicare utilized a composite rate reimbursement system for the tests. OIG rejected the 2008 proposal (*Advisory Opinion 08-06*). The reimbursement structure under the end-stage renal disease prospective payment system (ERSD PPS) has since changed; ERSD PPS was implemented in 2011, instituting a bundled payment system for separately reimbursable outpatient items and services related to end-stage renal disease. Labs and dialysis facilities can still be reimbursed separately for non-ESRD treatments.

"Following consultation with CMS, we conclude that the changes to the reimbursement structure for laboratory tests implemented through the ESRD PPS alter neither the concerns we articulated in the 1994 Special Fraud Alert nor our conclusion in OIG Advisory Opinion 08-06 that the Proposed Arrangement poses more than a minimal risk of fraud and abuse," the latest advisory opinion said.

The advisory opinion may be read in full here:

https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-12.pdf

Medicare, Medicaid Beneficiaries "Nominal Value" Gift Amounts Increase

In a December 7, 2016 policy statement, the Department of Health and Human Services Office of Inspector General (OIG) increased the permissible amounts for Medicare and Medicaid gifts of "nominal value." Civil monetary penalties (CMPs) of up to $10,000 may be assessed for "a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items." (Social Security Act §1128A(a)(5)). Gifts at or below the nominal value thresholds do not need to fit into an exception to Section 1128A(a)(5). OIG now interprets "nominal value" as having a retail value of no more than $15 per item or $75 total per patient annually. This is an increase from OIG's 2000 interpretation of $10 and $50, respectively. The gifts may not be cash or cash equivalents.

The policy statement may be read in its entirety here:

https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf

Updated MOON Notice in Effect by March 8, 2017

On December 8, 2016, the Centers for Medicare & Medicaid services (CMS) updated the Medicare Outpatient Observation Notice (MOON) for patients who received more than 24 hours of observation. The MOON is mandated by the Federal Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), which requires all hospitals to provide written and oral notification to beneficiaries when they are under observation and not admitted as an inpatient. The MOON notice assists hospitals by providing a standardized notice of beneficiaries of their patient status. The written status must be delivered within 36 hours of the start of observation services.

All hospitals are required to provide the MOON Notice by March 8, 2017. The MOON Notice and form instructions may be found on the CMS website at:

https://www.cms.gov/Medicare/Medicare-General-information/Bni/index.html

Changes to Form I-9, Employment Eligibility Verification

Changes to the Form I-9, Employment Eligibility Verification were released on November 14, 2016. Federal law requires that every employer who recruits, refers for a fee, or hires an individual for employment in the U.S. must complete Form I-9. The changes are designed to reduce errors and enhance form completion using a computer. By January 22, 2017, employers must use only the new version dated 11/14/2016. Among the changes in the new version, Section 1 asks for "other last names used" rather than "other names used" and includes additional prompts to ensure information is entered correctly.

Implementation of New Overtime Rules Blocked

On Nov. 22, a U.S. District Court judge in Texas granted an emergency motion for preliminary injunction to block the new overtime rules that were scheduled to go in effect on December 1. The rules were opposed by many business organizations and state attorneys general who claimed they were an overreach of federal regulatory authority and would be too costly for businesses and state agencies. While an appeal was filed by the Obama administration on December 2 to the 5th Circuit Court of Appeals, the case will not be heard until after President Obama leaves office. It is widely expected that Republicans will rescind the rules once president-elect Trump takes office. Many employers who had already adjusted employee pay rates in anticipation of the rules taking effect are evaluating options for proceeding given the current status of the rules.

STATE DEVELOPMENTS

NH Board of Medicine Adopts Opioid Prescribing Rules

On November 2, 2016, the New Hampshire Board of Medicine adopted opioid prescribing rules to take effect on January 1, 2017. The rules apply to prescribing opioids for acute and chronic pain and addresses prescription drug monitoring and medically assisted treatment programs. The Board developed a sample Checklist for the Prescribing of Opioids for the Management or Treatment of Pain covering the rules requirements. In addition, the Board is conducting an evaluation on appropriate risk assessment tools and shared the Screener and Opioid Assessment for Patients with Pain (SOAPP)® Version 1.0, a tool for clinicians to determine how much monitoring a patient on long-term opioid therapy may require. Approved assessment tools will be available by January 1, 2017.

The adopted opioid prescribing rules can be found here:

https://www.nh.gov/medicine/documents/med502_adopted_11-2-16.pdf

The SOAPP and Checklist, as well as approved opioid prescribing continuing medical education opportunities, may be found on the Board's website:

https://www.nh.gov/medicine/.

Also on the Board's website is a list of legislative initiatives for which the Board must appoint committee members. Physicians in the specialties of pain management, primary care, and pediatrics are all needed to participate in the review of various legislative initiatives.

Three NH Medicaid Expansion Waiver Amendments Rejected by CMS

On November 4, 2016, Centers for Medicare & Medicaid Services (CMS) denied New Hampshire's August 10, 2016 request to amend the state's Medicaid expansion program. One of the proposed amendments would have required eligible NH Medicaid beneficiaries to participate in work-related activities (i.e., job searching, training, working) for at least 30 hours per week. Another amendment would have required newly-eligible adults to prove US and NH citizenship by providing two forms of identification, including a state-issued picture identification card. The final proposed amendment would have required beneficiaries to pay an $8 copay for the first non-emergency emergency room visit, and a $25 copay for each visit thereafter. In its letter to the state, CMS said it could not approve the requested amendments because they "could undermine access, efficiency, and quality of care provided to Medicaid beneficiaries and do not support the objectives of the Medicaid program."

CMS' letter to the NH Department of Health and Human Services can be found here:

https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/health-protection-program/nh-health-protection-program-premium-assistance-cms-response-110116.pdf#sthash.sbqhGedW.dpuf

Law Requiring Health Care Provider Facilities to Disclose Employment Information Goes Into Effect January 1, 2017

A law requiring licensed health care provider facilities to disclose employment information regarding misconduct and competency about a health care worker upon the request of a prospective or current employer goes into effect on January 1, 2017. NH RSA 151:16-c also provides the facility and its directors and employees with immunity from civil liability for providing such information. Licensed facilities should be particularly concerned about how this statute impacts confidentiality and non-disparagement provisions of past and future settlement agreements with employees who terminate their employment.

Settlement Reached with Bristol-Myers

Bristol-Myers Squibb Co. has reached a $19.5M settlement in a case brought by 42 state attorneys general and the District of Columbia alleging improper marketing of the drug Abilify. In a statement released on December 8, Attorney General Joseph Foster announced that New Hampshire will receive $243,372 as its share of the settlement. The settlement arises out of allegations that Bristol-Myers improperly marketed Abilify, which is an antipsychotic medication, for pediatric use and for treatment of elderly patients with symptoms of dementia and Alzheimer's disease without first establishing the drug's efficacy and safety for

those uses.

2016 Legislative Updates
NH Legislators Begin Submitting Bills for the 2017 Session

Legislative Service Requests filed thus far for the upcoming legislative session include the following health care related bills:

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.
2017-123: relative to hypodermic syringes and needles containing residual amounts of controlled drugs and authorizing the operation of syringe exchange programs in New Hampshire.
2017-124: establishing a controlled substances scientific review board.
2017-0128: relative to medical specialty boards.
2017-0167: establishing a commission to study current mental health procedures for involuntary commitment.
2017-0196: extending the suspension of prior authorization requirements for a community mental health program on drugs used to treat mental illness.
2017-0222: relative to criminal records checks in the employee application process.
2017-0230: relative to medical payments coverage under motor vehicle liability.
2017-0238: relative to portability, availability, and renewability of health coverage.
2017-0268: relative to prices charged by drug manufacturers doing business in New Hampshire.
2017-0269: requiring drug manufacturers to reduce prices in proportion to rebates or discounts offered.
2017-0275: relative to the rules governing the privacy of mental health records.
2017-0290: relative to qualifying medical conditions for the therapeutic use of cannabis.
2017-0295: relative to the use of cannabis for therapeutic purposes.
2017-0332: relative to the certification of acupuncture detoxification specialists.
2017-0364: relative to the regulation of certain professions by the office of professional licensure and certification.
2017-0404: relative to live medical testimony in courts.
2017-0423: repealing licensure requirements for medical imaging professionals and radiation.
2017-0424: relative to the authority of the commissioner of the department of health and human services relative to certain vaccine requirements.
2017-0425: deleting certain immunization requirements for non-communicable diseases.
2017-0459: relative to procedures of the board of psychologists.
2017-0460: relative to liability for payment of criminal record background checks and drug tests.
2017-0499: establishing a commission to study a public option for health insurance.
2017-0502: adding rulemaking authority to require completion of a certain survey as part of the license renewal process for health care providers.
2017-0514: requiring the department of health and human services to develop a centralized state system for transporting persons subject to involuntary emergency admission.

2017-0515: establishing a commission to assess the benefits and costs of a "health care for all" program for New Hampshire.
2017-0516: relative to the law regarding therapeutic use of cannabis.
2017-0520: relative to the practices of pharmacy benefit managers.
2017-0534: establishing a scholarship fund for health care providers who stay in New Hampshire for 5 years and making an appropriation therefor.
2017-0573: relative to medical insurance covering automobiles.

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

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