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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.

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FEDERAL DEVELOPMENTS

HHS Issues Fall 2019 Regulatory Agenda, Including Proposals on Drug Pricing, HIPAA

In November, the U.S. Department of Health and Human Services ("HHS") posted its fall 2019 list of administrative agenda items, including several proposed rules that HHS intends to issue in 2020. Among this list is a proposed rule that would seek comments on modifications to Health Insurance Portability and Accountability Act ("HIPAA") to decrease or remove certain barriers to coordinate care and case management. This proposed rule would also maintain and potentially expand patients' ability to control the use or disclosure of their PHI and to access PHI. HHS intends to follow this rule with another HIPAA-related proposed rule that would solicit comments on proposals for the distribution of civil money penalty and monetary settlements with those harmed by a HIPAA offense and on proposals to some of the annual limits on civil money penalties under the HITECH Act.

Other proposals include: allowing HHS to negotiate prices for Medicare Part B drugs; allowing for the importation of prescription drugs from Canada if they meet certain safety and cost standards; and implementing changes to strengthen the Medicare Advantage and Medicare Part D programs.

HHS' regulatory agenda is available at: https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900&Image58.x=41&Image58.y=18&csrf_token=93B8BB1C82975E42D8161E92D9F36101C2FF96D68EE85697D3E248A8D344CF781CD9E47EEFC0497034842E4BB3570C83FB7B.

CMS Announces that Medicare Improper Payment Rates Are Lowest Since 2010

On November 18, the Centers for Medicare & Medicaid Services ("CMS") issued a fact sheet indicating that the estimated improper payment rate for fiscal year 2019 had decreased to the lowest point in almost a decade. CMS reports that the estimated improper payment rate for 2019 was 7.25%, down from 8.12% in 2018. CMS largely attributes this decrease to progress in home health claims, other Part B services, and durable medical equipment, prosthetics, orthotics, and supplies that were undertaken in response to President Trump's Executive Order instructing CMS to take action to detect and prevent fraud, waste and abuse and more aggressively. Consistent with the Executive Order, CMS has developed a program focusing on the following five "pillars": Stop Bad Actors; Prevent Fraud; Mitigate Emerging Programmatic Risks; Reduce Provider Burden; and Leverage New Technology.

CMS' Fact Sheet on the improper payment rates is available at: https://www.cms.gov/newsroom/fact-sheets/2019-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs.

A related press release is available at: https://www.cms.gov/newsroom/press-releases/fiscal-year-fy-2019-medicare-fee-service-improper-payment-rate-lowest-2010-while-data-points.

OIG Issues Report to CMS on Part B Drugs Meeting Price Substitution Threshold

On November 19, the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") issued a report notifying the Centers for Medicare & Medicaid Services ("CMS") which drugs saw their average sales price ("ASP") exceed their average manufacturer's price ("AMP") by five percent or more in the second quarter of 2019. By law, if the five percent threshold is met, HHS may disregard the drug's ASP when setting the reimbursement amount and shall substitute the payment amount with the lesser of the widely available market price or 103% of the AMP. OIG found that in the second quarter of 2019, 11 drug codes met the price substitution criteria by exceeding the five-percent threshold for two consecutive quarters or three of the previous four quarters, based on complete AMP data. Another 11 drug codes had ASPs that exceeded the AMPs by at least five percent in the second quarter of 2019, based on complete AMP data, but these drug codes did not meet other price-substitution criteria.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-03-20-00070.pdf.

OIG Reports CMS Overpaid Hospitals $500 Million in Outlier Payments

In November, the Department of Health and Human Services Office of Inspector General ("OIG") reported that over a four-year period from 2011 through 2014 the Centers for Medicare & Medicaid Services ("CMS") overpaid hospitals by $502 million in outlier payments. The OIG explained that this is because the associated cost reports did not meet the 10% threshold for reconciliation. As a remedy, OIG recommends that CMS reconcile all hospital cost reports with outlier payments during a cost-reporting period. CMS agreed with OIG's recommendation and is evaluating current outlier reconciliation criteria and will propose appropriate modifications in future rulemaking.

The OIG report, *Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process*, can be accessed here: https://oig.hhs.gov/oas/reports/region5/51600060.pdf

Over $2 Million Settlement for Hospital's Failure to Report PHI Breach

On November 27, the Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") announced it had secured a $2.175 million settlement with Sentara Hospitals for its failure to properly

report a breach of patient protected health information ("PHI") under the Health Insurance Portability and Accountability Act ("HIPAA"). HHS received a complaint in April 2017 that Sentara, comprised of 12 acute care hospitals with over 300 sites throughout Virginia and North Carolina, had sent a bill to an individual containing another patient's PHI. OCR investigated and discovered that Sentara incorrectly mailed 577 patients' PHI to wrong addresses. The PHI breached included names, account numbers, and dates of service. However, Sentara reported the incident as a breach that affected only 8 individuals because it concluded (incorrectly) that unless the disclosure contained patient diagnosis, treatment, or other medical information, no reportable breach occurred. The HHS press release states that "Sentara persisted in its refusal to properly report the breach even after being explicitly advised of their duty to do so by OCR." Sentara also failed to have a business associate agreement in place with Sentara Healthcare, a separate entity that provides business associate services for Sentara.

In addition to the settlement, Sentara entered into a corrective action plan that includes two years of monitoring.

The press release announcing the settlement may be found here: https://www.hhs.gov/about/news/2019/11/27/ocr-secures-2.175-million-dollars-hipaa-settlement-breach-notification-and-privacy-rules.html

OIG Reports Expected Investigative Recoveries for FY 2019 are More than $5 Billion

On December 2, the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") issued its Semiannual Report to Congress summarizing its activities for the 6-month period ending September 30, 2019. OIG cited among its accomplishments expected investigative recoveries of $5.04 billion, initiation of 809 criminal actions, 695 civil actions, and 2,640 individuals and entities excluded from the federal health care program. The report highlighted that OIG's audit work identified $573,037,000 in potential savings to HHS if HHS implemented all of OIG's audit recommendations.

The OIG's Semiannual Report to Congress may be found here: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2019/2019-fall-sar.pdf

OIG Concerned about Medicare Advantage Payments Based on Chart Reviews

On December 12, the Department of Health and Human Services Office of Inspector General ("OIG") posted a report, *Billions in Estimated Medicare Advantage Payment From Chart Reviews Raise Concerns*, in which it sounds the alarm on the fact that chart reviews, particularly those not linked to service records, could allow Medicare Advantage Organizations ("MAOs") the opportunity to avert Centers for Medicare & Medicaid Services ("CMS") face-to-face requirements and therefore inappropriately inflate risk-adjusted payments. As evidence of its concern, OIG noted that: (1) MAOs almost always used chart reviews to add, rather than delete, diagnoses; (2) diagnoses added on chart reviews and not reflected in service records accounted for $6.7 billion in risk-adjusted payments in 2017; (3) CMS based an estimated $2.7 billion in risk-adjusted payments on chart review diagnoses that MAOs did not link to a specific service provided or to a face-to-face visit; and almost half of MAOs reviewed had payments from unlinked chart reviews where there was not a single record of a service being provided to the beneficiary.

OIG recommended, and CMS agreed, that CMS should "(1) provide targeted oversight of MAOs that had risk-adjusted payments resulting from unlinked chart reviews for beneficiaries who had no service records in the 2016 encounter data, (2) conduct audits that validate diagnoses reported on chart reviews in the MA

encounter data, and (3) reassess the risks and benefits of allowing chart reviews that are not linked to service records to be used as sources of diagnoses for risk adjustment."

The OIG report can be read here: https://oig.hhs.gov/oei/reports/oei-03-17-00470.pdf

OCR Settles Second HIPAA Right of Access Case

On December 12, the Department of Health and Human Services Office for Civil Rights ("OCR") announced its second enforcement action and settlement under the Health Insurance Portability and Accountability Act ("HIPAA") Right of Access Initiative. The settlement involves Korunda Medical, LLC, a primary care and interventional pain management entity based in Florida. A Korunda patient complained to OCR in March 2019 that Korunda failed to forward the patient's medical records in electronic format to a third party, despite numerous requests from the patient. Furthermore, Korunda charged more than the reasonably cost-based fees allowed under HIPAA. OCR then provided technical assistance to Korunda to how to correct the matters and closed the complaint. However, Korunda continued to fail to provide the requested records, resulting in another complaint, and only then did Korunda provide the records in the requested format for free. Korunda agreed to take corrective actions and pay $85,000.

The announcement of the settlement can be read here: https://www.hhs.gov/about/news/2019/12/12/ocr-settles-second-case-in-hipaa-right-of-access-initiative.html

OIG Issues Report Estimating CMS Made Millions in Incorrect EHR Incentive Payments

On December 16, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") issued a report of its audit findings that the Centers for Medicare & Medicaid Services ("CMS") made an estimated $93.6 million in incorrect Medicare electronic health record ("EHR") incentive payments to acute-care hospitals. OIG conducted an audit of EHR incentive payments to acute-care hospitals from January 1, 2013 through September 30, 2017, in part because of previous audits that had shown that both CMS and states had made incorrect Medicare and Medicaid EHR incentive payments to hospitals. OIG's audit revealed that 50 of the 99 payments sampled were incorrect, because of failure to identify errors in hospitals' cost-report numbers and because CMS failed to include labor and delivery services in the payment calculations, resulting in inflated incentive payments. OIG recommended that CMS undertake to recoup that portion of the incorrect payment that were within the reopening period, and to notify affected hospitals so that they can exercise reasonable diligence to investigate and return any identified incorrect payments. CMS concurred with OIG's recommendations.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region9/91803020RIB.pdf.

CMS' Fact Sheet on the final rule is available at: https://www.cms.gov/newsroom/fact-sheets/2019-health-and-human-services-exchange-program-integrity-final-rule-fact-sheet.

OIG Issues Advisory Opinion Approving of Supermarket Rewards Points for Pharmacy Purchases

On December 17, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") posted Advisory Opinion 19-06 regarding a supermarket's proposal to expand its current loyalty program to allow customers to earn rewards points on out-of-pocket costs paid in connection with pharmacy purchases. Under the current loyalty program, customers can earn one point per dollar spent on purchases at the supermarket, and then redeem those points towards other purchases. However, customers can neither earn nor redeem points for out-of-pocket costs for pharmacy items. The proposed arrangement would permit

customers to earn points for out-of-pocket costs for pharmacy purchases, but would maintain the prohibition on redeeming the points for out-of-pocket costs.

OIG determined that the proposed arrangement would implicate the beneficiary inducement civil monetary penalty because the points earned by purchasing pharmacy products could induce a beneficiary of a federal health care program to select the supermarket as his or her supplier of reimbursable items of services. However, OIG concluded that the proposed arrangement would satisfy the requirements for the exception for certain retailer rewards programs. OIG also concluded that while the proposed arrangement would implicate the anti-kickback statute, it would pose only a minimal risk of fraud and abuse.

Advisory Opinion 19-06 is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-06.pdf.

Appeals Court Strikes Down Individual Mandate but Leaves ACA's Fate Uncertain

On December 18, the Court of Appeals for the Fifth Circuit issued a 2-1 decision striking down the individual mandate of the Affordable Care Act ("ACA") as unconstitutional following Congress' removal of the related tax penalty. A District Court judge in Texas had previously ruled that the removal of the tax penalty resulted in the entirety of the ACA—not just the individual mandate—being unconstitutional. In the latest decision, the Fifth Circuit remanded back to the District Court the question of whether the remaining pieces of the ACA can survive without the individual mandate. The District Court's decision is not expected before the 2020 general election.

The Fifth Circuit's decision is available at: http://www.ca5.uscourts.gov/opinions/pub/19/19-10011-CV0.pdf.

CMS Issues Final Rule Making Changes to Oversight of State Exchanges

On December 27, the U.S. Department of Health and Human Services published a final rule regarding the state insurance exchanges established under the Affordable Care Act. The final rule includes three main provisions. First, it strengthens the Centers for Medicare & Medicaid Services' oversight over exchanges through monitoring, reporting and auditing of exchange activities to ensure that states are correctly determining consumer eligibility for advance payments of the premium tax credit ("APTC") and cost-sharing reduction ("CSR") amounts. Second, it requires exchanges to conduct periodic data matching at least two times each year to determine whether enrollees have become eligible or ineligible for APTC and CSRs. Finally, the final rule requires qualified health plan issuers to bill consumers separately for the portion of the consumer's premium that is attributable to coverage for certain abortion services for which public funding is prohibited.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-12-27/pdf/2019-27713.pdf.

Trump Administration Appeals Ruling on Conscience Rule

On January 3, the Department of Justice ("DOJ") filed a notice of appeal with the U.S. District Court for the Southern District of New York, saying it will ask the Second Circuit to review the U.S. District Court's November 2019 decision vacating the "conscience rule," a rule issued by the Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") that provides broad protections for health care entities and individuals who refuse to provide or pay for medical services because of their religious or moral beliefs. In *New York v. United States Dep't of Health and Human Servs*., No. 19-CIV-4676 (PAE) (Nov. 6, 2019), the District Court held that the agency lacked statutory authority to promulgate "significant portions" of the rule and

rejected HHS' arguments that the rule wasn't substantive. It also held that rule violated the Administrative Procedure Act because it was contrary to the law—specifically, it conflicted with Title VII, applicable to employment discrimination, and with the Emergency Medical Treatment and Labor Act ("EMTALA"), which requires health care providers to screen and stabilize patients with emergency medical conditions. The District Court also held the rule was arbitrary and capricious because HHS' justifications for the regulation were contrary to the evidence, and that the rule's penalty, terminating a recipient's federal funding, was unconstitutional because it violated separation of powers and the spending clause. The District Court for the Northern District of California struck down the rule for similar reasons on November 19.

The conscience rule can be found as published in the *Federal Register*, here: https://www.federalregister.gov/documents/2019/05/21/2019-09667/protecting-statutory-conscience-rights-in-health-care-delegations-of-authority

The November 6 District Court ruling can be read here: https://law.justia.com/cases/federal/district-courts/new-york/nysdce/1:2019cv04676/516033/248/

CMS Proposes Changes to Medicare Advantage Risk Adjustment Model

On January 6, the Centers for Medicare & Medicaid Services ("CMS") released Part I of its 2021 Advance Notice of Methodological Changes for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies (the "Advance Notice"). The Advance Notice proposes updates to the Part C CMS-Hierarchical Condition Categories ("HCC") risk adjustment model and the use of encounter data. The Advance Notice is published in two parts due to the requirements of the 21st Century Cures Act which make some changes subject to a 60-day comment period and others subject to a 30-day comment period. CMS stated both Parts I and II will be finalized in the annual Rate Announcement on or before April 6, 2020.

Part I of the Advance Notice is a continued phase-in of the risk adjustment model for Medicare Advantage organizations and certain demonstrations finalized for calendar year 2020. It calculates risk scores using the sum of 75% of the risk score calculated with the 2020 CMS-HCC model and 25% of the risk score calculated with the 2017 CMS-HCC model. CMS stated in a fact sheet that the proposal under Part I of the Advance Notice represents a change from the CY 2020 model of 50% of the risk score calculated with the 2020 CMS-HCC model and 50% of the risk score calculated with the 2017 CMS-HCC model. Comments on Part I of the Advance Notice are due by March 6, 2020.

A CMS Fact Sheet on the Proposed Changes can be found here: https://www.cms.gov/newsroom/fact-sheets/2021-medicare-advantage-advance-notice-part-i-risk-adjustment

The CMS Advance Notice can be found here: https://www.cms.gov/files/document/2021-advance-notice-part-i.pdf

DOJ Recovered $3 Billion for False Claims in 2019

On January 9, the Department of Justice ("DOJ") announced that in fiscal year ending September 30, 2019, it had obtained more than $3 billion in settlements and judgments from civil cases involving fraud and false claims. Out of that total recovery, the DOJ stated that $2.6 billion related to matters in the health care industry and noted that the figure only represents federal dollars recovered and that often the cases recovered additional millions of dollars for state Medicaid programs. The DOJ highlighted the fact that two of the largest recoveries came from opioid manufacturers, $195 million from Insys Therapeutics for allegations it paid

kickbacks to physicians and nurse practitioners to prescribe Subsys, and $1.4 billion from Reckitt Benckiser Group plc for criminal and civil liability related to the marketing of the opioid addiction treatment drug Suboxone.

The DOJ press release can be accessed here: https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019

Hospitals Renew Challenge to Site-Neutral Payments for 2020

On January 13, the American Hospital Association, the Association of American Medical Colleges, and several hospitals filed a lawsuit renewing their previous challenge to the Centers for Medicare & Medicaid Services' ("CMS") rule expanding the site-neutral payment policy to grandfathered off-campus hospital-based departments. The site-neutral policy had previously been struck down as exceeding CMS statutory authority, however the court in that case held that it did not have jurisdiction to review the plaintiffs' claims regarding 2020 reimbursement rates which had not yet been implemented. This new complaint renews the challenge to the 2020 rates that went into effect on January 1. The plaintiffs are again arguing that the 2020 rates exceed CMS statutory authority.

HHS Issues Proposed Rule Eliminating Alternate-Provider Referral Requirement for Religious Providers

On January 16, the U.S. Department of Health and Human Services ("HHS") issued a proposed rule that removes an Obama administration requirement that religious health care providers who don't provide certain services must refer patients to alternate providers. The proposed rule also clarifies that HHS will not discriminate against religious providers and organization in awarding grants and federal funds. The proposed rule implements certain agenda items in President Trump's 2018 executive order titled "Establishment of a White House Faith and Opportunity Initiative."

Comments to the proposed rule are due by February 18.

The proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-01-17/pdf/2019-26923.pdf.

DOL Final Rule Establishes Test for Joint Employer Status

On January 16, the U.S. Department of Labor ("DOL") issued a final rule updating the rules on joint employer status for the first time in over 60 years. The rule sets forth a four-factor test for determining whether an employee's work performed for one employer simultaneously benefits another employer. The test considers whether the joint employer: (1) hires or fires the employee; (2) supervises and controls the employee's work schedule or conditions of employment to a substantial degree; (3) determines the employee's rate and method of payment; and (4) maintains the employee's employment records. The rule also provides other guidance on how to interpret this test and identifies certain factors that are not relevant to the analysis.

The final rule is effective March 16. The rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-01-16/pdf/2019-28343.pdf.

OIG Permits Drug Maker to Pay for Travel, Lodging and Other Assistance for Patients

On January 21, the Department of Health and Human Services Office of Inspector General ("OIG") issued an advisory opinion allowing a pharmaceutical manufacturer to provide financial assistance in the form

of travel, lodging, and other expenses to patients who use the manufacturer's drug (the "Arrangement"). OIG stated that it would not impose sanctions under the federal Anti-kickback Statute ("AKS") or the Beneficiary Inducements Civil Monetary Penalty ("CMP") for the Arrangement. The Arrangement involves a drug that is personalized medicine made from a patient's own cells and is a one-time potentially curative treatment. The drug manufacturer proposes to assist eligible patients 18-25 years old along with up to two caregivers with travel, lodging, meals, and certain other out-of-pocket expenses that they incur during and after the drug infusion. For patients 26 years or older, assistance is for the patient and one caregiver.

OIG noted that the arrangement implicates the AKS because free travel, lodging, meals, and other assistance are remuneration that may induce beneficiaries to purchase the drug and that the Arrangement constitutes remuneration to the centers and the physicians, in the form of the opportunity to earn fees related to administering the drug, that may induce them to order the drug. Nevertheless, OIG said it would not impose sanctions under the AKS because: (1) indigent or rural patients could be disproportionately impacted by significant health risks or even death if they cannot travel to a center to receive the drug and stay in close proximity after receiving the drug; (2) the lodging the manufacturer provides allows physicians to meet the FDA requirements in the drug's prescribing information and mitigates patient harm from potentially lethal side effects; (3) only physicians who accept responsibility for certain safety protocols may prescribe and administer the drug and the manufacturer certified that it does not require either physicians or a center to prescribe its drug exclusively and any center meeting the requirements may participate; (4) the drug is prescribed only for refractory indications, and the Arrangement is only available when the drug is prescribed and administered in accordance with its label, it is a one-time potentially curative treatment that does not raise the seeding concerns present in other similar arrangements, and the manufacturer does not advertise the Arrangement, all conditions that reduce the likelihood that it serves as a marketing tool; (5) requiring patients to reside a significant distance from a center in order to be eligible for the assistance mitigates the risk that the Arrangement as a marketing tool for patient referrals; and (6) the OIG is not aware of any existing authority that would allow the Secretary to pay for the non-medical items and services, like lodging and travel.

OIG said the Arrangement also implicates the Beneficiary Inducements CMP but concluded that it satisfies the Promotes Access to Care Exception.

OIG Advisory Opinion No. 20-02 may be read here:
https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-02.pdf

HHS Issues Rule Requiring Specificity in Prescription Reporting to Prevent Impermissible Fills of Schedule II Drugs

On January 24, the U.S. Department of Health and Human Services ("HHS") issued a final rule requiring covered entities under the Health Insurance Portability and Accountability Act ("HIPAA") to use the "Quantity Prescribed" field for retail pharmacy transactions for Schedule II drugs. This modification will enable covered entities to distinguish whether a prescription is a "partial fill," where less than the full amount prescribed is dispensed, or a refill, where the full amount prescribed is dispensed. HHS says that the availability of this data may help prevent impermissible refills of Schedule II drugs, which will help address the public health concerns associated with prescription drug abuse in the United States.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-01-24/pdf/2020-00551.pdf.

GAO Calls for More Oversight to Prevent Double-Dipping under 340B and Medicaid Rebate Programs

On January 27, the Government Accountability Office ("GAO") issued a report concluding that the Centers for Medicare & Medicaid Services ("CMS") needs to do more to ensure state Medicaid programs have policies and procedures in place to prevent drug manufacturers from being subject to "duplicate discounts" under the 340B Drug Pricing Program and the Medicaid Drug Rebate Program. In its report, GAO stated that because CMS conducts only limited oversight of state Medicaid programs' efforts to prevent duplicate discounts, it can't be sure states are excluding 340B drugs from Medicaid rebate requests, or, conversely, that states are seeking rebates for all eligible drugs. It also noted that the Health Resources and Services Administration ("HRSA"), which oversees the 340B Program, does not review states' policies and procedures for identifying 340B drugs so it can't tell whether covered entities are complying with the prohibition on duplicate discounts. GAO also found that unlike Medicaid fee-for-service, when duplicate discounts in Medicaid managed care claims are identified, HRSA doesn't require covered entities to address them.

GAO recommend that state Medicaid programs be designed to prevent duplicate discounts and foregone rebates, and that HRSA audits cover entities' compliance with state policies. GAO also recommended that covered entities be required to work with manufacturers regarding repayment of identified duplicate discounts in managed care. The Department of Health and Human Services ("HHS") agreed that CMS should ensure state Medicaid programs have written policies and procedures to identify 340B drugs and exclude them from Medicaid rebate requests, but stated that HRSA does not have the authority to include assessments of covered entities' compliance with state Medicaid policies and procedures in its audit process. HHS also did not agree with the recommendation that HRSA should require covered entities to work with drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care. GAO noted, however, that the recommendation only applied to instances where actual duplicate discounts have already been identified.

The full GAO report, *340B Drug Discount Program, Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, may be found here: https://www.gao.gov/assets/710/703966.pdf

CMS Issues NCD to Cover Comprehensive Genetic Analysis for Patients with Inherited Ovarian, Breast Cancer

On January 27, the Centers for Medicare & Medicaid Services ("CMS") issued a final National Coverage Decision ("NCD") Memorandum extending Medicare coverage for Food and Drug Administration-approved or cleared laboratory diagnostic tests to identify inherited mutations using Next Generation Sequencing ("NGS") for patients with certain forms of ovarian or breast cancer and risk factors for inherited ovarian or breast cancer. The NGS must be ordered by a treating physician and performed in a laboratory certified under the Clinical Laboratory Improvement Amendments. The NCD memorandum also gives Medicare Administrative Contractors discretion to determine coverage of NGS for patients with other inherited cancers and risk factors.

The CMS memorandum may be read here: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296

Medicaid Block Grant Plan Announced by Trump Administration

January 30, the Centers for Medicare & Medicaid Services ("CMS") brought forth a new initiative permitting states to carry out demonstrations under Section 1115 waivers that converts some of their federal Medicaid funding to block grants. Called the Healthy Adult Opportunity ("HAO") initiative, states that apply for

the waivers can provide Medicaid coverage using flexible benefit designs under either an aggregate or per-capita cap for certain populations without having to comply with identified Medicaid provisions. CMS Administrator Seema Verma stated that HAO "provides rigorous protections for *all* Medicaid beneficiaries, and for the first time it aligns financial incentives to improve quality of care and health outcomes for Medicaid adults by giving states unprecedented flexibility to administer and design their programs to meet this population's very unique needs."

The plan is controversial, and on January 29, prior to the announcement of the initiative, 36 Democrats wrote a letter to Department of Health and Human Services Secretary Alex Azar and Administrator Verma referring to it as a plan, based on "previous statements from those in the Administration" "to cut benefits and further limit access to publicly funded health care." The letter states that approval of the waivers would directly oppose federal statutes that describe how CMS must make matching funds available to state Medicaid programs, citing that although Section 1115 permits waivers for certain sections of the Social Security Act, it does not allow waivers for Section 1903, the section that directs federal matching funds to states.

The CMS letter to state Medicaid directors can be found here: https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf

Administrator Verma's remarks can be read here: https://www.cms.gov/newsroom/press-releases/cms-administrator-seema-vermas-remarks-healthy-adult-opportunity-event

The Democrats' January 29 letter is available here: https://kennedy.house.gov/imo/media/doc/1.29.20%20Medicaid%20Block%20Grant%20Letter.pdf

HHS Issues Proposed Rule for ACA Marketplace

On January 31, the Department of Health and Human Services ("HHS") issued its annual proposed rule that updates payment parameters and other policies for the Affordable Care Act ("ACA") marketplace. The proposed rule includes "recalibrated parameters" for risk adjustment methodology and changes to reduce the burden of small issuers associated with participating in risk adjustment data validation. For the 2021 plan year, the rule proposes that user fees be maintained at the 2020 plan year rates, 3.0 percent for a Federal-facilitated Exchange and 2.5 percent for a State-based Exchange of total monthly premiums, but the agency is seeking comment on alternatively reducing those user fees below the 2020 plan year levels.

The rule also proposes to raise the maximum annual limitation on cost sharing, which will increase cost-sharing and out-of-pocket spending for consumers who are close to the annual cost-sharing limit. Along with proposed options for qualified health plan issuers to implement value-based insurance plan designs, HHS is asking for comments on changing the automatic re-enrollment process so that enrollees would be automatically re-enrolled only if they paid in advance the premium tax credit.

Comments on the proposed rule are due March 2, 2020.

The proposed rule as published in the Federal Register on February 6 can be found here: https://www.federalregister.gov/documents/2020/02/06/2020-02021/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021

CMS Issues Proposed Rule Updating Medicare Advantage and Part D

On February 5, the Centers for Medicare & Medicaid Services ("CMS") issued the Contract Year 2021 and 2022 Medicare Advantage and Part D Proposed Rule. The proposed rule includes several enhancements to the Medicare Advantage and Part D programs, including: increasing predictability and stability in the Star Ratings; permitting a second "preferred" specialty tier in Part D; requiring Part D plans to implement a beneficiary real time benefit tool that will allow enrollees to view real-time formulary and benefit information; and establishing pharmacy performance measure reporting requirements. The proposal codifies existing longstanding Medicare Advantage and Part D policies, including: the existing network adequacy methodology for Medicare Advantage plans; existing policy with respect to supplemental benefits; and special enrollment periods that CMS has previously adopted through sub-regulatory guidance. The proposed rule also implements certain provisions of the Balanced Budget Act of 2018 and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.

Comments to the proposed rule must be received by April 6.

The proposed rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-02085.pdf.

CMS' Fact Sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-and-2022-medicare-advantage-and-part-d-proposed-rule-cms-4190-p-1.

STATE DEVELOPMENTS

Governor Issues Executive Order Regarding Medicaid to Schools Program

On December 4, 2019, Governor Sununu issued an Executive Order addressing federal requirements necessary to receive funding under the Medicaid to Schools Program. The Order designated certain health professional boards as Medicaid to School Boards and directed the Boards to work with the Office of Professional Licensure and Certification to expedite licensing and credential applications for qualified applicants to participate in the Medicaid to Schools Program. The need for licensing and credentialing of such applicants arose out of clarifying guidance issued by CMS on July 1, 2019.

The link to the Executive Order is at: https://www.governor.nh.gov/news-media/orders-2019/documents/2019-07.pdf

HHS also issued amended administrative rules to reflect the CMS guidance. A public hearing was held in January. The proposed rules will come before the Joint Legislative Committee on Administrative Rules on February 1, 2020.

The link to the proposed rules is at: https://www.dhhs.nh.gov/ombp/medicaid/mts/index.htm.

HHS Proposes Amendments to Hospital Licensing Requirements

HHS issued new rules governing the licensing of hospitals. The Department indicates the rules are intended to provide better clarity, program integrity and consistency with other recently adopted licensing requirements. The proposed rules include updated definitions, structure and terminology as well as substantive and editorial changes which HHS characterizes as minor.

The link to the proposed rules is at: https://www.dhhs.nh.gov/oos/aru/documents/hep802ip.pdf

NH Insurance Department to Seek Waiver to Create State-based Reinsurance Program

On January 10, 2020 the Governor announced that the NH Insurance Department would file a Section 1332 State Relief and Empowerment Waiver application with the federal government in an effort to promote stability in the individual health insurance market. The announcement notes that the individual health insurance market in NH has been under stress for years and that the intention of the waiver is to strengthen the market by lowering premium costs. The Governor estimated the waiver could reduce prices for individuals by 15%. Public hearings on the waiver application are scheduled in April, 2020.

The link to the press release is at: https://www.governor.nh.gov/news-media/press-2020/20200110-reduce-rates.htm

Information regarding public hearings may be found at: https://www.nh.gov/insurance/media/pr/2020/documents/press-release-1332-waiver-hearing-dates-02-03-20.pdf

Lori Shibinette Confirmed as Commissioner of Health and Human Services

On January 22, Lori Shibinette, was unanimously confirmed by the Executive Council to be the Commissioner of the NH Department of Health and Human Services. Ms. Shibinette, a registered nurse, previously served as the CEO of New Hampshire Hospital and as the CEO of the Merrimack County Nursing Home. She replaces former Commissioner Jeff Meyers who left the position in December.

REMINDERS:

- **Annual Reports for New Hampshire business entities are due to the Secretary of State by April 1, 2020.**

- **Annual Breach Notification Reports must be made to the Office of Civil Rights by February 29, 2020 at:** https://ocrportal.hhs.gov/ocr/breach/wizard_breach.jsf?faces-redirect=true

- **Non-Profit Reports for New Hampshire nonprofit corporations and associations are due every five years to the Secretary of State by December 31, 2020.**

In addition to notifying affected individuals and the media (where appropriate), covered entities must notify the Secretary of breaches of unsecured protected health information. Covered entities will notify the Secretary by visiting the HHS web site and filling out and electronically submitting a breach report form. If a breach affects 500 or more individuals, covered entities must notify the Secretary without unreasonable delay and in no case later than 60 days following a breach. If, however, a breach affects fewer than 500 individuals, the covered entity may notify the Secretary of such breaches on an annual basis. ***Reports of breaches affecting fewer than 500 individuals are due to the Secretary no later than 60 days after the end of the calendar year in which the breaches are discovered.***

LEGISLATIVE UPDATE

House Bills

HB 1106 This bill mandates that certain noncompete provisions in employment contracts for pastoral psychotherapists, clinical social workers, clinical mental health counselors, and marriage and family therapists licensed by the board of mental health practice and psychologists licensed by the board of psychologists, are not enforceable. **Introduced and referred to House Labor Committee.**

HB 1140 This bill establishes a commission to monitor the merger of hospitals. **Introduced and referred to House Commerce Committee.**

HB 1188 This bill repeals the provision allowing certain applicants for licensure as allied health professionals to practice on a conditional basis pending the results of a criminal history record check. **Introduced and referred to House Executive Departments and Administration Committee.**

HB 1246 This bill clarifies the information that hospitals must report regarding infections. **Introduced and referred to House HHS Committee.**

HB 1265 This bill changes the definition of "qualifying medical condition" in the statute governing the use of cannabis for therapeutic purposes. **Introduced and referred to House HHS Committee.**

HB-1275-FN This bill authorizes laboratory testing without a licensed medical practitioner's order. The bill adds rulemaking authority for the purposes of the bill. **Introduced and referred to House HHS Committee.**

HB 1280-FN This bill requires insurers to cap the total amount for insulin for covered persons. **Introduced and referred to House Commerce Committee.**

HB 1281 This bill requires insurance coverage for epipens. **Introduced and referred to House Commerce Committee.**

HB 1294 This bill provides for limited immunity from civil liability in class action litigation for actions of pharmacists. **Introduced and referred to House Judiciary Committee.**

HB 1315 This bill changes the renewal procedure for 2-year licenses issued to allied health professionals from December 31 to the month of issuance of the applicant's original license. **Introduced and referred to House Executive Departments and Administration Committee.**

HB 1386 This bill prohibits an employer from firing an employee solely because the employee has a positive drug test for cannabis if the employee is a qualified patient pursuant to New Hampshire's therapeutic cannabis program. **Introduced and referred to House Labor Committee.**

HB 1404 This bill authorizes physicians and advanced practice registered nurses to examine and provide prophylaxis or treatment for human immunodeficiency virus or acquired immune deficiency syndrome for a minor without parental consent under certain circumstances. This bill also authorizes pharmacists to administer up to a 60-day supply of pre-exposure prophylaxis for human immunodeficiency virus if certain conditions are met. **Introduced and referred to House HHS Committee.**

HB 1440 The bill adds 2 members to the board of psychologists and the board of licensing for alcohol and other drug use professionals. The bill also adds out-of-state applicants for licensure as licensed alcohol and drug counselors, licensed clinical supervisors, or master licensed alcohol and drug counselors to insurance credentialing verification requirements. **Introduced and referred to House Commerce Committee.**

HB 1484 This bill clarifies the law regarding retroactive denials of previously paid claims under accident and health insurance. **Introduced and referred to House Commerce Committee.**

HB 1491 This bill expands the professions in the allied health governing boards which grant temporary licensure to licensees from other states. **Introduced and referred to House Executive Departments and Administration Committee.**

HB 1513 This bill requires the commissioner of the department of health and human services to conduct a study of converting the current Medicaid program into a block grant via a section 1115 waiver. The bill makes an appropriation for the purposes of the bill. **Introduced and referred to House HHS Committee.**

HB 1520 This bill establishes the New Hampshire health policy commission to monitor health care delivery and spending. **Introduced and referred to House HHS Committee.**

HB 1521 This bill adds a peer support specialist to the board of licensing for alcohol and other drug use professionals. **Introduced and referred to House HHS Committee.**

HB 1530 This bill extends the report date for the Medicaid dental benefit working group. **Introduced and referred to House HHS Committee.**

HB 1536 This bill modifies the duties and responsibilities of a pharmacist-in-charge, clarifies the inspection services provided by the board of pharmacy, and repeals a provision on requirements for written orders for schedule II controlled drugs. The bill also adds disciplinary authority for the pharmacy board in the controlled drug act. **Introduced and referred to House Executive Departments and Administration Committee.**

HB 1543 This bill prohibits an employer from using a failed drug test for cannabis use as grounds for terminating the employment of, or to deny promotion to, any employee. **Introduced and referred to House Labor Committee.**

HB 1591-FN This bill requires alternative treatment centers to prepare information regarding the risk of cannabis use during pregnancy. The bill also requires the commissioner of the department of

health and human services to prepare a brochure relative to the risk of cannabis use during pregnancy and while breastfeeding. **Introduced and referred to House HHS Committee.**

HB 1600-FN-A This bill authorizes pharmacists to dispense smoking cessation therapy pursuant to a standing order from a physician or APRN and to be reimbursed under Medicaid. **Introduced and referred to House HHS Committee.**

HB 1616-FN This bill authorizes minors 12 years of age or older to have treatment for behavioral health services without the consent of a parent or guardian. **Introduced and referred to House HHS Committee.**

HB 1623-FN This bill clarifies prescribing certain drugs via telemedicine. **Introduced and referred to House HHS Committee.**

HB 1639-FN This bill requires the department of health and human services to amend the income standard used for eligibility for the "in and out" medical assistance policy. **Introduced and referred to House HHS Committee.**

HB 1655-FN This bill expands the New Hampshire vaccine association to include adult vaccines. **Introduced and referred to House HHS Committee.**

HB 1659-FN This bill allows a mentally competent person who is 18 years of age or older and who has been diagnosed as having a terminal disease by the patient's attending physician and a consulting physician to request a prescription for medication which will enable the patient to control the time, place, and manner of such patient's death. Under this bill, the request is witnessed and signed in essentially the same manner as an advance directive. The bill requires the division of public health services, department of health and human services, to collect certain information and compile a statistical analysis of such information. **Introduced and referred to House Judiciary Committee.**

HB 1675-FN This bill establishes the born alive infant protection act. Under this bill, a person shall not deny or deprive an infant of nourishment with the intent to cause or alter the death of an infant during an abortion. **Introduced and referred to House Judiciary Committee.**

HB-1686-FN-LOCAL This bill adds medical services to the services eligible for the Medicaid to Schools program. This bill also requires the commissioner of the department of health and human services to submit an annual report regarding the Medicaid to Schools program. **Introduced and referred to House Education Committee.**

Senate Bills

SB 255-FN: AN ACT relative to dementia training for direct care staff in residential facilities and community-based settings. This bill requires dementia training for direct care staff in residential facilities and community-based settings. The bill grants rulemaking authority to the commissioner for the purposes of the bill. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by

Committee (5-0) and the Senate. The Amendment eliminates the requirement for the Department to identify and designate approved trainings and makes other technical changes. Introduced in the House and referred to HHS Committee. This bill was retained in Committee during the 2019 legislative session. Voted Ought to Pass with Amendment by the House. The Senate concurred with the House amendment and the bill was signed into law by the Governor effective upon passage. The amendment makes a number of changes to the definitions, training requirements and departmental oversight requirements.

SB 420 This bill permits qualifying patients and designated caregivers to cultivate cannabis for therapeutic use. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee.**

SB 447 This bill adds requirements for pharmacy audits by managed care, insurance company, or third-party payers concerning the scope and time period of audits and prohibits auditor payment based on a percentage of recoupment. **Introduced and referred to Senate Commerce Committee.**

SB 466 This bill clarifies the patients' bill of rights. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. The amendment deleted a proposed change to the law limited the transfer of information to law enforcement. The remaining provision expands the prohibition on denying care to include denial on the basis of gender identity, sexual orientation, familial status, source of income, source of payment or profession.**

SB 506 This bill establishes a commission to study workplace safety in health care settings. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. The amendments revised the composition of the study commission.**

SB 507 This bill clarifies administration of certain drugs or treatment to prevent communicable disease. This bill is a request of the department of health and human services. **Introduced and referred to Senate HHS Committee.**

SB 519 This bill requires an applicant seeking to construct certain health care facilities for licensure under RSA 151 to submit a written notice of such intent to the chief executive officer of a nearby critical access hospital. Under this bill, if the critical access hospital notifies the department of health and human services that it objects to the proposed health care facility, then an expert report shall be prepared. **Introduced and referred to Senate HHS Committee.**

SB 531 This bill clarifies the prior authorization procedures under group health insurance policies and managed care. **Introduced and referred to Senate Commerce Committee.**

SB 540 This bill repeals the emergency medical services personnel licensure interstate compact. **Introduced and referred to Senate Executive Departments and Administration Committee.**

SB 546 This bill requires that boards regulating practitioners prescribing, administering and dispensing controlled substances adopt rules for management of chronic pain. The bill defines chronic pain

for the purposes of the controlled drug prescription health and safety program. **Introduced and referred to Senate HHS Committee.**

SB 555 This bill clarifies coverage for telehealth and telemedicine services under the Medicaid program and the New Hampshire telemedicine act. **Introduced and referred to Senate Commerce Committee.**

SB 580 This bill clarifies the scope of medical payments under a motor vehicle insurance policy. This bill is a request of the insurance department. **Introduced and referred to Senate Commerce Committee.**

SB 593 This bill prohibits the use of titles and descriptions of services of a physician licensed by the board of medicine by unlicensed persons. **Introduced and referred to Senate Executive Departments and Administration Committee.**

SB 594 This bill provides that licensed speech-language pathologists are exempt from the certification requirements for speech-language specialists. **Introduced and referred to Senate Executive Departments and Administration Committee.**

SB 596 This bill allows the public members on the New Hampshire board of nursing to preside at hearings of the board. **Introduced and referred to Senate Executive Departments and Administration Committee.**

SB 598 This bill adds physician assistants to the law governing advance directives. **Introduced and referred to Senate HHS Committee.**

SB 601 This bill modifies the management of optometrist's treatment of glaucoma and repeals the joint credentialing committee for glaucoma credentialing for optometrists. **Introduced and referred to Senate HHS Committee.**

SB 620-FN This bill requires insurers providing benefits for treatment and diagnosis of certain biologically-based mental illnesses and substance use disorders to submit an annual report to the insurance commissioner demonstrating compliance with the Paul Wellstone and Pete Domenici Mental Health Parity and Equity Act of 2008. The bill also clarifies authorization for medication-assisted treatment. **Introduced and referred to Senate Commerce Committee.**

SB 642-FN This bill clarifies the administration of epinephrine and places the law in a different RSA chapter. This bill is a request of the department of health and human services. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. The amendment added definitions of terms used in the Bill.**

SB 647-FN This bill clarifies medication assisted treatment (MAT) by telemedicine and telehealth services. **Introduced and referred to Senate HHS Committee.**

SB 670 This bill clarifies patient triage and transfer to a freestanding hospital emergency facility under certain circumstances. **Introduced and referred to Senate HHS Committee.**

SB 684-FN This bill: I. Authorizes the department of education to adopt rules relative to federal funding available to schools under New Hampshire's Medicaid program. II. Permits professionals certified by the department of education who are providing medical services in public schools to be licensed by medical and health care boards. **Introduced and referred to Senate Education Committee. Voted Ought to Pass with Amendment by Committee and Senate. The amendment includes extensive modifications including changes to the qualifications of professionals providing services in schools. Introduced and referred to House Education Committee.**

SB 686-FN This bill requires pharmacy benefit managers to pass rebates paid by manufacturers on to the consumer or health benefit plan. **Introduced and referred to Senate Commerce Committee.**

SB 687-FN This bill establishes a prescription drug affordability board to determine annual public payor spending targets for prescription drugs, develop and implement policies and procedures for the collection of prescription drug price data, implement a register of drug manufacturers for drug pricing data, and establish funding for the board by reasonable user fees and assessments. **Introduced and referred to Senate Commerce Committee.**

SB 688-FN This bill prohibits price gouging in the sale of prescription drugs. **Introduced and referred to Senate Commerce Committee.**

SB 689-FN This bill prohibits a referral of a patient to a pharmacy by a health carrier or pharmacy benefit manager for pharmacy care. **Introduced and referred to Senate Commerce Committee.**

SB 690 This bill prohibits prescription drug formulary changes during a contract year under the managed care law. **Introduced and referred to Senate Commerce Committee.**

SB 691 This bill clarifies the procedure for prior authorization for prescription drugs on the formulary under the managed care law. This bill is a request of the insurance department. **Introduced and referred to Senate Commerce Committee.**

SB 697-FN This bill allows qualifying patients to access all the alternative treatment centers under the use of cannabis for therapeutic purposes law. **Introduced and referred to Senate HHS Committee.**

SB 700-FN This bill adds autism to qualifying medical conditions under therapeutic use of cannabis. **Introduced and referred to Senate HHS Committee.**

SB 715-FN This bill clarifies the cost controls for long-term care services. **Introduced and referred to Senate HHS Committee.**

SB 716-FN This bill expands Medicaid coverage for services intended to support healthy childhood development. The bill also directs the department of health and human services to complete a fiscal impact study regarding expansion of Medicaid coverage for childhood mental health services and directs the department to develop a plan to maximize the use of EPSDT and IECMH benefits under Medicaid. **Introduced and referred to Senate HHS Committee. Voted Ought to**

Pass with Amendment by Committee and Senate. The amendment changes the date by which the commissioner must submit administrative rules and amend the state Medicaid plan from November 1, 2020 to January 1, 2021.

SB 729-FN This bill adds cardiac electrophysiology specialist and cardiovascular invasive specialist to the licenses administered by the medical imaging and radiation therapy board. The bill also adds a requirement for a criminal history records check for medical imaging and radiation therapy license applicants, and modifies procedures for the board. **Introduced and referred to Senate Executive Departments and Administration Committee.**

SB 739-FN This bill requires insurers providing benefits for mental health and substance use disorders to reimburse covered persons for benefits delivered through the psychiatric collaborative care model. **Introduced and referred to Senate Commerce Committee.**

SB 742-FN This bill revises the definition of Alzheimer's disease and related disorders and makes an appropriation for the purposes of the bill. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment. Amendments provide clarification to the definitions and appropriate $100,000 for the purposes of this act.**

2020 LEGISLATIVE SERVICE REQUESTS

2020-3127 relative to non-covered services under dental insurance plans.

2020-3129 establishing a dental benefit under the state Medicaid program.

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Cinde Warmington, Kara J. Dowal 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.

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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.

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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.

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