NH LEGAL UPDATE

Shaheen & Gordon ATTORNEYS AT LAW

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Health Care Practice Group

Cinde Warmington, Chair
cwarmington@shaheengordon.com

Steven M. Gordon
sgordon@shaheengordon.com

Lucy J. Karl
lkarl@shaheengordon.com

William E. Christie
wchristie@shaheengordon.com

Kara J. Dowal
kdowal@shaheengordon.com

Alexander W. Campbell
acampbell@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.

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FEDERAL DEVELOPMENTS

OIG Issues Special Fraud Alert on Drug, Device Manufacturer Speaker Programs

On November 16, the Office of Inspector General ("OIG") issued a Special Fraud Alert highlighting the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. OIG defines "speaker programs" as "company-sponsored events at which a physician or other health care professional (collectively, "HCP") makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company." OIG reports that in the last three years, drug and device companies have reported paying nearly $2 billion to HCPs for speaker-related services. The Special Fraud Alert communicates OIG's skepticism of the educational value of such programs, especially in light of the high risk of fraud and abuse that they present. OIG reports having pursued criminal and civil cases against companies and individual HCPs for violations of the Anti-Kickback Statute and other laws over speaker programs in which companies have, for example: selected high-prescribing HCPs to be speakers and rewarded them with lucrative speaker deals; conditioned speaker remuneration on sales targets; held speaker programs at entertainment venues or during recreational events or otherwise in a manner not conducive to an educational presentation; held programs at high-end restaurants where expensive meals and alcohol were served; and invited an audience of HCP attendees who had previously attended the same program or HCPs' friends, significant others, or family members who did not have a legitimate business reason to attend the program.

OIG recommends that companies assess the need for in-person programs given the risks associated with offering or paying related remuneration and consider alternative less-risky means for conveying

information to HCPs, and that HCPs consider the risks of soliciting or receiving remuneration related to speaker programs given other available means to gather information relevant to providing appropriate treatment for patients.

The Special Fraud Alert is available at: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf.

CMS Reports Decrease in Improper Payments for Medicare, Increase for Medicaid & CHIP

On November 16, the Centers for Medicare & Medicaid Services ("CMS") issued the results of its periodic review of improper payments made by the programs it administers. CMS reports that the improper payment rate for Medicare Fee for Service decreased from 725% in Fiscal Year ("FY") 2019 to 6.27% in FY 2020, corresponding to a drop in improper payments from $28.91 billion to $25.74 billion. The improper payment rate for Medicare Part C also decreased from 7.87% ($16.73 billion) to 6.78% ($16.27 billion), although the rate decreased for Medicare Part D from 0.75% ($0.61 billion) to 1.15% ($0.93 billion). Outside of Medicare, improper payments rose for Medicaid from a rate of 14.9% ($57.36 billion) to 21.36% ($86.49 billion), and CHIP saw a similar increase from 15.83% ($2.74 billion) to 27% ($4.78 billion). According to CMS, the major driver of improper payments in Medicaid and CHIP was eligibility errors.

A Fact Sheet on CMS' review improper payments is available at: https://www.cms.gov/newsroom/fact-sheets/2020-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs.

GAO Recommends Greater FDA Transparency of Safety and Efficacy Date to Support COVID-19 Emergency Use Authorizations

On November 17, the U.S. Government Accountability Office ("GAO") issued a report titled "Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations," in which it examined 1) the efforts of the administration's Operation Warp Speed to accelerate COVID-19 vaccine and therapeutic development, and 2) the U.S. Food and Drug Administration's ("FDA") use of emergency use authorizations ("EUAs") for COVID-19 therapeutics and vaccines. The GAO found that as of October 15, 2020, Operation Warp Speed had publicly announced financial support for the development or manufacturing of six COVID-19 vaccine candidates totaling more than $10 billion in obligations, and financial support for the development of several therapeutics. While a typical vaccine development process can take approximately 10 years or longer, efforts under Operation Warp Speed seek to greatly accelerate this process by completing key steps simultaneously. The GAO found that unlike in the normal approval process, FDA issuance of EUAs does not typically require FDA to uniformly disclose its scientific review of safety and effectiveness data. GAO recommended that, given the gravity of the COVID-19 pandemic, FDA should identify ways to uniformly disclose to the public the information from its scientific review of safety and effectiveness data when issuing EUAs for therapeutics and vaccines. HHS neither agreed nor disagreed with the recommendation, but said it shared GAO's goal of transparency and would explore approaches to achieve this goal.

The GAO's report is available at: https://www.gao.gov/assets/720/710691.pdf.

FDA Issues Emergency Use Authorization for At-Home Self-Testing Kit

On November 17, the U.S. Food and Drug Administration ("FDA") issued an emergency use authorization ("EUA") for the Lucira COVID-19 All-in-One Test Kit, which is a molecular test for self-testing at home that

provides rapid results. This is the first such test that has received FDA authorization. The Lucira COVID-19 All-In-One Test Kit test has been authorized for home use with self-collected nasal swab samples in individuals age 14 and older who are suspected of COVID-19 by their health care provider. It is also authorized for use in point-of-care (POC) settings (e.g., doctor's offices, hospitals, urgent care centers and emergency rooms) for all ages but samples must be collected by a healthcare provider when the test is used at the POC to test individuals younger than 14 years old. The test is currently authorized for prescription use only.

FDA's announcement of the EUA is available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-self-testing-home.

OCR Settles Twelfth HIPAA Right of Access Probe with University of Cincinnati Medical Center

On November 19, the Office for Civil Rights announced that it had settled its twelfth investigation under its HIPAA Right of Access Initiative. Under the settlement, the University of Cincinnati Medical Center ("UCMC") has agreed to take corrective actions and pay $65,000 to resolve a potential violation of the HIPAA Privacy Rule's right of access standard. According to OCR, it received a complaint in May of 2019 that UCMC had failed to respond to a patient's February 22, 2019, records access request directing UCMC to send an electronic copy of her medical records maintained in UCMC's electronic health record ("EHR") to her lawyers. OCR opened an investigation, which resulted in UCMC producing the records to the patient in August 2019.

OCR's press release about the settlement is available at: https://www.hhs.gov/about/news/2020/11/19/ocr-settles-twelfth-investigation-hipaa-right-access-initiative.html.

More information about patient's right of access under HIPAA is available at: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.

HHS Launches New COVID-19 Testing Pilot Program

On November 19, the U.S. Department of Health and Human Services ("HHS") launched a pilot program of fast molecular point-of-care tests for COVID-19. The program is being run in Alaska, Florida, Louisiana, New Jersey and Texas, and involves the use of portable, cartridge-based COVID-19 molecular test kits that provide rapid results. According to HHS, "[t]he pilot program will assess how to best integrate diagnostic technology developed by Cue Health, Inc., into strategies for disease surveillance and infection control in institutions such as nursing homes." The point-of-care tests can return results in about 20 minutes, compared to the 2-3 days it currently takes to receive results from samples that are sent to a lab.

HHS' announcement of the pilot program is available at: https://www.hhs.gov/about/news/2020/11/19/hhs-launches-pilot-program-fast-molecular-poc-test-covid-19.html.

HHS Issues Request for Information Seeking Innovative Approaches in Response to COVID-19

On November 24, the U.S. Department of Health and Human Services ("HHS") published a Request for Information ("RFI") seeking information from health care providers on the innovative approaches they have adopted to continue to provide services during the COVID-19 pandemic. In particular, HHS is looking for information about how healthcare systems and clinicians have reengineered their policies and programs to improve access, safety, quality, outcomes including mortality and morbidity, cost, and value for both COVID–

19 and non-COVID–19 related medical conditions. According to HHS, it "plans to identify and learn from effective innovative approaches and best practices implemented by non-HHS organizations in order to inform HHS priorities and programs."

Comments should be submitted through the Innovation RFI Response Portal (https://rfi.grants.nih.gov/?s=5f89e1e8400f00001a0036f2) and must be received by December 24, 2020.

The RFI is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-24/pdf/2020-25795.pdf.

CMS Issues Interim Rule Tying Medicare Drug Prices to International Benchmarks

On November 27, the Centers for Medicare & Medicaid Services ("CMS") published an interim final rule implementing a new "Most Favored Nation" ("MFN") Model for Medicare payment. According to CMS, "The MFN Model will test whether more closely aligning payment for Medicare Part B drugs and biologicals with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries."

Comments to the interim final rule must be received by January 26, 2021.

The interim final rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.

OIG Issues Final Rule Limiting Drug Discount AKS Safe Harbor

On November 30, the Office of Inspector General ("OIG") published a final rule amending the drug discount safe harbor under the Anti-Kickback Statute ("AKS"). The final rule modifies the safe harbor by excluding from the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D or pharmacy benefit managers ("PBMs") under contract with them. The final rue also creates safe harbors for two additional types of arrangements: certain point-of-sale reductions in price on prescription pharmaceutical products; and certain PBM service fees.

The earlier proposed rule from January 2019 was withdrawn later that year amid pushback from PBMs and some lawmakers. In July of 2020, President Trump directed that the rule be revived. The Congressional Budget Office previously estimated that the rule would result in an increase to Medicare Part D premiums and federal spending.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-30/pdf/2020-25841.pdf.

CMS, OIG Release Stark, AKS Final Rules

On December 2, the Office of Inspector General ("OIG") and the Centers for Medicare & Medicaid Services ("CMS") published long-awaited final rules enacting changes to regulations promulgated under the Anti-Kickback Statute ("AKS") and the Stark Law's prohibition against physician self-referrals ("Stark").

The Stark Final Rule includes the following changes: establishes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers; establishes a new exception for certain arrangements under which a physician receives limited

remuneration for items or services actually provided by the physician; establishes a new exception for donations of cybersecurity technology and related services; and amends the existing exception for electronic health records ("EHR") items and services. The Stark Final Rule also provides guidance and clarification on key concepts for compliance, including how to determine whether the fair market value compensation requirement has been met under certain exceptions.

The AKS Final Rule adds new safe harbors for value-based arrangements, patient engagement and support, participation in CMS-sponsored models, and the provision of cybersecurity technology and services. The AKS Final Rule also modifies several existing safe harbors and adds a new exception to the imposition of civil monetary penalties for beneficiary inducements.

The Stark Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf.

The AKS Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf.

Medical Biller's Alleged Fraud Scheme Results in Federal Indictment

On November 20, the U.S. Attorney for the Middle District of Florida announced the indictment of a medical biller—Joshua Maywalt—on four counts of health care fraud and four counts of aggravated identity theft. The charges stem from Maywalt's alleged misconduct in wrongfully accessing and utilizing a physician customer's patient information and the physician's name and identification number to submit false and fraudulent claims to a Florida Medicaid HMO for the medical services purportedly rendered by the physician, which were not actually rendered. Maywalt also allegedly altered the "pay to" information associated with the Florida Medicaid HMOs' payment processor so that the payments for the non-rendered medical services were sent to bank accounts under Maywalt's control. Maywalt faces a maximum penalty of 10 years in federal prison for each of the health care fraud counts, and up to 2 years' imprisonment for each aggravated identity theft count. The indictment also notifies Maywalt that the United States intends to forfeit $2.2 million dollars and real property located in Tampa, Florida, alleged to be traceable to proceeds of the offense.

The U.S. Attorney's announcement is available at: https://www.justice.gov/usao-mdfl/pr/tampa-bay-area-medical-biller-indicted-health-care-fraud-and-aggravated-identity-theft.

OIG Issues Updated Fraud Alert on COVID-19 Scams

On November 23, the Office of Inspector General ("OIG") updated its COVID-19 fraud alert webpage to include new information about fraud schemes related to COVID-19, including the following examples:

- Scammers posing as friends or government employees on social media and telling Medicare beneficiaries that they are eligible for government assistance grants. When the beneficiary provides bank information to cover a "processing fee," large sums of money are then withdrawn from their account.
- Scammers offering illegitimate tests to beneficiaries in exchange for personal information.
- Medical labs claiming to offer COVID-19 tests, but instead simply drawing blood and billing federal health care programs for unnecessary tests.

According to OIG, scammers are targeting beneficiaries through telemarketing calls, text messages social media platforms, and door-to-door visits. The updated fraud alert offers several tips and suggestions for beneficiaries to avoid becoming victims of COVID-19 scams and a hotline for reporting suspected fraud.

OIG's updated fraud alert is available at: https://oig.hhs.gov/coronavirus/fraud-alert-covid19.asp?utm_source=web&utm_medium=web&utm_campaign=covid19-fraud-alert

OIG Issues Report of Impacts of COVID-19 on Opioid Treatment Programs

On November 23, the Office of Inspector General ("OIG") posted a report titled "Opioid Treatment Programs Reported Challenges Encountered During the OVID-19 Pandemic and Actions Taken to Address Them." The report contained findings from OIG's review of opioid treatment programs ("OTPs") to identify challenges that OTPs have encountered during the COVID-19 pandemic and actions they have taken to address those challenges. OIG randomly selected 150 OTPs nationwide for interviews; it received responses from 142 OTPs located in 37 states and the District of Columbia. The OTPs reported several challenges, including: (1) maintaining pre-pandemic service levels; (2) managing impacts on facility operations; (3) implementing and using telehealth; (4) obtaining treatment medications, personal protective equipment, and cleaning supplies; and (5) maintaining patient participation in OTP activities. The OTPs reported taking several actions to address these challenges, including: (1) encouraging or requiring various personal safety measures for patients and staff; (2) implementing or expanding the use of telehealth to continue providing services; (3) increasing the number of take-home doses to reduce the number of patients visiting facilities; (4) making physical changes to facilities and increasing staffing flexibilities; and (5) ensuring that patients received treatment medications.

OIG provided a draft of its report to the Substance Abuse and Mental Health Services Administration ("SAMHSA"), responded with written comments describing actions it had taken after becoming aware of COVID-19's impact on operations for its behavioral health stakeholders, such as providing technical assistance and training during the pandemic.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region9/92001001.pdf.

Federal Court in Ohio Dismisses Claims Against Credentialing Hospitals for Physicians' Alleged Malpractice

On November 13, the U.S. District Court for the Southern District of Ohio issued an order dismissing medical malpractice brought against the University of Cincinnati Medical Center ("UCMC") and UC Health arising out of injuries allegedly caused by surgeons during an operation on the plaintiff conducted at West Chester Hospital, an affiliate of UC Health. In the complaint, the plaintiff brought claims against UCMC and UC Health under a theory that they are vicariously liable for the alleged conduct of their "credentialed" physicians, including the surgeons who operated on the plaintiff. In dismissing the claims against UCMC and UC Health, the court relied on the fact that the plaintiff failed to allege any facts showing that she believed UCMC or UC Health to be the provider of care when she went in for her operation. In the absence of sufficient factual allegations that the plaintiff "looked to" these defendants to provide medical care, the claims against them failed.

The opinion in *Burnett v. United States*, No. 19-cv-43 (S.D. Ohio Nov. 13, 2020), is available online at several locations, including: https://casetext.com/case/burnett-v-united-states-54.

CMS to Implement New ICD-10 Procedure Codes and MS-DRGs for COVID-19 Starting January 1

In December, the Centers for Medicare & Medicaid Services ("CMS") announced that it will be implementing new ICD-10 procedure and diagnosis codes for COVID-19 related therapies and conditions. As of January 21, CMS will implement 21 new ICD-10 procedure codes for COVID-19 vaccines and therapeutics, and will assign Medicare Severity-Diagnosis-Related Groups ("MS-DRG") to six new ICD 10 diagnosis codes related to COVID-19, including: pneumonia due to COVID-19; multisystem inflammatory syndrome; other systemic involvement of connective tissue; and encounter for COVID-19 screening.

Information about the MS-DRG assignment is available from CMS' MS-DRG Classifications and Software website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

CMS Issues CY 2021 Physician Fee Schedule Final Rule

On December 1, the Centers for Medicare & Medicaid Services ("CMS") issued a Final Rule implementing updates and changes to the calendar year ("CY") 2021 Physician Fee Schedule and other programs. The Final Rule includes a series of standard technical proposals involving practice expense, including the implementation of the third year of the market-based supply and equipment pricing update, and standard rate-setting refinements to update premium data involving malpractice expense and geographic practice cost indices. The final CY 2021 PFS conversion factor is $32.41, a decrease of $3.68 from the CY 2020 PFS conversion factor of $36.09.

CMS is also finalizing changes to the telehealth list, including adding services on a Category 1 (services similar to existing services on the telehealth list) basis—including group psychotherapy, home visits for established patients, and cognitive assessment and care planning services—and creating a new Category 3 for services added the telehealth list during the COVID-19 Publish Health Emergency ("PHE") that will remain on the list through the calendar year in which the PHE ends. Services added to Category 3 include physical and occupational therapy services, hospital discharge day management, and critical care services. The Final Rule also includes additional requirements for telehealth services and remote patient monitoring.

The Final Rule also implements the alignment of E/M visit coding and documentation policies with changes laid out by the CPT Editorial Panel for office/outpatient E/M visits, beginning January 1, 2021, and clarifies the definition of HCPCS add-on code G2211 for visit complexity.

The Final Rule is scheduled to be published in the Federal Register on December 28 and will be available starting on that date at: https://www.federalregister.gov/d/2020-26815. Until then, the unpublished version is available at: https://public-inspection.federalregister.gov/2020-26815.pdf.

CMS Issues CY 2021 OPPS and ASC Payment System Final Rule

On December 2, the Centers for Medicare & Medicaid Services ("CMS") issued a Final Rule implementing updates and changes to the calendar year ("CY") 2021 Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center ("ASC") Payment System. The Final Rule includes an overall increase to OPPS and ASC Payment System rates of 2.4%. The Final Rule also includes a number of other changes including: a three-year phase out of the Inpatient Only list; the addition of eleven new procedures to the ASC covered procedures list; continuation of the current 340B discount payment policy of paying Average

Sales Price minus 22.5% for 340B-acquired drugs; and update and simplification of the methodology used to calculate the Overall Hospital Quality Star Rating.

The Final Rule is scheduled to be published in the Federal Register on December 29 and will be available starting on that date at: https://www.federalregister.gov/d/2020-26819. Until then, the unpublished version is available at: https://www.cms.gov/files/document/12220-opps-final-rule-cms-1736-fc.pdf.

STATE DEVELOPMENTS

2021 Legislative Service Requests

2021-0010	HB	Title: relative to continued in-network access to certain health care providers.
2021-0012	HB	Title: relative to cannabis use during pregnancy.
2021-0014	HB	Title: relative to the therapeutic cannabis program.
2021-0015	HB	Title: requiring health care providers to provide cost quotes for non-emergency services.
2021-0043	HB	Title: relative to the therapeutic cannabis medical oversight board.
2021-0052	HB	Title: relative to administration of psychotropic medications to children in foster care.
2021-0069	HB	Title: establishing a dental benefit under the state Medicaid program.
2021-0082	HB	Title: relative to the age for minor's visits to mental health practitioners.
2021-0083	HB	Title: relative to reporting of health care associated infections.
2021-0084	HB	Title: adding qualifying medical conditions to the therapeutic use of cannabis law.
2021-0096	HB	Title: relative to funding for newborn screening.
2021-0105	HB	Title: relative to an electronic prescription drug program.
2021-0122	HB	Title: relative to noncompete agreements for certain mental health professionals.
2021-0129	HB	Title: extending certain civil immunity to public and private entities during major public health emergencies.
2021-0133	HB	Title: requiring health care providers to furnish upon request a list of ingredients contained in an injectable medication that is recommended or administered.
2021-0136	HB	Title: relative to regulation of audiologists and hearing aid dealers, relative to the interstate Audiology and Speech-Language Pathology Compact, and relative to the use of physical agent modalities by occupational therapists.
2021-0139	HB	Title: relative to licensure renewal dates for certain governing boards under the office of professional licensure and certification
2021-0142	HB	Title: relative to claims for medical monitoring.

2021-0158	HB	Title: expanding the New Hampshire vaccine association to include adult vaccines.
2021-0164	HB	Title: relative to treatment alternatives to opioids.
2021-0173	HB	Title: relative to the emergency powers of the commissioner of health and human services.
2021-0203	HB	Title: removing the work requirement of the New Hampshire granite advantage health care program.
2021-0205	HB	Title: relative to opting in to the state pediatric and adult vaccine registries.
2021-0206	HB	Title: establishing the medical freedom act.
2021-0210	HB	Title: relative to including certain children and pregnant women in Medicaid the children's health insurance program.
2021-0235	HB	Title: relative to adopting the interstate Audiology and Speech-Language Pathology Compact.
2021-0280	HB	Title: relative to prior authorizations and interfacility transports under group health insurance policies and managed care.
2021-0283	HB	Title: establishing a committee to study methods to reduce health care costs in New Hampshire.
2021-0398	HB	Title: relative to certification requirements for school nurses.
2021-0440	HB	Title: relative to policies required for health facilities and special health care service licenses.
2021-0535	HB	Title: permitting qualifying patients and designated caregivers to cultivate cannabis for therapeutic use.
2021-0565	HB	Title: relative to the board of pharmacy.
2021-0568	HB	Title: relative to reimbursements for telemedicine.
2021-0570	HB	Title: repealing the prohibition on entering or remaining on a public way or sidewalk adjacent to a reproductive health care facility.
2021-0708	HB	Title: relative to pharmacist administration of vaccines and allowing a licensed advanced pharmacy technician to administer vaccines.
2021-0735	HB	Title: relative to telehealth and telemedicine.
2021-0772	HB	Title: relative to prescriptions for the treatment of attention deficit disorder or attention deficit disorder with hyperactivity.
2021-0802	HB	Title: removing certain authority of the department of health and human services concerning immunizations.
2021-0809	HB	Title: authorizing individuals and certain businesses to purchase health insurance from out-of-state companies.
2021-0181	SB	Title: establishing a commission to study workplace safety in health care settings.

2021-0207	SB	Title: relative to hearings of the New Hampshire board of nursing.
2021-0208	SB	Title: relative to nursing home standards.
2021-0257	SB	Title: establishing a dental benefit under the state Medicaid program.
2021-0277	SB	Title: relative to telemedicine provided by out of state psychologists.

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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.

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.

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.