Health Care Practice Group

Cinde Warmington
Chair
cwarmington@
shaheengordon.com

William E. Christie
wchristie@
shaheengordon.com

Steven M. Gordon
sgordon@
shaheengordon.com

Lucy J. Karl
lkarl@
shaheengordon.com

Kara J. Dowal
kdowal@
shaheengordon.com

S. Amy Spencer
saspencer@
shaheengordon.com

Timothy J. McLaughlin
tmclaughlin@
shaheengordon.com

www.shaheengordon.com

Tenacity, Creativity and Results are the three words that best describe Shaheen & Gordon's approach to addressing complex legal issues. Our health care team closely monitors the rapidly changing legal environment so that our clients are prepared to meet the challenges of today as well as tomorrow. Relying on a wealth of experience, we offer practical advice and assist in implementing recommendations tailored specifically to meet the needs of both large and small health care clients.

FEDERAL DEVELOPMENTS

CMS Publishes ACA Insurance Market Stabilization Rule for 2018 Enrollment

On April 13, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule on Affordable Care Act ("ACA") market stabilization in anticipation of open enrollment for the 2018 benefit year. The final rule shortens the open enrollment period which begins on November 1, 2017 from three months to roughly six weeks, ending on December 15, 2017 rather than January 31, 2018. The rule claims that this change will reduce opportunities for adverse selection by those who learn they will need medical services in late December and January, and will encourage healthy individuals to enroll in full-year coverage. The final rule also increases pre-enrollment verification for special enrollment periods and makes several additional changes to CMS regulations regarding special enrollment periods that are intended to improve the risk pool, improve market stability, promote continuous coverage, and increase options for patients.

The final rule allows insurers to apply a premium payment to an individual's past debt owed for coverage from the same issuer or a different issuer in the same controlled group within the prior 12 months before applying the payment toward a new enrollment. CMS says that this change is intended to remove economic incentives individuals may have had to pay premiums only when they were in need of healthcare services, particularly toward the end of the benefit year, and to encourage continuous coverage.

Concurrently with the issuance of the final rule, CMS also published a number of related guidance documents.

The guidance documents may be read at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-04-13-2.html.

The final rule is published at 82 FR 18346 and may be read at: https://www.federalregister.gov/documents/2017/04/18/2017-07712/patient-protection-and-affordable-care-act-market-stabilization.

U.S. District Court Holds that the Stark Law's "Signed Writing" Requirement is Material Under the False Claims Act

On March 15, 2017, the U.S. District Court for the Western District of Pennsylvania issued an opinion in *United States ex rel. Tullio Emanuele v. Medicor Associates* in which it interpreted the U.S. Supreme Court's recent holding in *Universal Health Services, Inc. v. United States. ex rel. Escobar* on the "materiality" element of the False Claims Act ("FCA"). In *Emanuale*, the relator brought an FCA action against Medicor Associates that alleged that Medicor had been providing payment for professional services without an executed and effective professional services agreement, thus violating the "signed writing" requirement of the Stark Law.

The Court first noted that the signed writing requirement contained in the professional services agreement exception – and many other exceptions – to the Stark Law "is not a mere technicality," and held that, despite Medicor's attempt to cobble together contemporaneous writings as evidence of a signed agreement, no such agreement existed and therefore the arrangement failed to satisfy any exception to the Stark Law.

The Court then turned to the FCA claim itself to determine whether the failure to have a signed writing in place is material to the government's payment decision. In *Escobar*, the Supreme Court listed numerous factors for use in determining materiality, including" whether compliance with a statute is a condition of payment; whether the violation goes to "the essence of the bargain" or is "minor or insubstantial"; and whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations. The Court applied these factors and held that a reasonable jury could find that the defendant's failure to have a signed writing in place memorializing the arrangement is material under the FCA. The defendant will now have to persuade a jury that its failure to have a signed writing, and thus its violation of the Stark Law, was not material to the government's payment decision.

The District Court's decision in *Emanuele* can be read at: http://www.leagle.com/decision/In%20FDCO%2020170316E64/U.S.%20EX%20REL.%20EMANUELE%20v.%20MEDICOR%20ASSOCIATES.

Failure to Conduct Adequate Risk Assessment Results in $400,000 HIPAA Settlement for FQHC

On April 12, 2017, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") announced a $400,000 settlement with Metro Community Provider Network ("MCPN"), a Federally-qualified health center ("FQHC"), resulting from MCPN's failure to comply with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Privacy and Security Rules.

MCPN filed a breach report with OCR on January 27, 2012, concerning a phishing attack that obtained the electronic protected health information ("ePHI") of 3,200 individuals. However, a further investigation by OCR reveled that MCPN failed to conduct any risk analysis until mid-February, and had not conducted a risk analysis to assess the risks and vulnerabilities in its ePHI environment, and, consequently, had not implemented any corresponding risk management plans to address the risks and vulnerabilities identified in a risk analysis. When MCPN later conducted a risk analysis, that risk analysis, as well as all subsequent risk analyses, were insufficient to meet the requirements of the Security Rule.

OCR's Press Release announcing the settlement can be read at: https://www.hhs.gov/about/news/2017/04/12/overlooking-risks-leads-to-breach-settlement.html.

The Resolution Agreement and Corrective Action Plan may be found on the OCR website at: http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/MCPN.

CMS Proposes 2.9% Increase in Medicare Payment to IPPS Hospitals

On April 14, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule (published in the *Federal Register* on April 28) containing a number of policy updates for 2018 Medicare payments. In a fact sheet also issued on April 14, CMS projected that the total increase in Inpatient Prospective Payment System ("IPPS") operating payments will be 2.9%, composed of a 1.7% increase in IPPS operating payments plus proposed changes in uncompensated care payments of 1.2%. The proposed

increase would result in higher Medicare spending of $3.1 billion in fiscal year 2018. The proposed rule also contained changes for payment rates under the Long-Term Care Hospital ("LTCH") Prospective Payment System ("PPS"), which would decrease by 3.75% or $173 million from the previous year. The proposed changes, applying to approximately 3,330 acute care hospitals and 420 LTCHs would affect discharges on or after October 1, 2017.

Under the proposed rule CMS is also proposing to distribute approximately $7 billion in uncompensated care payment in FY 2018. CMS explained that this increase of approximately $1 billion from FY 2017 is the result of CMS' proposal to incorporate data from its National Health Expenditure Accounts into the estimate of the percent change in the rate of uninsurance, which is used to calculate the amount of payments available to be distributed.

The proposed rule contains five changes to the Hospital-Acquired Conditions ("HAC") Reduction Program policies, including "(1) [s]pecifying the dates of the time period used to calculate hospital performance for the FY 2020 HAC Reduction Program; (2) requesting comments on additional measures for potential future adoption; (3) requesting comments on social risk factors; (4) requesting comments on accounting for disability and medical complexity in the CDC NHSN [Centers for Disease Control National Healthcare Safety Network] measures in Domain 2 [one of the two applicable scoring measures for the HAC Reduction Program]; and (5) updating the HAC Reduction Program's Extraordinary Circumstances Exception policy."

The proposed rule also includes proposed changes to the Hospital Readmissions Reduction Program ("HRRP"), including a proposal by CMS to implement changes to the payment adjustment factor in accordance with the 21st Century Cures Act and penalties based on a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and full-benefit Medicaid.

Other changes contained in the 2018 IPPS Proposed Rule include: changes to the "meaningful use" electronic health records policy, such as creating exemptions for providers who offer "substantially all" of their services at ambulatory surgery centers; easing the enforcement of the Critical Access Hospital 96-hour certification requirement by making it a low priority in medical record reviews; and shortening the EHR reporting periods from a full year to any continuous 90-day period for new and returning participants attesting to CMS or state Medicaid agencies.

Comments on the proposed rule were due to CMS by June 13, 2017.

You can access the proposed rule (82 Fed. Reg. 19796) here: https://www.gpo.gov/fdsys/pkg/FR-2017-04-28/pdf/2017-07800.pdf

CMS Issues Proposed Rule Increasing Medicare Pay to IRFs

On April 27, 2017, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule containing payment and policy changes for Medicare Inpatient Rehabilitation Facilities ("IRFs"). The proposed rule would increase IRF prospective payment system ("PPS") payments by 1.0%, or $80 million in fiscal year 2018. The proposed rule maintains current the facility-level adjustment factors at current levels. The proposed rule would also eliminate the current 25% penalty for IRF patient assessment instrument submissions that are not timely transmitted to CMS' data repository.

After analyzing the presumptive methodology lists in ICD-10-CM over the past year, CMS is proposing refinements to the lists to ensure that they continue to reflect the list of 60% rule qualifying conditions. The proposed rule seeks comments on the 60% rule, qualifying conditions, and the proposed refinements.

Comments are due June 27. The proposed rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-08428.pdf.

A CMS Fact Sheet on the proposed rule is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-04-27-2.html.

Improper Disclosure of PHI in Press Release Results in $2.4 Million HIPAA Settlement

On May 10, 2017, the U.S. Department of Health and Human Services Office of Civil Rights ("OCR") announced a $2.4 million settlement of violations of the Health Insurance Portability and Accountability Act ("HIPAA"). Memorial Hermann Health System ("MHHS") agreed to pay $2.4 million and adopt a corrective action plan to settle allegations that it improperly disclosed a patient's protected health information ("PHI") without authorization.

The HIPAA violation stemmed from an incident in 2015 in which a MHHS patient presented a fraudulent identification card. MHHS staff alerted law enforcement, properly disclosing the patient's PHI in the process, but subsequently released the patient's name in a press release concerning the incident.

"Senior management should have known that disclosing a patient's name on the title of a press release was a clear HIPAA Privacy violation that would induce a swift OCR response," said OCR Director Roger Severino. "This case reminds us that organizations can readily cooperate with law enforcement without violating HIPAA, but that they must nevertheless continue to protect patient privacy when making statements to the public and elsewhere."

OCR's press release is available at: https://www.hhs.gov/about/news/2017/05/10/texas-health-system-settles-potential-hipaa-disclosure-violations.html.

The resolution agreement and corrective action plan is available at: https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/MHHS/index.html.

Compliance Deadline for Home and Community-Based Care Medicaid Rule Extended for Three Years

On March 9, 2017, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") announced that that it was extending the deadline for state Medicaid programs to meet the Home and Community Based Services ("HCBS") settings requirements for settings operating before March 17, 2014. State Medicaid programs will now have until March 17, 2022 to demonstrate compliance with the Final Rule on HCBS that was issued on January 16, 2014. The extension was given in response to states' request for more time to demonstrate compliance with the regulatory requirements and ensure that compliance activities are collaborative, transparent, and timely.

The 2014 Final Rule offered states new flexibilities in providing necessary and appropriate services for the elderly and disabled populations, and amended Medicaid regulations to provide home and community-based setting requirements related to the Affordable Care Act's Community First Choice State

plan option.

CMS' announcement of the extension is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-05-09.html.

The January 16, 2014 Final Rule on HCBS is available at: https://www.gpo.gov/fdsys/pkg/FR-2014-01-16/pdf/2014-00487.pdf.

$1.9 Billion Recovered from Medicaid Fraud Control Units in 2016

On May 19, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") reported fiscal year 2016 recoveries by Medicaid Fraud Control Units (MFCUs) of almost $1.9 billion. In its annual MFCU report, the OIG reported civil recoveries amounting to $1.5 billion and criminal recoveries of $368 million. MFCUs reported a total of 1,564 convictions, 74% of which were cases involving fraud while the remaining 26% were involving cases of patient abuse or neglect. The largest category of convictions came from personal care services, at about 35% of the total reported convictions, followed by nursing care at 11% and nurse aides at 10%. MCFUs reported 998 civil settlements and judgments, 46% of which involved pharmaceutical manufacturers. The OIG highlighted drug diversion as a "significant and growing case area for the MCFUs." The OIG also noted that both convictions and civil settlement and judgments were at a five-year high and that MFCUs recovered approximately $7 for every $1 spent.

The annual report is available at: https://oig.hhs.gov/oei/reports/oei-09-17-00210.pdf

Update to Ransomware Guidance

On May 15 and 17, the Department of Health and Human Services ("HHS") issued updates to its ransomware guidance for health care organizations in response to the WannaCry cyber attack. The WannaCry ransomware strain infected computers in over 150 countries, including those in Britain's National Health Service. HHS advised that any health care entity that is the victim of a ransomware attack should immediately contact the Federal Bureau of Investigation ("FBI") Field Office Cyber Task Force. It also recommended reporting cyber incidents to the United States Computer Emergency Readiness Team ("US-CERT") and the FBI's Internet Crime Complaint Center. HHS also reinforced that pursuant to its prior guidance issued in 2016, the Office of Civil Rights ("OCR") presumes a breach in the event of a ransomware attack. The OCR noted, "[i]f the data is not encrypted by the entity to at least NIST specifications when the ransomware attack is deployed, then OCR presumes a breach occurred, due to the ransomware attack. As such, the entity would need to prove, through forensic or other evidence, that the ePHI was encrypted when the attack occurred, and the ransomware containerized (or encrypted again) already-encrypted ePHI."

The guidance is available at: http://www.aha.org/content/17/170515-hhscyberupdate.pdf and at: https://content.govdelivery.com/accounts/USHHSONC/bulletins/19b26e7#HHSOfficeofCivilRigh

Direct Enrollment Available for Individual Market Coverage for 2018 Plan Year

On May 17, 2017, the Centers for Medicare & Medicaid Services ("CMS") Center for Consumer Information and Insurance Oversight issued new guidance allowing consumers purchasing individual market coverage on HealthCare.gov for the 2018 open enrollment period to complete their applications through the third-party website of direct enrollment ("DE") entities. Rather than redirecting consumers to complete applications on the federal platform, under the guidance, DE entities can collect consumer information and input it directly into HealthCare.gov via a "proxy direct enrollment" pathway. The guidance cited an effort to

improve the customer experience, make accessing coverage easier, and easing regulatory burdens on DE entities as reasons for the update. CMS stated it will be implementing restrictions on DE entities, including requiring that they submit to auditing and testing.

ACA Innovation Waiver "Checklist" Available for States

On May 16, the Centers for Medicare and Medicaid Services ("CMS") released a checklist to assist states with meeting the requirements to apply for Section 1332 Affordable Care Act ("ACA") innovation waivers. The innovation waivers allow states to establish high-risk/state-operated reinsurance programs, that CMS Administrator Seema Verma stated "will help lower premiums, stabilize the health insurance exchange, and meet the unique needs of each state."

The checklist can be accessed here: https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/Checklist-for-Section-1332-State-Innovation-Waiver-Applications-5517-c.pdf#sthash.Lv5xbSPR.dpuf

Delay of HRSA Rule 340B CMPs, Ceiling Prices Extended

On May 19, the Department of Health and Human Services ("HHS") Health Resources and Services Administration ("HRSA") announced another delay to the effective date of the final rule imposing civil monetary penalties ("CMPs") on drug manufacturers when they overcharge safety net providers for outpatient drugs sold under the 340B Program. The final rule also establishes the calculation of ceiling prices (the maximum amounts drug manufacturers may charge for covered outpatient drugs). The new effective date will be October 1, 2017, pushed back from May 22, 2017. HHS stated that the extension would help stakeholders prepare for complying with the new requirements.

The final rule (82 Fed. Reg. 1210) may be found here: https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf

The announcement of the delayed effective date may be found here: https://www.gpo.gov/fdsys/pkg/FR-2017-05-19/pdf/2017-10149.pdf

House Passes ACA Repeal Bill; CBO Estimates 23 Million Would Lose Insurance

On May 4, 2017, the U.S. House of Representatives narrowly passed the American Health Care Act ("AHCA"), which would repeal and replace large pieces of the Affordable Care Act ("ACA"). After a previous attempt to pass the bill was withdrawn at the last minute due to a lack of Republican support, the AHCA passed on a party-line vote of 217-213. The increase in support came largely from members of the House Freedom Caucus, who had previously felt the bill did not go far enough in repealing the ACA, after an amendment by Rep. Tom McArthur (R-NJ) that would allow states to waive the requirement that insurance plans cover essential health benefits. Some moderates who had previously expressed displeasure at the bill's earlier iteration were won over by another amendment that would provide a fund of money to assist individuals with pre-existing conditions.

The AHCA includes provisions to end Medicaid expansion, eliminate the individual mandate and allow insurers to charge a fee to individuals who fail to maintain continuous coverage, and impose a one-year freeze on federal funding to abortion providers.

Various organizations, such as AARP and the American Hospital Association, expressed their opposition and criticism of the bill. Comments from senators indicate that Senate is likely to largely ignore

the content of the AHCA and craft its own bill, hoping for a more bi-partisan approach. Over 75 consumer advocacy groups sent a letter to Senate leaders on May 22 stating opposition to the AHCA and urging them to reject certain of its provisions.

The Congressional Budget Office ("CBO") released an updated score for the AHCA on May 24. After previously estimating that the previous version of the bill would increase the number of uninsured Americans by 24 million, the CBO updated that number to 23 million, and estimated that it would reduce the federal deficit by $119 billion. Most of the cost savings of the bill would be the result of reduction in Medicaid spending and replacement of ACA subsidies with tax credits. The CBO offered varying estimates for state populations, depending on whether and to what extent a state obtains a waiver to modify the coverage requirements. For states that do not obtain waivers or that make moderate changes, premiums would be likely to decrease by 2026 by up to 20%, in part due to insurers offering fewer benefits. For states that make significant changes to market regulations, premiums "would vary significantly according to health status and the types of benefits provided, and less healthy people would face extremely high premiums."

The text of the AHCA is available at: https://www.congress.gov/bill/115th-congress/house-bill/1628/text.

The CBO score for the AHCA is available at: https://www.cbo.gov/publication/52752.

The May 22 opposition letter from advocacy groups is available at: http://www.medicareadvocacy.org/more-than-75-national-organizations-urge-u-s-senate-to-defend-medicare-and-medicaid/.

Anthem-Cigna Merger Dies, Insurers Likely to Maintain Court Battle Over Damages

On May 12, 2017, a day after the Delaware Court of Chancery denied its motion for a preliminary injunction to prevent Cigna from terminating the merger, Anthem announced that it had provided notice to Cigna terminating the merger. The merger of two of the largest health insurers in the country had been beset by an antitrust challenge from the DOJ which had resulted in an injunction against the merger from the U.S. District Court in February, which was subsequently ratified in April by the D.C. Circuit. The District Court found that the merger would likely harm competition and be anticompetitive in the market for the sale of health insurance to "national accounts" – customers with more than 5,000 employees, usually spread over at least two states – within the fourteen states where Anthem operates as the Blue Cross Blue Shield licensee. The Court also found evidence that the merger would have anticompetitive effects on the sale of insurance to large groups in at least one market: Richmond, VA. The court was not convinced by Anthem's argument that any anticompetitive effects of the merger would be outweighed by the efficiencies it would generate, stating that the purported efficiencies of the merger "are not verifiable, and it is questionable whether they are efficiencies at all." The Court of Appeals affirmed the District Court's injunction, holding that the District Court did not abuse its discretion in enjoining the merger and that Anthem had failed to show that its claimed efficiencies would result in significant cost-savings. The Court of Appeals noted in its decision that by the time the injunction was heard on appeal, Cigna had turned against the merger and was wholly uncooperative to Anthem's case before the appellate body. Although Anthem petitioned for certiorari to the U.S. Supreme Court on May 5, the appeal is likely moot since the merger has been abandoned.

While the antitrust challenge played out in Federal court, the insurers were also engaged in a battle in the Delaware Court of Chancery. On February 14, Cigna terminated the merger and filed suit in Delaware, seeking a declaratory judgment affirming the termination and award of a contractual $1.85 billion

breakup fee and $13 billion in damages. Anthem then obtained a temporary restraining order enjoining Cigna from terminating the merger, but its subsequent request for a preliminary injunction was ultimately denied, resulting in Anthem terminating the merger. In its press release announcing the termination, Anthem stated its position that Cigna is not entitled to the contractual breakup fee and that "Cigna's repeated willful breaches of the Merger Agreement and its successful sabotage of the transaction has caused Anthem to suffer massive damages, claims which Anthem intends to vigorously pursue against Cigna." Industry experts expect that a court battle between the insurers over breakup damages could continue for years.

Anthem's May 12, 2017 press release is available at: http://ir.antheminc.com/phoenix.zhtml?c=130104&p=irol-newsArticle&ID=2272685.

OIG Issues Semiannual Report on Fraud Enforcement Efforts

In its Semiannual Report to Congress, covering the period October 1, 2016 through March 31, 2017, the U.S. Department of Health and Human Services, Officer of Inspector General ("OIG") announced the results of its fraud enforcement efforts during the six-month period. OIG reported 468 criminal actions and 461 civil actions brought against individuals or entities, including 49 charges and 152 criminal actions brought as a result of Health Care Strike Force efforts. OIG reported expected recoveries of $2.04 billion for the first half of FY 2017, compared with $2.77 billion reported for the same period of FY 2016. OIG also reported the exclusion of 1,422 individuals and entities from participation in Federal health care programs.

OIG's Semiannual Report is available at: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-spring-2017.pdf.

CMS Expects New Medicare Beneficiary Cards to Prevent Fraud

On May 30, 2017, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") announced that it will be issuing new Medicare beneficiary cards starting in April 2018. The new cards will no longer bear the Social Security-based Health Insurance Claim Number ("HICN") but will use a unique, randomly-assigned number called a "Medicare Beneficiary Identifier" ("MBI"). Providers and beneficiaries will both be able to use secure look up tools that will support quick access to MBIs when they need them. There will also be a 21-month transition period where providers will be able to use either the MBI or the HICN, further easing the transition. CMS expects to complete the transition to the new cards by April 2019.

"We're taking this step to protect our seniors from fraudulent use of Social Security numbers which can lead to identity theft and illegal use of Medicare benefits," said CMS Administrator Seema Verma. "We want to be sure that Medicare beneficiaries and healthcare providers know about these changes well in advance and have the information they need to make a seamless transition."

The change in beneficiary cards is part of CMS' "Social Security Number Removal Initiative" ("SSNRI"), which it is undertaking to comply with the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA").

CMS' announcement is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-05-30.html#sthash.XxcKZwXq.dpuf.

Information on CMS' SSNRI is available at: https://www.cms.gov/medicare/ssnri/index.html#sthash.XxcKZwXq.dpuf.

Following Lawsuit, CMS Proposes Ending Ban on Pre-Dispute Arbitration

On June 8, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a proposed rule that would end the prohibition on long term care ("LTC") facilities entering into pre-dispute arbitration agreements with residents and also ends the prohibition that prevents facilities from requiring residents to sign arbitration agreements as a condition of admission. These prohibitions were originally added to the Medicare and Medicaid participation requirements for LTC facilities in a final rule published by CMS on October 4, 2016. The introduction of these prohibitions was a reversal of CMS' position: prior to the final rule CMS had issued sub-regulatory guidance supporting arbitration between facilities and residents.

On October 17, 2016, following publication of the final rule, the American Health Care Association and a group of affiliated LTC facilities brought an action against CMS in United States District Court in Mississippi. The plaintiffs sought a preliminary and permanent injunction on the enforcement of the arbitration bans. The District Court issued a preliminary injunction on November 7, 2016, concluding that it would likely hold that the final rule's prohibition against LTC facilities entering into pre-dispute arbitration agreements was in conflict with the Federal Arbitration Act (FAA), and that it was unlikely that CMS could justify the rule, or could overcome the FAA's presumption in favor of arbitration, by relying on the agency's general statutory authority under the Medicare and Medicaid statutes to establish rights for residents or to promulgate rules to protect the health, safety and well-being of residents in LTC facilities.

In the proposed rule, CMS removes the arbitration prohibitions. CMS provides as justification its belief that a policy change regarding pre-dispute arbitration will achieve a better balance between the advantages and disadvantages of pre-dispute arbitration for residents and their providers and that a ban on pre-dispute arbitration agreements would likely impose unnecessary or excessive costs on providers.

CMS is requesting comments on the proposed rule by August 7, 2017.

CMS' proposed rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-06-08/pdf/2017-11883.pdf.

CMS Seeks Ideas from Public for Streamlining ACA Rules

On June 8, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a Request for Information ("RFI"), seeking public input on ways to streamline the regulation of individual and small health insurance markets under the Affordable Care Act ("ACA"). The request from CMS is intended to assist in compliance with Executive Order 13765, "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal," which directs the Secretary of Health and Human Services to work to reduce regulatory burdens and improve health insurance options under the ACA.

The RFI is scheduled to be published in the Federal Register on June 12, 2017. Responsive comments must be submitted on or before July 12, 2017.

The RFI is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-12130.pdf#sthash.cTChgmR4.dpuf.

CMS Predicts Nearly 100% of Advanced APMs Providers Will Receive Incentive Payment

In a recent update to its APM webpage, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") announced its prediction that approximately 100% of eligible clinicians in the Advanced Alternative Payment Models ("APMs") will be Qualifying APM Participants ("QPs") in performance year 2017 and will be eligible to receive a 5% APM Incentive Payment in 2019. CMS states that its prediction in based on claims with dates of service between 1/1/16 and 8/31/16 that were processed between 1/1/16 and 11/30/16. Providers are eligible for the 5% incentive payment if they receive 25% of Medicare payments or see 20% of their Medicare patients through an advanced APM.

The Advanced APMs were created to implement the Medicare Access and CHIP Reauthorization Act ("MACRA"), which seeks to modernize provider reimbursement and increase the focus on quality. Providers have the option of participating in the Advanced APMs, which allows for bonuses and incentives based on quality measures, or to remain in the traditional fee-for-service payment system with the addition of the new Merit-Based Incentive Payment System ("MIPS").

CMS' website on Advanced APMs is available at: https://qpp.cms.gov/learn/apms#sthash.zNzQ7qn5.dpuf.

HHS' Latest Status Report on Medicare Appeals Backlog Shows Slight Improvement

In its latest court-ordered status report, the U.S. Department of Health and Human Services (HHS") reported that it expects to have roughly 950 thousand pending appeals by the end of fiscal year 2021. This is slightly less than the over 1 million expected appeals it reported in March of this year. HHS is required to make regular updates to the U.S. District Court for the District of Columbia every 90 days. The District Court issued an order in December of 2016 requiring HHS to reduce its current backlog of appeals by 30% at the end of 2017, 60% at the end of 2018, 90% at the end of 2019, and in full by the end of 2020. HHS' report states that as of June 2, 2017 there were 607,402 appeals pending before the Office of Medicare Hearing Appeals. Based on current projections, HHS is unlikely to meet the court-ordered reduction goals, without additional funding. HHS recently included an additional $135 million in a recent budget request, which, if appropriated, HHS projects would result in a backlog of 353,603 appeals by the end of fiscal year 2021.

CMS Publishes Educational Resources for Understanding and Navigating MIPS

The U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") publishes educational resources for assisting providers in understanding and navigating the Merit-Based Incentive Payment System ("MIPS"), which was created as part of the implementation of the Medicare Access and CHIP Reauthorization Act ("MACRA"). MIPS is intended to introduce a greater emphasis on quality to the traditional fee-for-service Medicare payment system; alternatively, providers are able to participate in Advanced Alternative Payment Models. Recently-added resources include: MIPS Participation Fact Sheet; MIPS Improvement Activities Fact Sheet; MIPS 2017 Qualified Registries; and MIPS Data Verification Criteria.

The MIPS resources are available at: https://qpp.cms.gov/resources/education.

STATE DEVELOPMENTS

Insurance Department Releases Information about 2018 Marketplace Plans

On May 16, the NH Insurance Department announced that it has received initial filing forms from insurance companies that intend to offer medical and dental plans on the 2018 NH Marketplace. Three

companies have applied to offer small-group business plans including Anthem, Harvard Pilgrim and Minuteman. The same three insurers plus Ambetter from NH Healthy Families will offer individual plans. Delta Dental and Anthem will offer dental plans. The companies have until June 2 to submit their initial rate filing to the Insurance Department. By law, the Insurance Department is prohibited from releasing rate information about the 2018 Marketplace Plans until November 1, however information sessions on the networks likely to be available in 2018 will be held on June 26 and 28.

More information can be found at:
https://www.nh.gov/insurance/media/pr/2017/documents/051617.pdf

New Hampshire Office of Professional Licensure and Certification Transitioning to New License Processing Application

The New Hampshire Office of Professional Licensure and Certification has announced that it will be transitioning to a new and improved license processing application during the first few days of August. During the transition period, the processing of licensing applications will be delayed until the new system is fully functional. Any licensees who would normally renew in early August are encouraged to complete their renewal applications earlier. The OPLC oversees the professional licensure of numerous medical and non-medical professionals.

A complete list of those affected by this transition may be found at: https://www.oplc.nh.gov/

Board of Nursing Seeking Comments on Proposed Rule

On June 15, the Board of Nursing will hold a public hearing on a proposal to change the Board's Administrative Rules relative to the administration of medication by LNAs. The proposed rule would revise NH Admin. Rule 404(b)(4)(b) and (c) to impose requirements that LNAs administer medication to stable patients under specific circumstances.

More information about the proposed change and the scheduled hearing may be found at:
https://www.oplc.nh.gov/nursing/

Board of Medicine Reprimand Related to Marijuana Certification

In a Settlement approved on May 3, 2017, the Board of Medicine reprimanded a physician based on facts related, in part, to the qualification of a patient for a Medical Marijuana Certification form. The facts upon which the physician was reprimanded include his pain management of the patient, the failure to document patient phone calls for medication refills and the certification of the patient for medical marijuana. The Settlement Agreement includes concerns raised by the patient's parole office that the patient had a prior history of marijuana related convictions, including concerns of selling marijuana in the past, and that the patient had not had a recent brain scan to confirm the need. However, the physician felt that the patient's health conditions which included degenerative joint disease, peripheral neuropathy, hypertension and diabetes as well as 13 prior concussions resulting in traumatic brain injury, qualified him to receive medical marijuana and that overall he felt marijuana would be a better pain management medication than the patient's current treatment. Among the sanctions imposed by the Board was a requirement that the physician participate in 10 hours of continuing medical education including 2 in the area of medical marijuana.

2017 Legislative Updates

We are currently tracking the following Bills:

HB 157: This bill adds moderate to severe chronic pain to the definition qualifying medical conditions under therapeutic use of cannabis. **Status: Voted Ought to Pass with Amendment by the House. Adopted as amended by the Senate. Bill Enrolled.**

HB 160: This bill adds post-traumatic stress disorder to the qualifying medical conditions under therapeutic use of cannabis. **Status: Voted Ought to Pass with Amendment by the House. Amendment removes the requirement that a patient with post-traumatic stress disorder also experience one of the qualifying symptoms listed in the statute. Introduced in Senate and referred to Senate HHS Committee. Bill was further amended to expand on the statement given with the registry identification card to clarify the potential implications of possessing a registration card and using cannabis.**

HB 184-FN: This bill repeals RSA 328-J, the regulation of medical imaging and radiation therapy under the board of medical imaging and radiation therapy. **Status: Voted Ought to Pass by the House and Senate. Bill was amended by the House to change the bill from a repeal of the license requirement to an extension of the enactment date of the registration requirement from July 1, 2017 to July 31, 2018. The Senate passed the amended bill, signed into law by the Governor to be effective upon passage, April 17.**

HB 208: This bill establishes a commission to study current mental health procedures for involuntary commitment. **Status: Voted Out to Pass with Amendment by the House and Senate. Amendments changed the composition of the commission. The House concurred with the Senate amendment.**

HB 250: This bill establishes a commission to study the benefits and costs of a "health care for all" program for New Hampshire. **Status: Voted Ought to Pass with Amendment by the House. Amendment reduces commission from 16 members to 5 and adds additional questions for study. Introduced in Senate and referred to Senate Commerce Committee. The Senate Voted Inexpedient to Legislate.**

HB 291: This bill removes veterinarians from the requirements of adopting rules for prescribing opioids and querying the controlled drug prescription health and safety program. **Status: Voted Ought to Pass with Amendment by the House and Senate. The Amendment changes the training/continuing education requirements for veterinarians. The Bill has been enrolled.**

HB 322: This bill declares that certain licensing boards for health care providers may adopt rules to require completion of a certain survey as part of the license renewal process. This bill is a result of the commission established in 2016, 252. **Status: Voted Ought to Pass by the House. Senate Voted Ought to Pass with Amendment. The Amendment allows the State Office of Rural Health to receive and collect data regarding the surveys. The House concurred with the Amendment. The Bill has been enrolled.**

HB 329: This bill establishes a committee to study balance billing by health care providers. **Status: Voted Ought to Pass by the House; voted Ought to Pass with Amendments by the Senate. Amendment changes the committee's composition from 3 representatives and 2 senators to 4 representatives and 1 senator. Non-germane amendment adds an authorization for municipal ratification of town**

meetings and elections that were rescheduled due to March 14 snowstorm. The House did not concur with the non-germaine amendments. In a Committee of Conference, the House and the Senate concurred on a Bill that establish a committee to study balance billing and also allows municipalities to ratify the actions, votes and proceedings at municipal meetings that were postponed due to weather. The amended Bill was signed by the Governor on April 21 and was effective upon passage.

HB 334: This bill exempts from licensure by the board of medical imaging and radiation therapy persons who perform sonography in certain circumstances. **Status: Voted Ought to Pass with Amendment by the House. Amendment changes the exemption to an exemption from licensure for any "person who is regulated in another profession [and] acting within the scope of that person's license, registration, or certification." Senate voted Ought to Pass with amendment. The amendment expands the Medical Imaging and Radiation Therapy Exemptions. The House concurred with the Senate Amendment.**

HB 362: This bill declares that immunization/vaccine requirements shall not be established for diseases that are noncommunicable in a child care or school setting, including hepatitis B. **Status: Voted Ought to Pass with Amendment by the House; Voted Ought to Pass by Senate. The final amended bill states that nothing in RSA 141-C:20-a will require an immunization or vaccine requirement for diseases that are noncommunicable. The bill has been enrolled.**

HB 455-FN: This bill prohibits pharmacy benefit managers from requiring providers to attain accreditation, credentialing, or licensing other than by the pharmacy board or other state or federal entity. **Status: Voted Ought to Pass by the House. Voted Ought to Pass in the Senate with a provision repealing the prohibition on May 1, 2018. The House concurred with the Senate amendment.**

HB 468-FN: This bill allows persons licensed as mental health practitioners in other states to practice in this state 60 days after application to the board of mental health practice, pending final approval. **Status: Voted Ought to Pass by the House; Voted Ought to Pass with Amendment by the Senate. The Senate clarified the language of the Bill. The House concurred with the Senate amendment.**

HB 469: This bill requires licensed pharmacies to establish continuous quality improvement programs to identify weaknesses in processes and systems and make appropriate corrections. This bill is a request of the pharmacy board. **Status: Voted Ought to Pass by the House. Voted Ought to Pass with Amendment in the Senate. The amendments are substantial and include expanding the types of vaccines that can be administered by pharmacists and adds provisions to the insurance regulations concerning federal health care reform and repeals these same provisions on July 1, 2020. The House concurred with the Senate amendments.**

HB 471-FN: This bill requires the department of health and human services to publish an annual report consisting of an aggregate statistical summary of all induced terminations of pregnancy performed in New Hampshire. This report shall be available to the public. Data submitted by providers shall be for statistical purposes only and not public records. **Status: Retained in House HHS Committee.**

HB 472: This bill permits qualifying patients and registered caregivers to cultivate cannabis for therapeutic use. **Status: Voted Ought to Pass by the House. Introduced in Senate and referred to Senate HHS Committee and then re-referred to committee.**

HB 511: This bill establishes a commission to study creating a public health oversight program within the department of health and human services. **Status: Voted Ought to Pass with Amendments by both the House and the Senate. Amendments change the size and scope of commission to study environmentally-triggered chronic illness. House concurred with Senate amendments.**

HB 572-FN: This bill extends the suspension of prior authorization requirement for a community mental health program on drugs used to treat mental illness. **Status: Retained in House Finance Committee.**

HB 575-FN: This bill allows the board of acupuncture to certify individuals as acupuncture detoxification specialists. **Status: House voted Ought to Pass with Amendment. Amendment clarifies requirements for board certification. Senate voted Ought to Pass with Amendment. The amendment adds additional certification requirements. The House voted to nonconcur with the Senate amendment and the Bill will now go to a Committee of Conference.**

HB 578-FN: This bill prohibits an abortion of a viable unborn child, except in cases of medical emergency. **Status: Laid on table by the House.**

HB 596-FN: This bill permits a person who has been involuntarily committed to a treatment facility under RSA 135-C to request a review hearing every 2 years. **Status: Retained in House Judiciary Committee.**

HB628-FN: This bill establishes a system of paid family and medical leave insurance. **Status: Retained in House Labor Committee.**

HB 630-FN-A: This bill establishes the state health information and analysis program. Under this bill, the commissioner of the department of health and human services, the insurance commissioner, the commissioner of the department of corrections, and the attorney general shall enter into a memorandum of understanding to collaborate in the development of publicly available information on health care system patient safety, cost, quality, access to coverage and care, system performance, and efficiency and information pertaining to the delivery and financing of the health care system in New Hampshire, including information on new health system projects and associated costs. The bill establishes a health information and analysis planning council to provide consultation for the development of a public data resource for New Hampshire. The bill also establishes a fund for the implementation and administration of the requirements of the program. **Status: Retained in House HHS Committee.**

HB 650-FN: This bill makes various changes to the regulation of psychology practitioners including the requirements of the board of psychologists relating to investigation and hearings concerning disciplinary proceedings, the form of complaints against licensees, and the disclosure of patient records. **Status: Voted Ought to Pass with Amendment by the House. Voted Ought to Pass with Amendment by Senate. Senate Amendment adds procedural requirements for board hearings. The Bill has been enrolled.**

SB 15: This bill adds a new qualifying medical condition for the purposes of receiving cannabis for therapeutic use, severe pain that has not responded to previously prescribed medication or surgical measures or for which other treatment options produced serious side effects. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by House but was then Laid on the Table.**

SB 17: This bill clarifies hepatitis C as a qualifying medical condition for the use of cannabis for therapeutic purposes. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by House. The Bill has been**

enrolled.

SB 26: This bill clarifies the definition of "facility caregiver" for purposes of the use of cannabis for therapeutic purposes law to include community living facilities certified under RSA 126-A:19 and RSA 126-A:20. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by House. Signed by the Governor to be effective July 11.**

SB 54: This bill increases the number of hours of alcohol and drug use education required for initial licensure as a master license alcohol and drug counselor or as a licensed alcohol and drug counselor. **Senate voted Ought to Pass with Amendment. The amendments provide that qualified alcohol and drug counselors from other states are able to practice in NH not more than 60 days after making an application for licensure and require the certain regulatory boards and commissions provide information on their websites regarding reciprocity for those holding licenses in other states. House voted Ought to Pass.**

SB 59: This bill creates a process for certain individuals to request a blood testing order when they have been exposed to a source individual's bodily fluids. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House. Amendments clarify the bill's applicability to nurses, physicians and physician assistants, individuals who give aid at the scene of an emergency, require private insurance to pay for such testing for those not covered by workers compensation, and also make other non-substantive changes. Senate voted to concur with the House amendments.**

SB 61: This bill clarifies the procedure for receipt of medical records of a deceased spouse or next of kin. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House. Amendments clarify criteria for determining who may receive a deceased individual's medical records and how. Senate voted to concur with House amendment. The bill has been enrolled.**

SB 65: This bill adds certain vaccines to the law which allows licensed pharmacists to administer vaccines including hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by the House . The bill has been enrolled but note contingencies in SB 150 and HB 469 which affect implementation.**

SB 126: This bill requires the public utilities commission to award funds from the renewable energy fund to hospitals with renewable energy projects. **Status: Voted Ought to Pass by Senate. Voted inexpedient to legislate by the House.**

SB 144-FN: This bill clarifies the definition of "qualifying medical condition" to include certain conditions which trigger certain medical symptoms. This bill also deletes the requirement that a medical provider document how the injury affects activities of daily living. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House. Amendments clarify the statements signed by applicants for a registry identification card. The Senate voted to nonconcur with the House amendments and requested a Committee of Conference. The House refused to accede to the Senate Request for a Committee of Conference.**

SB 146-FN: This bill requires the commissioner of the department of health and human services to

develop a centralized state system for transporting persons subject to involuntary emergency admission. This bill is a result of the committee established in 2016, 101. **Status: Senate Laid on Table.**

SB 149: This bill authorizes individuals and certain businesses to purchase health insurance from out-of-state companies. The bill grants rulemaking authority to the insurance commissioner for the purposes of the bill. **Status: Senate Laid on Table.**

SB 150: Under this bill, a pharmacy intern under the direct supervision of a pharmacist may administer immunizing vaccines. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by the House. Signed by the Governor to be effective July 11.**

SB 151: This bill prohibits a nursing facility from requiring that a patient sign a mandatory arbitration agreement. **Status: Introduced and referred to Senate HHS Committee. Re-referred to committee.**

SB 152: This bill allows for temporary employment in a residential care facility or as a licensed nursing assistant by persons awaiting the results of a criminal history background check. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House. Amendments impose additional restrictions on the temporary license. Senate concurred with House amendments.**

SB 154: This bill allows pharmacies to dispense oral contraceptives to persons 18 years of age or older without a prescription. **Status: Introduced and referred to Senate HHS Committee. Rereferred to committee.**

SB 155: This bill declares that step 2 of the Medicaid managed care program shall not be implemented until July 1, 2019. **Status: Senate voted Ought to Pass with Amendment. The Amendment provided that nursing facility services would be incorporated into the Medicaid managed care program beginning January 1, 2019. The Commissioner of HHS would procure contracts with a program start date of January 1, 2019. The House voted Ought to Pass with Amendment reversing the Senate amendment and requiring that Step 2 of the program not be implemented before July 1, 2019 and to require the Commissioner of HHS to re-procure contracts with vendors to administer the Medicaid Managed Care program, provided that the program shall not be implemented before July 1, 2019. The Senate voted to nonconcur with the amendment. The bill will go to a Committee of Conference.**

SB 157: This bill adds rulemaking for persons with substance use disorder for the purposes of the managed care law. This bill also requires health carriers to notify covered persons of their rights as a managed care consumer. **Status: Senate voted Ought to Pass with Amendment. House voted Ought to Pass with Amendment. Amendment alters the language of the consumer rights notification. The Senate concurred with the House amendment.**

SB 158: This bill declares that if substance use disorder services are a covered benefit under a health benefit plan, no prior authorization shall be required for prescribed medications for a substance use disorder. **Status: Voted Ought to Pass with Amendment by Senate. Introduced in House and referred to House HHS Committee. Amendment changes authorization renewal frequency from once every 24 months to once every 12 months. House voted Ought to Pass.**

SB 159: This bill adds Ehlers-Danlos syndrome to the definition of "qualifying medical conditions" for the purposes of therapeutic cannabis. **Status: Voted Ought to Pass by Senate. House voted Inexpedient to Legislate.**

SB 189-FN: This bill requires insurance policies to cover 3-D tomosynthesis mammography. **Status: Introduced and referred to Senate Commerce Committee. Re-referred to committee.**

SB 212: This bill adopts the physical therapy licensure compact, implemented by the physical therapy governing board. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass with Amendment. The amendment did not substantially alter the bill. The Senate concurred with the House amendment.**

SB 220-FN: This bill changes the definition of mental illness for the purpose of involuntary commitment to include ingestion of opioid substances. **Status: Introduced and referred to Senate HHS Committee. Re-referred to committee.**

SB 236: This bill makes the Medicaid expansion law permanent. The program would currently expire December 31, 2018. **Status: Senate Laid on Table.**

SB 237-FN: This bill allows medical providers who practice in metropolitan areas to be reimbursed by Medicaid for telehealth services. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by the House and signed into law by the governor effective July 8.**

SB 238-FN: This bill clarifies the term "usual and customary price" for the purposes of filling prescriptions to mean the price an individual would pay for a prescription at a retail pharmacy if that individual did not have a prescription drug benefit or insurance. **Status: Voted Ought to Pass by Senate. Voted Inexpedient to Legislate by the House.**

~~*

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

BIOS

CINDE WARMINGTON, ESQ.
Cinde, a partner at Shaheen & Gordon, leads the Health Care Practice Group and focuses her practice entirely on representing health care clients. Her prior clinical and administrative experience makes her uniquely qualified to assist providers in facing a rapidly changing regulatory environment.

KARA J. DOWAL, ESQ.
Kara Dowal practices health care law and corporate business law at Shaheen & Gordon, P.A. Kara works with health care providers on a variety of legal issues, including corporate governance, contracting,

employment, regulatory compliance, and provider transition matters.

S. AMY SPENCER, ESQ.
Amy assists individual practitioners, group practices, and hospitals with a variety of health related business, regulatory, and litigation issues. Amy also practices in the areas of criminal defense and civil litigation.

ALEXANDER W. CAMPBELL, ESQ.
Alex practices health care law and civil litigation at Shaheen & Gordon, P.A. Alex focuses his health care practice on assisting providers in regulatory compliance, contracting, provider transition, and litigation.

The information provided in this update is for general information purposes only. It is not intended to be taken as legal advice for any individual case or situation. The receipt or viewing of this information is not intended to create, and does not constitute, an attorney-client relationship between Shaheen & Gordon, P.A. or any of its attorneys and the receiver of this information, nor, if one already exists, does it expand any existing attorney-client relationship. Recipients are advised to consult their own legal counsel for legal advice tailored to their particular needs and situation.