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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

CMS Issues 2018 Marketplace Proposed Rule

On August 29, the Centers for Medicare and Medicaid Services (CMS) issued the proposed 2018 Notice of Benefit and Payment Parameters, which includes improvements to the risk adjustment program and other key updates. CMS proposes to incorporate partial-year adjustment factors in the adult risk adjustment model, citing the current model's shortcomings in predicting claims costs for enrollees who are only enrolled for part of the year. Furthermore, CMS intends to use drug utilization data to gather enrollee health information in benefit year 2018. The rule also proposes changing the treatment of high-cost enrollees in order to better predict risk for plan issuers, allotting a portion of medical costs exceeding $2 million for an individual to be shared among issuers.

The proposal would update the marketplace user fee rates to 3.5% of premium for the 2018 Federal marketplace and 3% of premium for the 2018 state-run marketplaces. The proposal adjusts the maximum annual limitation on cost sharing to $7,350 for an individual and $14,700 for a family. Additionally, the proposed rule will enhance the qualified health plan network breadth indicator as well as improve consumer protections concerning the direct enrollment channel. The proposed rule was published in the Federal Register at 81 FR 61455 on September 6. Comments are due by October 6.

You can find the proposed rule here: https://www.federalregister.gov/documents/2016/09/06/2016-20896/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2018

IRS Issues Information Reporting Proposed Regulations

On August 2, the U.S. Internal Revenue Service (IRS) proposed changes to a rule requiring entities to report minimum essential coverage. Section 6055 of the Internal Revenue Code requires entities that provide minimum essential coverage to individuals to report certain information to the IRS to allow it to verify taxpayers' coverage attestations. The current rule does not require reporting when minimum essential coverage is supplemental to other minimum essential coverage if both plans have the same sponsor or if the coverage supplements government-sponsored coverage. The rule change clarifies that when these scenarios arise, one of the plans must report to the IRS.

Other Federal Developments

OIG Updates 2016 Review List

On June 7, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued its Mid-Year Work Plan Update,

which covers FY 2016 and FY 2017. New additions to the list of planned reviews include skilled nursing facility prospective payment system requirements, national background checks for long-term care employees, and Medicare home health fraud. Among the updates are the following: reviews of Accountable Care Organizations (ACOs); review of the Centers for Medicare and Medicaid Services' (CMS's) implementation of its new Medicare Clinical Diagnostic Laboratory Tests payment system; reviews of Medicare Part D price increases for both brand-name and generic drugs, as well as physician-administered drugs for dual-eligible enrollees; review of Medicaid waiver oversight and effectiveness; review of state compliance with Medicaid Managed Care organizational requirements for treatment of healthcare related taxes; review of the Affordable Care Act's Risk Corridors program; and review of controls over Opioid Treatment Programs.

You can find the Mid-Year Work Plan Update here: https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Documents/061016/WorkPlan_April%202016_Final.pdf

OIG Advises States on Avoiding Duplicate Discounts on MCO Drug Rebates

In a June 9 report, the U.S. Department of Health and Human Services Office of Inspector General (OIG) found that most states use methodologies that may be inaccurately identifying 340B claims when calculating Medicaid Managed Care Organizations' (MCOs') drug manufacturer rebates. Accurate identification of 340B claims is necessary in order to avoid an illegal duplicate discount—when the drug manufacturer applies a rebate to an already discounted 340B drug. OIG explained that there are two types of methods that states typically use to prevent duplicated discounts—provider-level and claims-level. The provider-level method identifies covered entities that use 340B-purchased drugs for their Medicaid patients and exclude drug claims billed by those entities from utilization data. The claims-level method excludes drug claims that covered entities have explicitly identified as 340B claims from utilization data. OIG found that 30 of the 35 states that have 340B claim identification procedures in place used provider-level methodologies to mitigate instances of duplicate discounts. OIG noted that provider-level methodologies might not be accurate in identifying 340B claims because they tend to treat all drug claims from a given covered entity in the same way – that is, as either 340B claims or non-340B claims—and do not allow covered entities to differentiate among specific claims. OIG found that 14 of the 35 states utilized claims-level methodologies in some capacity to identify 340B claims. Many of the states reported that they used more than one method for identifying claims, while others used one method as a primary and another as a backup. This results in the discrepancy in the reporting methodologies. OIG recommends claims-level methodologies to mitigate instances of duplicate discounts because they allow covered entities to differentiate among specific claims. OIG also noted that 24 of the 30 states using provider-level methods said they were using the Medicaid Exclusion File (MEF) to identify 340B claims. The Healthcare Resources and Services Administration (HRSA) recently gave guidance that the MEF should only be used for fee-for-service drugs and not MMCO drugs. As such, OIG recommended that the Centers for Medicare and Medicaid Services (CMS) make the use of claims-level methodologies to identify 340B claims mandatory, and also urged the HRSA to clarify its guidance on preventing duplicate discounts. The OIG noted that CMS did not agree with its recommendation, citing that the statute does not contemplate the requirement.

GAO Finds Efforts to Slow Medicare Appeals Backlog are Insufficient

In a June 9 report, the Government Accountability Office (GAO) concluded that efforts to stem the growth of the Medicare appeals backlog have not been successful, with the volume of third and fourth-level appeals continuing to surpass the adjudication capacity of the government. In *Medicare Fee-for-Service: Opportunities Remain to Improve Appeals Process*, GAO found that unless additional action is taken, delays

beyond the statutory timeframe for appeals decisions would continue. Third-level appeals in front of an administrative law judge (ALJ) grew the most from the FY 2010-FY 2014 timeframe analyzed in the report, increasing by 936%. A 2000% increase in hospital and inpatient stay appeals is the cause for the influx of third-level appeals, according to the report. Furthermore, GAO noted that 96% of ALJ decisions were issued outside of the 90-day statutory timeframe in FY 2014.

Although the U.S. Department of Health and Human Services (DHHS) and the Centers for Medicare and Medicaid Services (CMS) have attempted to reduce the backlog, so far they have not been successful. Related claims still have to be evaluated individually and DHHS does not have strong enough data collection to monitor the appeals system. GAO recommended that DHHS find ways to improve efficiencies on both of those points.

ONC Issues Health IT Reports

On June 10, the Office of the National Coordinator for Health Information Technology (ONC) issued two studies concerning health information technology (IT) safety. The first, *Report of the Evidence on Health IT Safety and Interventions*, focuses on recent evidence in the health IT field since the 2011 publication of the Institute of Medicine's report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, and found that no single area or function of health IT is most commonly associated with adverse safety outcomes and that safety issues "typically arise from the interplay of multiple, interrelated factors." It urged health care organizations to promote a culture of safe use when implementing health IT and urged health IT developers to be responsive when problems are found and to constantly improve health IT safety features. The second report, *Goals and Priorities for Health Care Organizations to Improve Safety Using Health IT*, examined goals and priorities concerning health IT safety, and ultimately found that a collaborative effort between developers and health IT users is the key to improving safety.

AMA Adopts Telemedicine Guidelines

On June 13, the American Medical Association (AMA) adopted a new set of guidelines for the ethical practice of telemedicine. In a policy based on a report from the AMA Council on Ethical and Judicial Affairs, the guidelines call for physicians to disclose financial or other interests in specific telemedicine applications or services. The new guidelines provide additional guidance to physicians who respond to health queries on websites and to physicians who provide clinical services via telemedicine. The policy requires that a valid physician-patient relationship exist before telemedicine services are provided. The guidelines also state that physicians must protect patient privacy and confidentiality. AMA stated that it would release the full guidelines in a peer-reviewed journal in the coming months but as of this publication, it has not been released.

CMS Issues Conditions of Participation Proposed Rule

On June 13, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule concerning updates to the Conditions of Participation (COPs) for both hospitals and critical access hospitals (CAHs). In a fact sheet, CMS states that the rule seeks to update COPs and improve quality of care by reducing hospital readmissions, reducing barriers to care, reducing hospital-acquired conditions, improving antibiotics use, improving patient protections, and addressing workforce shortages. The rule proposes that all Medicaid and Medicare-participating hospitals will have to implement hospital-wide infection prevention and control programs as well as antibiotic stewardship programs. The proposed rule also calls for hospitals and CAHs to establish sweeping anti-discrimination policies and calls for medical records to contain much more detail in regard to patient encounters in hospitals in order to document a complete record of services provided to each patient. Comments were due on August 15.

You can find the proposed rule here:
https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Documents/061716/81fr39447.pdf

OIG Calls for Elimination of Provider-Based Designation

In a June 16 report, the U.S. Department of Health and Human Services Office of Inspector General (OIG) renewed its call for the Centers for Medicare and Medicaid Services (CMS) to either eliminate Medicare's provider-based designation or equalize payment for specific services rendered in outpatient settings. OIG noted that Medicare services rendered in a provider-based facility are often compensated at a rate more than 50% higher than the compensation rate for the same service provided in an independent facility. OIG cited its concern that CMS still struggles to ensure that provider-based facilities are billing Medicare services appropriately. The report—*CMS is Taking Steps to Improve Oversight Of Provider-Based Facilities, but Vulnerabilities Remain*—found that more than three-quarters of hospitals that owned provider-based facilities had not attested for at least one of them, and also found that 37 of the 50 hospitals that did not voluntarily attest for all of their provider-based facilities owned off-site facilities that did not meet at least one provider-based designation requirement. OIG stated that if CMS opts not to eliminate provider-based designations, the organization should: implement systems to monitor all billing by provider-based facilities; make attestations for any and all provider-based facilities mandatory; ensure provider-based requirements are being appropriately applied by contractors in attestation reviews; and take appropriate action against hospitals and their off-site provider-based facilities that the report found were not meeting requirements.

CMS Issues CLFS Final Rule

On June 17, the Centers for Medicare and Medicaid Services (CMS) issued the Clinical Laboratory Fee Schedule (CLFS) final rule that calls for the use of private insurer rates to calculate Medicare payments for laboratory tests. At the request of many stakeholders, the rule has a delayed implementation date of January 1, 2018. Under the rule, labs are expected to see a $3.93 billion reduction in compensation, with a 5.6% revenue reduction in FY 2018, a five-year prospective reduction of 4.9%, and a ten-year prospective reduction of 5.6%. The rule applies to labs that receive at least $12,500 in Medicare revenues from the CLFS and more than 50% of its Medicare revenues from lab and physician services. CMS estimates that 95% of physician office labs and about half of independent labs will not fall under the applicability criteria. The Protecting Access to Medicare Act of 2014 calls for civil monetary penalties of up to $10,000 per day for each failure to report or each misrepresentation in reporting private payer prices. The rule also adopts a six-month data collection period, with the first period ranging from January 1 to June 30, 2016.

CMS Issues Medicaid Eligibility Programs Proposed Rule

On June 20, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule concerning the Payment Error Rate Measurement (PERM) and the Medicaid Eligibility Quality Control (MEQC) programs. The rule seeks to implement provisions of the Affordable Care Act (ACA) that would change the way states adjudicate Medicaid and the Children's Health Insurance Program (CHIP) eligibility. Under the rule, the timing of the review by the PERM program would change to July through June of each year instead of October through September so states have the time needed to collect data for reporting deadlines in November. The rule also requires PERM reviews to be performed by Federal contractors rather than the states themselves, and modifies the sample size requirements so that state-level precision is maximized while also meeting the specific needs for each state.

The proposed rule also seeks to change the MEQC program to better compliment the PERM program and to reduce redundancies between the two programs. Under the proposed rule, MEQC pilots will

review items not fully reviewed under the PERM program, and proposes that each state runs at least one pilot during their two off-years between PERM cycles. The MEQC sets a 3% threshold for eligibility-related improper payments in any fiscal year, with Federal payments being withheld with respect to the amount of improper payments that are above the 3% threshold. States will have flexibility in what areas they choose to review in their MEQC pilots, unless they are above the 3% threshold, in which case CMS will give direct instruction concerning the pilot. In addition to all of this, the rule also would require states to submit corrective action for identified errors. Comments were due August 22.

OIG Issues HHA Data Brief and Fraud Alert

On June 22, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a data brief and a fraud alert concerning home health fraud. The data brief—*Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases*—identifies five distinct common characteristics of home health agencies (HHAs) and physicians in cases of home health care fraud. The five characteristics outlined in the report are as follows:

1. "High percentage of episodes for which the beneficiary had no recent visits with the supervising physician
2. High percentage of episodes that were not preceded by a hospital or nursing home stay
3. High percentage of episodes with a primary diagnosis of diabetes or hypertension
4. High percentage of beneficiaries with claims from multiple HHAs
5. High percentage of beneficiaries with multiple home health readmissions in a short period of time."

OIG identified 562 HHAs (5% of all HHAs) and 4,502 physicians (1% of all physicians) that were outliers in regard to two or more characteristics. The report also highlighted 27 hot spots in 12 states across the nation that were outliers in regard to at least two of the characteristics (those states are Arizona, California, Florida, Illinois, Louisiana, Michigan, Nevada, New York, Oklahoma, Pennsylvania, Texas, and Utah). OIG noted that the report was not meant to root out actual fraud, but rather was intended to highlight which providers and geographical areas of the country should be subject to more scrutiny.

OIG also issued a fraud alert alongside its report on home health fraud titled *Alert: Improper Arrangements and Conduct Involving Home Health Agencies and Physicians*. OIG noted that in recent home health fraud cases, HHAs violated the Anti-Kickback Statute in many different ways, including "making (or accepting) payments for patient referrals, falsely certifying patients as homebound, and billing for medically unnecessary services or for services there were not rendered." Of particular concern are compensation arrangements for services provided where one purpose of the arrangement is to compensate physicians for past or future referrals. OIG also emphasized that payments under compensation arrangements must be fair market value and commercially reasonable in the absence of Federal healthcare program referrals.

Supreme Court Issues Ruling in FCA Implied Certification Case

On June 16, the U.S. Supreme Court issued a unanimous ruling in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), a case concerning implied certification under the False Claims Act (FCA). The Court held that the implied false certification theory can be a basis for liability under the FCA under certain conditions, which effectively narrowed the application of the theory.

On April 19, the Court heard oral arguments to decide whether "implied certification" may give rise to liability under the False Claims Act (FCA). The trial court in the underlying case found that the fraudulent misrepresentation by a mental health provider that treatment was provided by licensed and supervised

providers as required by state regulations could not form the basis of an FCA claim, distinguishing between conditions of payment versus conditions of participation. However, the First Circuit reversed that finding, citing its "broad view" of what qualifies as a false claim and applying the theory of implied certification. *United States v. Universal Health Services, Inc.*, 780 F.3d 504 (1st Cir. Mar. 17, 2015).

Concerning implied certification, the Court held that the implied certification theory "can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods and services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Universal Health Services, Inc. v. United States ex rel. Escobar,* 136 S. Ct. 1989, 2001 (2016). In this case, the Court found that when Universal Health submitted claims using payment codes corresponding to specific counseling services, it represented that it had provided those services, without disclosing the violations of staff and licensing requirements, resulting in the claims being misrepresentations. *Id*. at 2000-2001.

The Court next addressed the FCA's materiality requirement. Concerning FCA materiality, the Court identified factors that are relevant to materiality, including, that the provision is identified as a condition of payment, although, it determined that being identified as a condition of payment is not "dispositive" to the question of materiality; and also whether there exists "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id*. at 2003. On the other hand, if the government typically pays the underlying claim in full with actual knowledge that certain requirements were violated, it would be "strong evidence that the requirements are not material." *Id*. at 2004.

The Court vacated the judgment of the First Circuit and remanded the case for reconsideration consistent with its opinion.

You can read the full ruling here: https://www.supremecourt.gov/opinions/15pdf/15-7_a074.pdf

CMS Proposes HHPPS Rule

On June 27, the Centers for Medicare and Medicaid Services (CMS) issued the Medicare home health prospective payment system (HHPPS) proposed rule, which is expected to decrease 2017 payments to home health agencies by $180 million. In a fact sheet, CMS explained that the decrease is the result of a payment increase being offset by the last year of a four-year rebasing adjustment to the national standardized 60-day episode rate, as well as a decreased payment rate in the national standardized 60-day episode rate to account for 2012-2014 nominal case-mix growth and a change to the ratio used to determine outlier payments.

CMS Summarizes Public Notice Requirements for Medicaid Payment Changes

In a June 24 bulletin, the Centers for Medicare and Medicaid Services (CMS) clarified public notice procedures that states must follow when changing provider payments under their state Medicaid plans. States must follow the following procedures: "public notice policies that pertain to all proposed changes to provider payment rates or methodologies; public input process policies which apply when states reduce rates or restructure payments, and are designed to obtain input related access to care; and public input process policies that are specific to changes to institutional provider payment rates."

You can find the bulletin here: https://www.medicaid.gov/federal-policy-guidance/downloads/cib062416.pdf

SCOTUS Declines to Review Finding that State-Mandated Incident Reports are not Privileged Patient Safety Work Product

On June 27, the U.S. Supreme Court (SCOTUS) declined to review the Kentucky Supreme Court's decision that information routinely included in state-mandated incident reports does not qualify as patient work safety product under the Patient Safety and Quality Improvement Act (PSQIA). The Kentucky Supreme Court held that patient medical records and billing information as well as information gathered and existing separately from a patient safety evaluation system are not privileged under the PSQIA. *Tibbs v. Bunnell*, No. 2012-SC-000603-MR (K.Y. Aug. 21, 2014).

DOJ Final Rule Increases Fraud Penalties and DHHS Increases CMPs

In an interim final rule published June 30, the U.S. Department of Justice (DOJ) significantly increased the civil monetary penalties (CMPs) for violating the False Claims Act (FCA) in accordance with mandates under the Federal Civil Penalties Inflation Adjustment Improvement Act of 2015 (2015 Act). The rule, effective August 1, raises the current per-claim amount range for FCA violations from $5,500-$11,000 to $10,781-$21,563. Per-occurrence Anti-Kickback Statute violations were raised to $21,563 from $11,000. According to the interim final rule, the adjustments are based on the Bureau of Labor Statistics' Consumer Price Index for October 2015. Comments on the interim final rule were due on August 29.

Also as a result of requirements under the 2015 Act, on September 6, the U.S. Department of Health and Human Services (DHHS) issued an interim final rule increasing all maximum civil monetary penalties (CMPs) under its administrative control in order to account for inflation. The adjusted CMPs took effect after August 1. The rule includes a table for the adjusted CMPs, indicating pre-inflation penalty amounts along with percentage increases.

You can find the rule here: https://www.gpo.gov/fdsys/pkg/FR-2016-09-06/pdf/2016-18680.pdf#sthash.NgUzRg1x.dpuf

DHHS Increases Buprenorphine Prescribing Limit

On July 6, the U.S. Department of Health and Human Services (DHHS) issued a final rule that increases the patient limit for qualifying physicians to prescribe buprenorphine, an opioid use disorder treatment. The rule was part of the administration's approach to addressing the nation's opioid addiction crisis by focusing on three key priorities: expanding access to treatment, preventing overdose deaths, and improving opioid prescribing practices. The rule allows physicians who had waivers to prescribe buprenorphine for 100 patients per year to obtain a waiver to treat 275 patients per year. DHHS cited existing evidence demonstrating the underutilization of buprenorphine in addiction treatment.

CMS Issues 2017 Medicare Physician Fee Schedule Proposed Rule

On July 7, the Centers for Medicare and Medicaid Services (CMS) issued the 2017 Medicare physician fee schedule proposed rule which increases primary care, behavioral health, cognitive care, and mobility-related care payments via coding and payment updates. The rule would introduce an additional $900 million in funding in 2017. The rule also includes provisions to expand the Medicare Diabetes Prevention Program starting on the first of January 2018, provisions related to Medicare Advantage (MA) provider and supplier contracting requirements, provisions related to MA price transparency, and the addition of telemedicine codes including end-stage renal care and advanced care planning services. Comments were

due September 6.

CMS Issues 2017 OPPS Proposed Rule

On July 6, the Centers for Medicare and Medicaid Services (CMS) issued the 2017 Hospital Outpatient Prospective Payment System (OPPS) proposed rule. The rule would increase OPPS rates by 1.6% and Ambulatory Surgical Center (ASC) rates by 1.2%. Additionally, the rule would implement Section 603 of the Bipartisan Budget Act of 2015, which attempts to balance care payments for those performed in hospital off-campus locations with those performed in other locations. The provision calls for certain items and services rendered in hospital off-campus outpatient departments that began OPPS billing on or after November 2, 2015 to no longer bill under OPPS. Starting in 2017, those departments would bill under the Medicare Physician Fee Schedule for the majority of non-excepted items and services. CMS says that this is a transitional policy as it explores the potential for these departments to bill under Medicare Part B starting in 2018. The rule will allow for billing to the OPPS of excepted items and services, items and services rendered and billed prior to November 2, 2015, and items and services rendered at a department within 250 yards of a remote location of the hospital. The proposal is estimated to reduce OPPS spending by roughly $500 million in 2017.

In 2018, the rule would remove the pain management dimension of the Hospital Value-based Purchasing Program (VBP) in response to stakeholder concerns. Stakeholders were concerned that the pain management dimension questions of the VBP encouraged over-prescription of opioids in order to achieve high scores.

Additionally, the rule includes a proposal for clinicians and hospitals to use a 90-day electronic health record (EHR) reporting period for 2016 in order to decrease the reporting burden for providers.

The rule also proposes modifying the Hospital Outpatient Quality Reporting Program (OQR) by adding two new claims-based measures and five new Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems survey-based measures for 2020 and subsequent years' payment determinations. Additionally, the rule would add seven new measures for the ASC Quality Reporting Program for 2020 and subsequent years' payment determinations. Comments on the proposed rule were due September 6.

OCR Issues Ransomware and Breach Notification Guidance

On July 11, the U.S. Department of Health and Human Services (DHHS) Office of Civil Rights (OCR) issued guidance clarifying that ransomware attacks typically yield breaches of protected health information (PHI) that trigger the Health Insurance Portability and Accountability Act (HIPAA) breach notification requirements. Ransomware attacks are malware-variant attacks that encrypt native data with a key held remotely by the attacking hacker, rendering the encrypted data inaccessible until a ransom is paid to the hacker. The guidance cited a recent U.S. Government interagency report that there are an average of 4,000 daily ransomware attacks. The encryption of PHI during a ransomware attack constitutes a HIPAA breach because when an unauthorized third party accesses PHI, it is considered an impermissible disclosure under HIPAA's Privacy Rule. The guidance clarified that breaches of PHI already encrypted in accordance with HIPAA would not trigger breach notification requirements, as those requirements only apply to breaches of *unsecured* PHI. OCR also provided suggested practices for detecting ransomware and for preparing for data recovery following a ransomware attack.

DHHS Reports Security Oversights in Health Data Protections

In a July 17 report to Congress, the U.S. Department of Health and Human Services (DHHS) highlighted the lack of clear and precise requirements concerning access, privacy, and security of health information that is collected, used, and shared by those entities not regulated by the Health Insurance Portability and Accountability Act (HIPAA). Since the genesis of HIPAA, many new entities and technologies—such as mobile fitness devices and telehealth websites—have emerged as examples of the types of entities not covered under the statute. The DHHS Office of the National Coordinator for Health Information Technology (ONC) in conjunction with the DHHS Office of Civil Rights (OCR) and the Federal Trade Commission (FTC) noted that such entities fall outside of the purview of HIPAA and are not subject to HIPAA privacy and security standards. The report recommends that these gaps in health data protections be filled, and notes that organizations like DHHS and the FTC have made an effort to do so but are limited in their statutory authority. The report also notes that no cohesive code of conduct surrounding health data protections has surfaced in the private sector, underscoring the need for some kind of action to be taken to assure the safety of health data when it comes to these specific entities.

OCR Issues HIPAA Audit Document Requests

On July 11, the U.S. Department of Health and Human Services (DHHS) Office for Civil Rights (OCR) requested documents from 167 covered entities as part of the Health Insurance Portability and Accountability Act (HIPAA) Phase 2 compliance audits. The selected covered entities had ten days to respond to the request, and OCR noted that the review would focus on compliance with certain HIPAA standards, including HIPAA notice of privacy practices and right to access, breach notification requirements, and risk analysis and management. OCR also noted that desk audits of business associates would begin in the fall.

CMS Proposes New Cardiac Care Bundled Payment Model

On July 25, the Centers for Medicare and Medicaid Services (CMS) announced in a proposed rule a new cardiac care bundled payment model that would launch in 98 randomly selected metropolitan statistical areas (MSAs). Under the proposed mandatory model, hospitals in the 98 MSAs would be paid a set amount by Medicare for each inpatient stay in the event of a heart attack or cardiac bypass surgery plus 90 days after discharge. Over the course of the 5-year demonstration, CMS would set target rates for each episode of care based on hospital-specific data for the first two years, and regional-specific data thereafter. Hospitals that deliver care under the price targets would get to keep the cash windfall, whereas hospitals that deliver care over the price targets would owe the excess money to Medicare. Due to the experimental nature of the payment model, CMS stated it would limit the risk and rewards of the model by rolling it out incrementally: the first two performance years carry a 5% risk/reward payment cap, the third year carries a 10% cap, and the final two years carry a 20% cap. CMS also stated that it would not include rural areas in the demo and would limit the financial risk for rural hospitals in the randomly selected MSAs.

CMS also proposed a new payment model with the hope of encouraging the utilization of cardiac rehabilitation services. Under this payment model, hospitals would receive incentive payments whenever a beneficiary utilizes cardiac rehabilitation services within the 90-day post-discharge period. CMS would make this model available in 45 MSAs included in the demonstration and 45 MSAs not included in the demonstration.

The proposed rule also sets forth new ways for physicians participating in bundled payment models to qualify as advanced Alternative Payment Models (APMs) under the Quality Payment Program (QPP). Beginning in 2018, physicians could qualify for the advanced APMs, even if they are not participating as long

as they collaborate with hospitals participating in the payment models.

Additionally, CMS expanded the existing Comprehensive Care for Joint Replacement model—a model that was finalized in November 2015—alongside the mandatory cardiac payment model in the proposed rule. Comments on the rule are due by October 1.

OIG Modifies Advisory Opinion on Patient Assistance Program

On July 22, the U.S. Department of Health and Human Services Office of Inspector General (OIG) announced a modification to favorable Advisory Opinion 10-12, issued in August 2010, which concerned a charity's patient assistance program (PAP). The charity operates a PAP that provides cost-sharing assistance for drugs and devises to patients diagnosed with brain tumors who are in financial need. The Charity was informed by OIG that it would need to modify its programs in order to maintain a favorable advisory opinion because the OIG found that features of the arrangement approved in the favorable opinion had since been deemed problematic by the OIG. In order to retain its favorable advisory opinion, the charity made the following certifications:

- Disease funds will not be defined by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states, and the charity will cover, at a minimum, all drugs approved by the Food and Drug Administration for treatment;
- The charity will not maintain disease funds that provide copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; and
- Disease funds will not be specific to high-cost or specialty drugs.

The charity also proposed two modifications to its PAP: (1) revising the definition of its disease fund to cover drugs and devices for primary malignant brain tumors; and (2) cross-posting contact information on its PAP and non-PAP websites. OIG issued favorable opinions concerning both modifications, noting that neither would significantly raise the risk of fraud or abuse.

OIG Report Underscores the Importance of EHR Contingency Plans

In a July 25 report, the U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) highlighted the critical role electronic health records (EHR) contingency plans play in mitigating and minimizing EHR systems disruptions. The report states that 59% of hospitals receiving Medicare EHR incentive payments in 2014 and 2015 encountered unplanned disruptions to their EHR systems. Hardware malfunctions and internet connectivity issues accounted for a combined 92% of those disruptions, with only 8% attributable to power failures and natural disasters.

OIG found that 95% of the hospitals in the report had EHR contingency plans, with 68% addressing all four Health Insurance Portability and Accountability Act (HIPAA) contingency plan requirements—a data back-up plan; a disaster recovery plan; an emergency mode operations plan; and testing and revising contingency plans. OIG did not review a fifth HIPAA requirement of maintaining an applications and criticality assessment. OIG noted that larger hospitals were more likely to have written contingency plans and alternative sites for maintaining data.

You can find the full report here: https://oig.hhs.gov/oei/reports/oei-01-14-00570.pdf

FDA Offers Regulatory Guidance on General Wellness Products

In non-binding guidance issued July 29, the U.S. Food and Drug Administration (FDA) clarified that it would not regulate low-risk general wellness products as devices under the Food, Drug, and Cosmetic Act (FDCA). The guidance defines "general wellness product" as any product that has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact. An example set forth in the guidance of a general wellness product not subject to regulation is a mobile application that tracks food consumption or daily activity, because it is a product that encourages a general state of health. Furthermore, the guidance states that general wellness products are not "low-risk", and are therefore subject to regulation, when they are invasive, implanted, or involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied. The FDA noted that in determining whether or not a product would or would not be regulated, concerned parties should look towards similar products and see if those are regulated or not.

CMS Unveils Hospital Star Ratings

On July 27, the Centers for Medicare and Medicaid Services (CMS) released overall hospital star ratings, although concerns remain about the accuracy of the ratings. The one to five star rating system is based on the 64 existing quality measures on the Hospital Compare website. In April, Congress and the American Hospital Association (AHA) expressed serious concerns about the accuracy of the ratings, citing the potential to mislead consumers. In particular, critics were concerned about the failure of the system to take into account socioeconomic factors. As a result of the criticism, CMS had postponed the scheduled April release to address some of the concerns, however, hospital groups and other stakeholders are still worried that the data is inaccurate and flawed, and that it "unfairly penalizes teaching hospitals and those serving higher numbers of the poor," according to a statement released by the AHA.

You can find the link to the Medicare Hospital Compare website here:
https://www.medicare.gov/hospitalcompare/Data/Hospital-overall-ratings-calculation.html

CMS Extends Ambulance & Home Health Enrollment Moratoria

On July 29, the Centers for Medicare and Medicaid Services (CMS) announced a six-month extension of the temporary provider enrollment moratoria on new Medicare Part B non-emergency ambulance suppliers and home health agencies (HHAs). The moratoria also apply to Medicaid and the Children's Health Insurance Plan (CHIP). States affected are: New Jersey, Pennsylvania, and Texas for ambulances; Florida Texas, Illinois, and Michigan for HHAs. CMS stated that it would immediately lift the temporary moratoria on emergency ambulances, and has set up a waiver process for affected states to utilize if there is a demonstrable need for enrollment due to problems with access to care, and for development and improvement of methods of investigating and prosecuting fraud.

CMS Selects 14 Regions for CPC+

On August 1, the Centers for Medicare and Medicaid Services announced that practices in 14 selected regions are now able to apply to participate in the new Comprehensive Primary Care Plus (CPC+) initiative. The 14 regions are as follows: Arkansas; Colorado; Hawaii; Kansas and Missouri: Greater Kansas City Region; Michigan; Montana; New Jersey; New York: North Hudson-Capital Region; Ohio: Statewide and Northern Kentucky Region; Oklahoma; Oregon; Pennsylvania: Greater Philadelphia Region; Rhode Island; and Tennessee.

CMS explained in April that the CPC+ model will benefit patients by supporting primary care practices

with their delivery of "advanced primary care," a model of primary care with five main components: (1) accessible services with enhanced in-person hours and 24/7 telephone or electronic access; (2) proactive, relationship-based care management services for high risk patients; (3) comprehensive and coordinated care; (4) patient-centered care; and (5) analysis of quality and service utilization in order to improve care and develop capabilities.

Up to 5,000 primary care practices will participate in one of two tracks. Participants in Track 1 will receive a monthly care management fee in addition to the Medicare fee-for-service (FFS) payments. Participants in Track 2 will also receive a monthly care management fee, but rather than the FFS payments for Evaluation and Management Services, the practices will receive hybrid payments consisting of FFS payments and an upfront Comprehensive Primary Care Payment (CPCP), a payment that will front a percentage of expected evaluation and management reimbursement claims with reduced FFS payments. CMS explained in an April 11 press release that "[t]he hybrid payment design will allow greater flexibility in how practices deliver care outside of the traditional face-to-face encounter." CPC+ will also provide up-front incentive payments to practices in both tracks that will either be kept or paid back contingent on performance. The initiative is slated to launch in January 2017.

CMS Issues IRF Final Rule

In a final rule published on August 5 and effective October 1, the Centers for Medicare and Medicaid Services (CMS) announced that Inpatient Rehabilitation Facilities (IRFs) would see a $145 million (1.9%) increase in Medicare reimbursements in FY 2017. The Prospective Payment System (PPS) rule will also continue the phase-out of the rural adjustment for IRFs in rural designation zones that were changed to urban designation zones under new guidelines from the Office of Management and Budget (OMB). The rule also finalizes modifications to the IRF Quality Reporting Program (QRP), adding three quality measures to satisfy resource use and other measure domains and one quality measure to satisfy the medication reconciliation domain requirements under the Improving Medicare Post-Acute Care Transformation Act of 2014.

CMS Issues SNF Final Rule

In a final rule published on August 5 and effective October 1, the Centers for Medicare and Medicaid Services (CMS) determined that Skilled Nursing Facilities (SNFs) would see a $920 million (2.4%) increase in Medicare payments in FY 2017. The rule also finalizes modifications to the SNF Quality Reporting Program (QRP), adding three quality measures to satisfy resource use and other measure domains and one quality measure to satisfy the medication reconciliation domain requirements under the Improving Medicare Post-Acute Care Transformation Act of 2014. Additionally, the final rule makes changes to the SNF Value-Based Purchasing (VBP) program. Those changes call for the SNF 30-Day Potentially Preventable Readmission Measure to be identified as the all-cause, all-condition risk-adjusted potentially preventable hospital readmission measure. The rule also establishes performance standards and analysis frameworks for the SNF VBP program.

CMS Issues IPPS Final Rule

On August 2, the Centers for Medicare and Medicaid Services (CMS) issued the Inpatient Prospective Payment System (IPPS) final rule, which increased IPPS Medicare payments in FY 2017 while decreasing payments to Long Term Care Hospitals (LTCHs) with updates to the LTCH Prospective Payment System. The CMS fact sheet regarding the final rule remarked that the policies in the final rule reflect an effort to "increasingly shift Medicare payments from volume to value." The final rule becomes effective October 1, 2016. According to CMS, it will apply to approximately 3,330 acute care hospitals and 430

LTCHs.

The final rule provides that acute care hospitals paid under the IPPS that successfully participate in Hospital Inpatient Quality Reporting (IQR) and are meaningful electronic health record (EHR) users will see increases in payment rates of approximately 0.95%. Those IPPS hospitals that do not successfully participate in either or both programs will see reductions. Hospitals that do not participate in the Hospital IQR Program and do not submit the required quality data will see a one-fourth reduction of the market basket update, while any hospitals which are not meaningful EHR users will see a three-fourths reduction. In its fact sheet, CMS projects that total Medicare spending on inpatient hospital services will increase by about $746 million in FY 2017.

For LTCHs, CMS expects that changes made to the LTCH PPS will result in a payment decrease of 7.1% in FY 2017. CMS cites the "continued phase-in" of adjustment changes required by the Pathway for SGR Reform Act of 2013 that establishes two different types of LTCH PPS payment rates based on a patient meeting certain clinical criteria as the reason for the decreases. However, LTCH PPS payments that qualify for a higher-level payment track under the Pathway for SGR Reform Act of 2013 will see a 0.7% increase.

Notably, the rule also permanently shelved the controversial 0.2% Medicare rate cut under the "two-midnight" policy, both retrospectively and prospectively. Upon review of the rule, and amid stakeholder criticism, CMS decided to permanently remove the policy and increase the reimbursement rate by 0.8% to offset its effects in FY 2014, 2015, and 2016.

Under the final rule, Medicare disproportionate share hospital (DSH) payments will decrease by about $400 million from the FY 2016 amount, with CMS distributing nearly $6 billion in DSH payments in FY 2017.

The final rule also finalizes the extension of the Medicare-Dependent Hospital (MDH) Program and low-volume hospital adjustment provided by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The extensions were implemented in an interim final rule issued by CMS on August 17, 2015, and provide that a hospital can qualify as a low-volume hospital if it is located more than 15 road miles from another hospital and has fewer than 1,600 Medicare discharges.

With respect to the Hospital-Acquired Condition (HAC) Reduction Program, the final rule makes five changes, as summarized in the CMS fact sheet:

1. "Establishing National Healthcare Safety Network (NHSN) CDC Healthcare Associate Infections (HAI) data submission requirements for newly opened hospitals;
2. Clarifying data requirements for newly opened hospitals;
3. Establishing performance periods for the FY 2018 and FY 2019 HAC Reduction Program;
4. Adopting the refined PSI 90: Patient Safety for Selected Indicators Composite Measure (NQF # 0531); and
5. Changing the Program scoring methodology from the current decile-based scoring to a continuous scoring methodology."

CMS also made changes to the Hospital Value-Based Purchasing (VBP) Program, which was established under the ACA and adjusts payments for inpatient services based on meeting a certain set of measures. The rule expands the number of hospital units to which two National Healthcare Safety Network

measures apply beginning with the FY 2019 program. CMS also finalized expansion of the cohort used to calculate the 30-day pneumonia mortality measures, and the addition of two condition-specific payment measures (one for acute myocardial infarction and one for heart failure), both beginning with the FY 2021 program year. It also added a 30-day mortality measure following coronary artery bypass graft surgery beginning with the FY 2022 program year.

Additionally, the rule: finalizes a number of updates to the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, including two new measures beginning with the FY 2019 payment determination; adds a measure of Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program; updates the public reporting policy under the Hospital Readmissions Reduction Program to require that excess readmission rates will be timely posted to the *Hospital Compare* website; and includes requirements for hospitals reporting clinical quality measures for the Medicare and Medicaid HER Incentive Programs.

CMS Posts Medicare Outpatient Observation Notice Comment Period

On August 1, the Centers for Medicare and Medicaid Services (CMS) requested comments on its proposed Medicare Outpatient Observation Notice (MOON). Hospitals must notify Medicare beneficiaries when they are under observation for more than 24 hours and not admitted as inpatients under the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act). The status as an outpatient under observation carries different cost and care implications: Medicare will pay for post-acute care at a skilled nursing facility after a hospital inpatient stay, but not after an observation-classified stay. The deadline for hospitals to comply with the notice requirements under the NOTICE Act was August 6, 2016, however, CMS delayed the deadline for "no later than 90 days" under the 2017 IPPS final rule in order to give more time to revise the standardized notification form hospitals use to notify patients about the status. Comments on the proposed MOON were due by September 1.

OIG Updates IRO Independence Guidance

On August 24, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued updated guidance concerning Independent Review Organization (IRO) independence. This update adopts the standards for auditor independence and objectivity set forth by the Government Accountability Office in the 2011 revision of its Government Auditing Standards.

You can read the full guidance here: https://oig.hhs.gov/fraud/cia/docs/iro-guidance-2016.pdf

Federal Court Rejects Increased Risk Theory of Standing in Data Breach Case

On August 10, the U.S. District Court for the District of Columbia dismissed a class action lawsuit against CareFirst BlueCross BlueShield for lack of standing (*Attias v. CareFirst, Inc.*, No. 15-cv-00882 (D.D.C. Aug. 10, 2016)). The lawsuit arose out of a 2014 cyber-security breach that compromised the privacy of 1.1 million policyholders. CareFirst reported the breach in May 2015, disclosing that protected health information (PHI) had been compromised, but not sensitive PHI such as social security and credit card numbers. Plaintiffs alleged imminent injury as a result of the breach, citing hackers' intended misuse of the acquired PHI. The court rejected that assertion, characterizing it as too speculative to satisfy the Supreme Court's "certainly impending" injury standard articulated in *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138 (2013). The court noted that the Plaintiffs were not likely to be at an increased risk of identity theft because their social security and credit card numbers were not compromised. The court also rejected the plaintiffs' other claims for economic harm for purchasing credit-monitoring services and overpayments for their insurance coverage, loss of the intrinsic value of their personal information, and violation of their

statutory rights under consumer protection acts.

DHHS Announces $53 Million for Opioid Treatment and Prevention

On August 31, the U.S. Department of Health and Human Services (DHHS) announced $53 million in funding for opioid misuse treatment and prevention. The funds are intended to support the following six programs:

- Medication-Assisted Treatment Prescription Drug Opioid Addiction Grants will provide up to $11 million to expand access to medication-assisted treatment for individuals struggling with opioid misuse.
- Prescription Drug Opioid Overdose Prevention Grants will provide up to $11 million to reduce opioid overdose-related deaths.
- The Strategic Prevention Framework Partnerships for Prescription Drugs Grants will provide up to $9.3 million to 21 states and four tribes to strengthen drug misuse prevention efforts.
- The Prescription Drug Overdose: Prevention for States provides up to $11.5 million in supplemental funding to support the ongoing work of awardees, allowing awardees to address issues such as high overdose death rates in tribal communities, and improve toxicology and drug screening.
- The Prescription Drug Overdose: Data-Driven Prevention Initiative will provide $6 million to advance and evaluate state-level prevention activities to address opioid misuse and overdose.
- The Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality program will provide $4.27 million in order to better track fatal and nonfatal opioid-involved overdoses.

CMS Announces 2017 Medicare EHR Payment Adjustment

On September 2, the Centers for Medicare and Medicaid Services (CMS) announced the 2017 Medicare payment adjustments for hospitals participating in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs that are not meaningful users of Certified EHR Technology. CMS explained that hospitals that do not meet meaningful use requirements during reporting periods within payment adjustment years would see decreased Medicare payments for that year. CMS specified that the adjustment is applied as a reduction to the applicable percentage increase to the Inpatient Prospective Payment System (IPPS) rate, reducing the update to the IPPS standardized amount for hospitals that fail to demonstrate meaningful use. Those hospitals will see a 25% decrease for 2015 (2013 reporting year); 50% decrease for 2015 (2014 reporting year); and 75% decrease in 2017 (2015 reporting year). CMS noted that hospitals may apply for hardship exceptions to avoid the adjustments. However, applications must be submitted no later than April 1 of the year before the applicable payment adjustment year.

CMS Adds Flexibility to MACRA Participation

On September 8, the Centers for Medicare and Medicaid Services (CMS) released four participation options for physician practices complying with the requirements under the Medicare Authorization and CHIP Reauthorization Act of 2015 (MACRA), scheduled for implementation January 1, 2017. In a blog post, acting administrator of CMS, Andy Slavitt, encouraged physicians to "pick your pace" for the Quality Payment Program and summarizes the four options as follows: Option 1 provides that as long as a physician practice submits some data to the Quality Payment Program, including data from after January 1, 2017, they will avoid a negative payment adjustment. Slavitt explained that this option is intended to make sure that practices are prepared for increased participation in 2018 and 2019. Option 2 involves practices who submit data for a partial year, providing that they can still qualify for a small positive payment adjustment, even if the data for their first performance period begins after January 1. Option 3 is for providers already prepared for MACRA on January 1, which, if they submit data

for a full calendar year, can qualify for a modest positive payment adjustment. Finally, Option 4 is for those practices participating in an advanced alternative payment model, giving those practices the opportunity to qualify for a five percent incentive payment in 2019. Option 3 and Option 4 are part of the original participation options which allow physicians to participate in one of two payment tracks – the Merit-based Incentive Payment System and the Advanced Alternative Payment Model (APM). Slavitt stated that the final rule, which will be released November 1, will describe the options more fully.

October 1 Marks End to ICD-10 Grace Period

On October 1, the one-year grace period established by the Centers for Medicare and Medicaid Services (CMS) for the new ICD-10 code set ends, and physicians can now expect that claims will be processed normally and rejected if they do not utilize the specificity required in the new code set. The ICD-10 code was implemented on October 1, 2015, to the dread of many practitioners, and in response to concerns that it would result in substantial coding errors as practices adjusted to the new codes, CMS instituted the one-year grace period so that contractors would not audit claims during the one-year grace period after implementation so long as they included a valid ICD-10 code from the right family.

STATE DEVELOPMENTS

Medicaid Substance Use Disorder Benefits Now Available to All Medicaid Recipients

Effective July 1, the population of Medicaid recipients eligible to receive substance use disorder (SUD) treatment expanded to include the 140,000 standard Medicaid recipients. This ensures these individuals access to the same coverage currently available to the approximately 49,000 individuals enrolled in New Hampshire Health Protection Program. Coverage includes access to comprehensive SUD services, including assessment, outpatient services, residential treatment, opioid treatment, recovery support services and recovery monitoring.

Medical Marijuana Dispensary Opens in Merrimack

On August 11, the Prime Alternative Treatment Center (ATC) opened for business operations, making it the fourth and final medical cannabis dispensary to begin operating in the state. The ATC dispensary participates in the state's Therapeutic Cannabis program, which is designed to provide qualifying patients with effective, alternative treatment.

Cigna to Provide Coverage for 3D Mammography

On August 23, Cigna announced a revision to its medical review policy to allow coverage for 3D mammography for routine breast screening procedures performed on or after August 23, 2016. Previously, Cigna covered 3D mammography only for diagnostic mammography procedures. Cigna stated that policies are regulatory reviewed and changed based on new evidence and guidance and specifically cited recent new guidance from the National Comprehensive Care Network.

Maine-Based Community Health Options to Withdraw From New Hampshire in 2017

On September 1, Maine-based Community Health Options announced its intention to withdraw its business from New Hampshire to focus on its core market in Maine. The announcement follows reports of higher than expected costs which prompted MCHO to curtail new sale of individual plans in 2016. Over 11,500 individuals in New Hampshire currently have insurance coverage through Community Health Options. The withdrawal of Community Health Options from the New Hampshire marketplace in 2017 will leave policyholders four alternative insurance companies with numerous plans to choose from when open enrollment begins in November.

New Hampshire Attorney General Joins in Effort to Block Anthem-Cigna Merger

On July 21, New Hampshire Attorney General Joseph Foster announced that New Hampshire has joined with the U.S. Department of Justice and 11 other states in bringing suit to block Anthem's proposed acquisition of Cigna. The suit alleged that the acquisition would harm competition by reducing the number of competing providers of health insurance. Reports show that Anthem and Cigna combined control approximately 64% of the New Hampshire insurance market. Noting the benefits of robust competition has had in inspiring innovation among competitors while keeping cost under control, Attorney General Foster expressed concern about the detrimental effect the proposed merger would have on New Hampshire consumers.

Minuteman Health Sues Over Risk Adjustment Program

Minuteman Health, a non-profit health insurer operating in New Hampshire, has sued the U.S. Department of Health and Human Services and CMS after it was ordered to pay $16.7 Million under the Affordable Care Act's risk adjustment program. The risk adjustment program evaluates the actuarial risk based relative health status of insured and adjusts payment to the insurer accordingly. Minuteman claims its premiums are lower not because its customers are healthier but because it focuses on maintaining lower costs.

New Hampshire Board of Medicine Approves Proposed Opioid Prescribing Rules

On September 7, the NH Board approved final proposed rules governing the prescribing of opioids. These rules modify existing rules effective in May. Modifications include the addition of new requirements on the use of opioids for the treatment of acute pain including requirements to complete a risk assessment, document a treatment plan and utilize an informed consent. It limits the amount of opioids to be prescribed in an emergency room, urgent care setting or walk-in clinic to a 7 day supply. For the treatment of chronic pain, the proposed rules require re-evaluation of the treatment plan and the use of opioids twice a year rather than every 4 months. The proposed rules which are intended to be effective on January 1, 2107 will be considered by the Joint Legislative Committee on Administrative Rules.

A copy of the final proposed rules may be found at
https://www.nh.gov/medicine/documents/med502fpwithchanges_9-7-16.pdf

New Opioid CME Requirement for New Hampshire Prescribers

Effective September 1, 2016, prescribers who are required to register with the Prescription Health and Safety Program and who possess a DEA number will have to complete 3 hours of board-approved continuing education or pass an online examination in the area of pain management and/or addiction disorder in order to obtain or renew a license. A list of the approved CME course and on-line examination will be available on the website of the Board which licenses the particular prescriber.

State Seeks 1115 Waiver Amendments

On August 10, the New Hampshire Department of Health and Human Services (NHDHHS) submitted a proposal to amend its Medicaid Section 1115 Waiver to the Centers for Medicare and Medicaid Services (CMS). The proposal would include a work requirement similar to the Federal Temporary Assistance for Needy Families Program (TANF) work requirement for the New Hampshire Health Protection Program (NHHPP), the state's expanded Medicaid program. The work requirement would call for beneficiaries to be engaged in at least 30 hours per week of qualified activities in order to receive NHHPP benefits. The proposal also contains amendments that would redesign cost-sharing for

emergency room visits in non-emergency situations, as well as extend coverage to veterans who want to receive their medical care in any of the state's hospitals. The state requested that the amendments, should they be approved, become effective on January 1, 2017.

2016 Legislative Updates

A final report on bills considered in the last legislative session.

House Bills

HB 1210: This bill clarifies when it is appropriate for practitioners to adjust or prescribe controlled drugs to patients by telemedicine. It was amended to address the amount charged for filling prescriptions requiring it to be the pharmacy's usual and customary price or the contracted copayment, whichever is less**. Signed into law by the Governor. Parts of the bill were effective upon passage with the remaining provisions effective August 8, 2016.**

HB 1246: This bill exempts certain persons employed as speech language assistants from requirements for certification by the governing board of speech language pathologists. This primarily addresses the exemption of individuals working at a public or non-public school working under the direction of a licensed person. As amended the bill also requires rulemaking to address the new licensure/certification requirements**. Signed into law by the Governor on June 9, 2016, the bill became effective on August 8, 2016.**

HB 1269: This bill amends RSA 151-G:1,II(e) and extends the New Hampshire health care quality assurance commission until July 1, 2021. As amended, the bill provides for three at large members with one appointed by the Speaker of the House, one appointed by the President of the Senate and one appointed by the Governor. **The bill was signed into law by the Governor on June 3, 2016 and was effective upon passage.**

HB 1423: This bill requires the Board of Medicine, the Board of Dental Examiners, the Board of Nursing, the Board of Registration in Optometry, the Board of Podiatry, the Naturopathic Board of Examiners, and the Board of Veterinary Medicine to adopt rules for prescribing controlled drugs. This bill contains mandatory standards for such rules and requires using the controlled drug prescription health and safety program database. The bill delays the requirement for providers to check the program database until 90 days after upgrades to the program have been completed which upgrades are to be completed by October 3, 2016. That deadline may be further extended by the Governor if upgrades have not been made to the program by then. **Signed into law by the Governor on June 7, 2016. Except for specific effective dates noted, the bill became effective upon passage.**

HB 1453: This bill adds ulcerative colitis to the list of qualifying medical conditions for purposes of therapeutic cannabis. The bill was signed into law by the Governor on June 3, 2016 and was effective on August 2, 2016.

HB 1490: This bill revises the requirements for the qualifications, standards, and supervision of collaborative pharmacy practice agreements between pharmacists and health care practitioners. The bill was amended to allow registered pharmacies to establish a drug take-back program provided the program complies with federal requirements and to amend the definition of hazardous waste to exclude household

pharmaceutical waste**. The bill was signed into law by the Governor on June 7, 2016 and became effective on August 6, 2016.**

HB-1608-FN: This bill requires all health insurers, HMOs, health services corporations, medical services corporations and preferred provider programs to use and accept only the uniform prior authorization forms developed by the Commissioner of Insurance beginning December 31, 2017. Rules governing the contents and format of such prior authorization forms will be adopted by March 1, 2017. **This bill was signed into law by the Governor on June 9, 2016 and became effective upon passage.**

Senate Bills

SB 329: This bill adopts the revised model act for the nurse licensure compact under RSA 326-B:46. As amended, the bill clarifies that a nurse licensed in another state working under the compact is not included in the definition of Medical Technician. **The bill was signed into law by the Governor on June 10, 2016. The revised nurse licensure compact shall become effective upon the legislative enactment of the compact by no less than 26 states or December 31, 2018, whichever is earlier. The remainder of the bill became effective upon passage.**

SB 369-FN: The Senate version of this bill requires public schools to include an age appropriate drug and alcohol education in their health education curriculum whereas the House version encourages it. The final bill requires schools to provide age and developmentally appropriate drug and alcohol education to pupils. **The bill was signed into law by the Governor on June 21, 2016 and became effective on August 20, 2016.**

SB 417: This bill prohibits certain geographic area restrictions in partnership, employment, or other professional relationship contracts for physicians licensed by the board of medicine. The bill was signed into law by the Governor on June 6, 2016 and became effective on August 5, 2016.

SB 481-FN: This bill replaces some of the functions of the Certificate of Need process which is due to sunset on June 30, 2016. This bill establishes procedures to acquire a health care service license under the law governing health facility licensure. It will require persons offering certain health care services including cardiac catheterization laboratory services, open heart surgery, radiation therapy and certain other diagnostic or therapeutic tests or process to obtain a special health care services license. **The bill was signed into law by the Governor on June 6, 2016 and became effective on July 1, 2016.**

SB 496: This bill clarifies the definition of a severely disabled person and allows access to the community for such persons under the law governing personal care for the severely physically disabled. As amended, the bill designates that personal care services must be medically necessary and may be delivered in non-institutional locations in which normal life activities occur. The bill was signed by the Governor on June 21, 2016 and became effective on August 20, 2016.

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

BIOS

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