## Health Care Practice Group

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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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## REMINDERS

- **Annual Reports for New Hampshire business entities are due to the Secretary of State by April 1, 2021.**

- **Annual Breach Notification Reports must be made to the Office of Civil Rights by March 1, 2021 at:** https://ocrportal.hhs.gov/ocr/breach/wizard_breach.jsf?faces-redirect=true

*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.***

## FEDERAL DEVELOPMENTS

### *HHS Announces FCA Working Group to Combat Fraud*

On December 4, the U.S. Department of Health and Human Services ("HHS") announced a new False Claims Act Working Group made of former prosecutors and HHS attorneys to combat fraud and abuse in HHS programs. According to the Former HHS Secretary Alex Azar: "This working group strengthens [HHS'] partnership with DOJ and OIG on using the False Claims Act to pursue bad actors and protect taxpayer funds."

The Working Group will take a number of steps to enhance the mission of preventing fraud and abuse, including providing enhanced and targeted training to the HHS programs that are most vulnerable to fraud and abuse and providing a focal point within the agency for consultation about legal requirements and recommendations about alleged violations.

HHS' announcement of the Working Group is available at: https://www.hhs.gov/about/news/2020/12/04/hhs-announces-false-claims-act-working-group-enhance-efforts-combat-fraud-and-focus-resources-bad-actors.html.

***U.S. Supreme Court Agrees to Hear Challenges to State Medicaid Work Requirements***

On December 4, the U.S. Supreme Court agreed to hear two challenges to Medicaid work requirements in Arkansas and New Hampshire. These requirements, as well as similar requirements in Michigan and Kentucky, had all received federal approval prior. Subsequent to the approvals, they have been successfully challenged in federal court. Recently, in February of 2020, the D.C. Circuit affirmed the District Court's decision finding that the U.S. Department of Health and Human Services had failed to consider the impact that a work requirement would have on Medicaid coverage when issuing its approval, and there the approval was arbitrary and capricious. The Supreme Court is expected to hear oral arguments in the case in the coming months.

The Circuit Court's order in *Gresham v. Azar*, 950 F. 3d 93 (D.C. Cir. 2020), is available at: https://scholar.google.com/scholar_case?case=5251918899457822307&hl=en&as_sdt=6&as_vis=1&oi=scholarr.

***U.S. Supreme Court Declines to Hear Appeal of Dismissal of Whistleblower Action for Upcoding Claims***

On December 7, the U.S. Supreme Court declined to hear a challenge to a Fifth Circuit decision affirming the dismissal of a False Claims Act whistleblower complaint that a hospital network had submitted $68.1 million in fraudulently upcoded claims. In affirming the District Court's dismissal, the Fifth Circuit reviewed the plaintiff's allegations that the hospital system had engaged in a coordinated campaign to include in its claims and to upcode complications and comorbidities, resulting in greater reimbursement from Medicare. In dismissing the complaint, the Court concluded that the hospital system "was simply ahead of the healthcare industry in following CMS guidelines" concerning coding and documentation or complications and comorbidities, and that there had not been any fraud. The Supreme Court's decision not to hear an appeal from the Circuit Court means that the dismissal will stand.

The Fifth Circuit's decision in *United States ex rel. Integra Med Analytics, LLC v. Baylor Scott& White Health*, No. 19-50818 (5th Cir. May 28, 2020), is available at: http://www.ca5.uscourts.gov/opinions/unpub/19/19-50818.0.pdf.

***Federal Court Orders Hospital to Turn over Peer Review Documents***

On December 7, the District Court for the Eastern District of California granted a motion to compel the production of records of the peer review process conducted by a defendant hospital in a claim brought by a physician against the California Department of Public Health ("CDPH"). As part of its defense, the CDPH subpoenaed the hospital at which the physician performed surgery for peer review records relating to a particular procedure. The non-party hospital objected to producing the records, arguing that they were protected by California's peer review privilege, the self-critical analysis privilege, and the right to privacy under the California Constitution. In granting CDPH's motion to compel, the Court noted that the state peer review

privilege was inapplicable and that the Ninth Circuit has consistently declined to recognize a federal common law peer review privilege.

The decision in *Chaudhry v. Angell*, No. 1:16-cv-01243-SAB (E.D. Cal. Dec. 7, 2020) is available at: https://casetext.com/case/chaudhry-v-angell-1.

***HHS Publishes HIPAA Proposed Rule***

On December 10, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") issued a Proposed Rule that proposed changes to the HIPAA Privacy Rule to "support individuals' engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the health care industry," according to OCR. One of the biggest changes in the Proposal Rule is to modify provisions concerning the individuals' right of access their own protected health information ("PHI") by: allowing individuals to take notes or use other personal resources to view and capture images of their PHI; shortening covered entities' required response time to no later than 15 calendar days (from the current 30 days) with the opportunity for an extension of no more than 15 calendar days (from the current 30-day extension); clarifying the form and format required for responding to individuals' requests for their PHI; requiring covered entities to inform individuals that they retain their right to obtain or direct copies of PHI to a third party when a summary of PHI is offered in lieu of a copy; reducing the identity verification burden on individuals exercising their access rights; limiting the individual right of access to direct the transmission of PHI to a third party to electronic copies of PHI in an EHR.

In additions to changes to the individuals' right of access, the Proposed Rule also amends the definition of health care operations to clarify the scope of permitted uses and disclosures for individual-level care coordination and case management that constitute health care operations, creates an exception to the ''minimum necessary'' standard for individual-level care coordination and case management uses and disclosures, and clarifies or expands certain other permitted disclosures.

The Proposed Rule was published in the Federal Register on January 21 and is available at: https://www.govinfo.gov/content/pkg/FR-2021-01-21/pdf/2020-27157.pdf.

Comments must be received by March 22, 2021.

***DOJ Requires Divestiture in Harvard Pilgrim-Tufts Deal***

On December 14, the U.S. Department of Justice ("DOJ") announced that it was requiring that Tufts Health Plan divest its New Hampshire business—Tufts Health Freedom Plan—as a condition of DOJ's approval of Tuft's merger with Harvard Pilgrim Health Care. Both DOJ and the New Hampshire Attorney General's Office objected to the merger on antitrust grounds and filed suit in federal court to block the transaction. The same day the suit was filed, the parties filed a proposed settlement that required Tufts to sell Tufts Health Freedom Plan to UnitedHealth.

The DOJ's announcement is available at: https://www.justice.gov/opa/pr/justice-department-requires-divestiture-tufts-health-freedom-plan-order-harvard-pilgrim-and.

***CMS Announces New Demonstration Project Aimed at Curbing IRF Medicare Fraud***

On December 15, the Centers for Medicare & Medicaid Services ("CMS") announced a new Review Choice Demonstration for Inpatient rehabilitation Facility ("IRF") services. Under the demonstration, IRFs participating in the demonstration can choose between pre-claim review and post-payment review to

demonstrate compliance with Medicare program policies. Under the pre-claim review choice, services can begin prior to the submission of the pre-claim review request and continue while the decision is being made. The pre-claim review request with required documentation must be submitted and reviewed before the final claim is submitted for payment. Under the post-payment review choice, IRFs would provide services, submit all claims for payment following their normal processes, and then submit required documentation for medical review. This would determine whether the inpatient rehabilitation services for the beneficiary complied with applicable Medicare coverage and clinical documentation requirements.

CMS chose IRFs for a demonstration due to the potential for high rates of improper payments in these facilities. In fiscal year 2020, the estimated amount of improper payments to IRFs under Medicare fee-for-service was more than $2.4 billion, or 30.8%, the second-largest amount among Medicare service areas.

CMS plans to implement the demonstration in Alabama, and then expand to Pennsylvania, Texas, and California. These states were selected due to particularly high rates of improper payments for IRF services. The demonstration would begin in 2021.

CMS' announcement of the new demonstration project is available at: https://www.cms.gov/newsroom/press-releases/cms-solicits-public-comment-new-demonstration-offer-inpatient-rehabilitation-providers-flexibilities.

***Final Rule Provides Plans Flexibility to Increase Cost-Sharing Without Losing ACA "Grandfathered" Status***

On December 15, the Internal Revenue Services, U.S. Department of Labor, and U.S. Department of Health and Human Services published a Final Rule that provide greater flexibility for certain grandfathered health plans to make changes to certain types of fixed- amount cost-sharing requirements without causing a loss of grandfather status under the Patient Protection and Affordable Care Act.

The Final Rule only addresses the requirements for grandfathered group health plans and grandfathered group health insurance coverage and does not apply to or otherwise change the current requirements applicable to grandfathered individual health insurance coverage.

The Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-12-15/pdf/2020-27498.pdf.

***EEOC Issues Guidance on Employers Requiring COVID-19 Vaccination***

On December 16, the Equal Employment Opportunity Commission ("EEOC") updated its guidance titled "What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws." The update clarifies that employers may require vaccinations without violating either the Americans with Disabilities Act ("ADA") or the Rehabilitation Act, because a vaccination requirement may be considered a "safety-based qualification standard" under those statutes. The guidance does state, however, that employers must also have a process for responding to and accommodating, if possible, employees whose health status precludes them from obtaining vaccination or whose sincerely-held religious belief is contrary to vaccination.

EEOC's guidance is available at: https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

***CMS Announces New Medicaid CMO Payment Model for Medicare-Medicaid Dually Eligible Beneficiaries***

On December 17, the Centers for Medicare & Medicaid Services ("CMS") announced a new model opportunity for Medicaid managed care organizations ("MCOs") serving dually-eligible beneficiaries. According to CMS, the purpose of the model will be to encourage Medicaid MCOs to partner with providers and suppliers and implement care coordination programs that can improve quality and reduce Medicare fee-for-service costs. CMS hopes that the model will test whether holding Medicaid MCOs or their corporate affiliates accountable for health outcomes and Medicare fee-for-service costs for their full-benefit dually eligible Medicaid MCO enrollees, in addition to the risk the Medicaid MCOs currently have under Medicaid, will lead to innovative strategies for improving care for this high-risk population.

CMS expects to begin accepting applications in early 2021, with participation in the direct contracting model starting in January 2022.

A CMS Fact Sheet on the new model is available at: https://www.cms.gov/newsroom/fact-sheets/direct-contracting-model-professional-and-global-options-medicaid-managed-care-organization-mco.

***OIG Approves Provision of Medicaid Enrollment Application Services at Below Fair Market Value***

On December 18, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued Advisory Opinion 20-06 approving of a proposed arrangement wherein a management company that provides services to skilled nursing facilities ("SNFs") and home health agencies ("HHA") would provide Medicaid enrollment assistance services to patients, and potential patients, of the SNFs and HHAs at a below fair market fee. The fee would be paid either directly by the patients or by the SNFs, under certain circumstances.

OIG found that the proposed arrangement's provision of services at below market value implicated both the Anti-Kickback Statute and the prohibition against beneficiary inducements. Nonetheless, OIG concluded that the proposed arrangement posed a minimal risk of fraud and abuse for the following reasons: the remuneration to patients satisfies the "promotes access to care" exception of the prohibition against beneficiary inducements; the remuneration would be unlikely to interfere with clinical decision making, to increased federal health care program costs, or lead to overutilization; the remuneration would only be offered to patients who already selected a SNF or HHA for the health care needs; and wouldn't affect Medicaid's normal eligibility determination process.

Advisory Opinion 20-06 is available at:
https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-06.pdf.

***OIG Approves of Providers Paying Remittance to Patients and Payers Through Web-Based Platform***

On December 21, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued Advisory Opinion 20-07 approving of a proposed arrangement between an online platform, participating providers, and patients, including Medicare beneficiaries. Under the proposed arrangement, the platform would provide a list of potential providers providing a particular service in the area that patients could search. Participating providers would agree to enter into contracts with patients for remittances, which would be split between the patient and the payor, after the platform deducts an administrative fee. The platform would also provide a personalized concierge service to patients to assist with health insurance and cost comparison.

OIG found that the proposed arrangement included several remuneration streams that implicated both the Anti-Kickback Statute and the prohibition against beneficiary inducements. Nonetheless, OIG concluded that the proposed arrangement posed a minimal risk of fraud and abuse, for the following reasons: the remittances would be limited to medically necessary services and would only be paid out if certain payment requirements are satisfied by the payor; the platform would only collect the administrative fee after patients receive remittances; the amount of the remittances would not vary by payor; and the platform would not steer patients to a particular provider.

Advisory Opinion 20-07 is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-07.pdf.

***OCR Settles Thirteenth Investigation in HIPAA Right of Access Initiative***

On December 22, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") announced that it had entered into its thirteenth settlement in its HIPAA Right of Access Initiative, this time with a solo physician for $36,000. According to OCR, it received a complaint in April 2019 alleging that the physician had failed to respond to a patient's request for access to his medical records. In May 2019, OCR provided technical assistance to the physician on the HIPAA right of access requirements and closed the complaint. In October 2019, OCR received a second complaint alleging that the physician still had not provided the patient with access to his medical records. OCR initiated an investigation and determined that the physician's failure to provide the requested medical records was a potential violation of the HIPAA right of access standard. As a result of OCR's investigation, the patient received a copy of his medical record in May 2020.

A press release from OCR on the settlement is available at: https://www.hhs.gov/about/news/2020/12/22/ocr-settles-thirteenth-investigation-in-hipaa-right-of-access-initiative.html.

**OIG Approves FQHC Offering Gift Card Incentives to Pediatric Patients for Attending Care Appointments**

On December 23, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued Advisory Opinion 20-07 approving of a proposed arrangement wherein a Federally-qualified health center ("FQHC"), in attempt to increase the rate at which its pediatric patients make and keep appointments for necessary preventative and early intervention care appointments, would contact patients with a history of missing previously-scheduled appointments and inform them that if they schedule and keep an appointment, they will be provided with a $20 gift card. The gift cards would not otherwise be advertised and the FQHC would implement controls to ensure that patients only receive one gift card. OIG noted that the proposed arrangement would implicate the prohibition against beneficiary inducements, but ultimately concluded that it would not impose civil monetary penalties because: the risk of inappropriate patient steering would be minimized due to the narrowly defined pool of eligible patients; the proposed arrangement would be unlikely to lead to increased costs to Federal health care programs or patients through overutilization or inappropriate utilization; the proposed arrangement is unlikely to harm competition; and the scope of the proposed arrangement appears reasonably tailored to accomplish requestor's goal of improving attendance rates at care appointments.

Advisory Opinion 20-08 is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-08.pdf.

***Federal Court Enjoins CMS Rule to Tying Medicare Drug Prices to International Benchmarks***

In a December 28 opinion, the U.S. District Court for the Northern District of California in *California Life Sciences Ass'n v. Ctrs. for Medicare & Medicaid Servs.*, No. 20-cv-08603-VC (N.D.Cal. Dec. 28, 2020) issued a preliminary injunction against the implementation by the Centers for Medicare & Medicaid Services ("CMS") of its Interim Final Rule tying Medicare drug reimbursement to certain international benchmarks. The Interim Final Rule had been issued by CMS in November with a January 1, 2021 effective date. Several groups challenged the rule on the basis that CMS had failed to go through the required notice-and-comment process. In the Interim Final Rule, CMS explained that it was foregoing that process because the COVID-19 pandemic made it necessary to quickly obtain this change in drug reimbursement.

In the opinion temporarily enjoining the effect of the Interim Final Rule, the District Court found CMS' proffered explanation was "contrived," and that the real explanation is that there was not enough time left in President Trump's term of office to go through the required process.

The Interim Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf.

***Hospital Group Urges HHS to Exercise Enforcement Discretion for Hospital Price Transparency Rule***

On December 29, the Court of Appeals for the D.C. Circuit affirmed the lower District Court's ruling that the November 2019 Centers for Medicare & Medicaid Services ("CMS") rule requiring hospitals to disclose their gross charges, negotiated charges, and discounted cash prices was permissible under the Affordable Care Act ("ACA"). The plaintiffs had argued that CMS' requirements in the rule were broader than what is permitted by the ACA. The Court of Appeals disagreed and held that "the statute allows the Secretary to define standard charges more broadly." On January 7, the American Hospital Association ("AHA")—a plaintiff in the challenge to the price transparency rule—sent a letter to Health and Human Services ("HHS") Secretary Alex Azar urging HHS to exercise enforcement discretion with respect to the rule during the ongoing COVID-19 pandemic. According to the AHA, "[h]ospitals ability to comply with the rule at this time is particularly challenged by an increase in the volume of COVID-19 patients and the need to distribute multiple vaccines."

The Court of Appeals' decision is available at: https://www.cadc.uscourts.gov/internet/opinions.nsf/CCDF215AFCAF25F98525864D005716BC/$file/20-5193-1877500.pdf.

The AHA's letter to Secretary Azar is available at: https://www.aha.org/system/files/media/file/2021/01/aha-urges-hhs-exercise-enforcement-discretion-with-respect-hospital-price-transparency-rule-letter-1-7-20.pdf.

***HHS Final Rule on Increased Transparency in Civil Enforcement Actions***

On January 14, the Department of Health and Human Services ("HHS") published a final rule to increase transparency in civil enforcement actions. The final rule implements President Trump's Executive Order 13892. It is designed to "ensure that regulated parties receive fair notice of laws and regulations they are subject to, and have an opportunity to contest an agency determination prior to the agency taking an action that has a legal consequence." A press release by HHS describes that the final rule prohibits HHS from

treating the failure to follow a standard or practice announced only in a guidance documents as a violation of law. The final rule sets forth steps that HHS must follow to ensure fairness, such as only applying standards or practices that have been publicly stated in a manner that would not cause unfair surprise, and conducting all civil administrative inspections according to published, publicly available, rules of agency procedure. Additionally, prior to taking any civil enforcement action with legal consequence, HHS must provide written notice and opportunity to be heard and a written response, unless an exception otherwise applies.

The final rule as published in the *Federal Register* may be found here: https://www.govinfo.gov/content/pkg/FR-2021-01-14/pdf/2021-00592.pdf

The HHS press release on the final rule may be accessed here: https://www.hhs.gov/about/news/2021/01/12/hhs-improves-agency-procedures-relating-transparency-fairness-civil-enforcement-actions.html

***DOJ Recovers $2.2 Billion for Civil Fraud Cases in FY 2020***

On January 14, the Department of Justice ("DOJ") announced that it had obtained more than $2.2 billion in recoveries from civil fraud cases from the fiscal year ending September 30, 2020. Out of that total, $1.8 billion is attributed to settlements and judgements in the health care industry. The DOJ made clear that the $1.8 billion figure only reflects federal losses, and that additional sums in the tens of millions were recovered for state Medicaid programs. The DOJ stated that the largest recoveries from the past year came from the drug industry, citing as an example, Novartis Pharmaceuticals Corporation, which paid over $591 million to resolve claims that it paid kickbacks to doctors to induce them to prescribe its drugs.

The DOJ press release may be read here: https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020#:~:text=The%20Department%20of%20Justice%20obtained,Justice's%20Civil%20Division%20announced%20today.

***OCR to Exercise Discretion over Enforcement for COVID-19 Vaccination Schedule Apps***

On January 19, the Department of Health and Human Services Office for Civil Rights ("OCR") announced it will not impose penalties under the Health Insurance Portability and Accountability Act rules for violations resulting from "good faith use" of online or web-based scheduling applications ("WSBAs") for scheduling COVID-19 vaccination appointments during the public health emergency. The notification of enforcement discretion is retroactive to December 11, 2020. Enforcement discretion applies to covered health care providers and their business associates, including WBSA vendors. The notification encourages the use of reasonable safeguards to protect the privacy and security of individuals' protected health information, such as using only the minimum necessary information, the use of encryption, and enabling all available privacy settings.

The OCR press release may be read here: https://www.hhs.gov/about/news/2021/01/19/ocr-announces-notification-enforcement-discretion-use-online-web-based-scheduling-applications-scheduling-covid-19-vaccination-appointments.html

The notification itself may be read in full here: https://www.hhs.gov/sites/default/files/hipaa-vaccine-ned.pdf

***OIG Recommends CMS Use CERT Data to Scrutinize "Error-Prone" Providers***

On January 19, the Department of Health and Human Services Office of Inspector General ("OIG") issued a report recommending that the Centers for Medicare & Medicaid Services ("CMS") focus on providers with higher error rates by utilizing data on improper Medicare fee-for-service ("FFS") payments. OIG used data from CMS' Comprehensive Error Rate Testing ("CERT") program and identified 100 "error-prone" providers, which it defines as providers having an error rate of 25% or more in the four CERT years analyzed or a total error amount of at least $2,500. OIG found those "error-prone" providers received $3.5 million in overpayments (of $5.8 million reviewed by CERT), representing a 60.7% error rate. The national average, meanwhile, is 11.3% for all Medicare providers over the same period.

OIG recommended that (1) CMS review the list of 100 error-prone providers identified in the audit and apply specific actions such as prior authorization, prepayment reviews, and post-payment reviews; and (2) CMS use annual CERT data to identify providers at increased risk of receiving improper payments and apply additional program integrity tools to them. CMS disagreed with OIG's methodology for identifying error-prone providers using CERT data and indicated that it previously found CERT data was ineffective for identifying error-prone providers and suppliers and discontinued the practice.

The OIG report may be found here: https://oig.hhs.gov/oas/reports/region5/51700023.pdf

***GAO Says Closure of Rural Hospitals Leads to Reduced Access to Care***

On January 21, the Government Accountability Office ("GAO") released a report on the significant impact the closure of rural hospitals has on access to care. The report states that between January 2013 and February 2020, 101 rural hospitals closed their doors. GAO looked at data from the Department of Health and Human Services and the North Carolina Rural Health Research Program to analyze rural hospitals that closed and those that were open during the years 2013 through 2017.

The GAO found that when rural hospitals closed, residents living in the closed hospitals' service areas had to travel substantially farther to access certain health care services. For example, in service areas with closed hospitals covering emergency department services the median distance traveled by patients was 3.3 miles in 2012, compared to 24.2 miles in 2018, while in the service areas of the 11 closed hospitals that offered treatment services for alcohol or drug abuse, the median distance traveled by residents increased 39.1 miles from 2012 compared to 2018.

According to the GAO report, in 2017, Medicare fee-for-service beneficiaries in service areas with rural hospital closures were less healthy compared to those in service areas without closures, in that they had a higher prevalence of all of the ten most common chronic conditions, compared to those in service areas without closures, the report said.

The GAO Report, *Rural Hospital Closures: Affected Residents Had Reduced Access to Health Care Services* (GAO-21-93), may be found here: https://www.gao.gov/assets/720/711499.pdf

***Federal Court Dismisses Claims Related to Care Rendered by Drug-Addicted Physician***

On January 26, the U.S. District Court for the Southern District of California dismissed a medical malpractice suit by a patient against a drug-addicted anesthesiologist. The patient had been treated by the anesthesiologist during and following a surgical procedure; he experiences unusual pain following the surgery and ultimately passed away. The patient's family filed suit against the anesthesiologist following the loss of his

license, including several state law claims and two federal claims stemming from Section 1983, a federal statute intended to address civil rights violations by state government employees. In dismissing the two counts relating to Section 1983, the Court held that the plaintiff had failed to allege any injury under that statute. The Court then dismissed the remaining state law claims for lack of federal jurisdiction.

The decision in *Lopez v. Hay*, No. 20-cv-171-GPC-MSB (S.D. Cal. Jan. 26, 2021) is available at: https://www.casemine.com/judgement/us/601284d14653d07ee5e4afed.

***GAO Urges Government to Improve National Response to Pandemics***

On January 28, the Government Accountability Office ("GAO") published a report urging that the government move swiftly to implement 27 of its 31 previously recommended actions to combat the COVID-19 public health emergency ("PHE"). The report also adds 13 new recommended actions to improve public health and economic recovery efforts, including the development of a national testing strategy.

To access the full GAO report, follow this link: https://www.gao.gov/products/GAO-21-265

***Federal Court Remands COVID-19 Wrongful Death Action Back to State Court***

On February 2, the U.S. District Court for the Northern District of New York issued a decision remanding back to state court a wrongful death suit brought by the son of a nursing home resident who contracted COVID-19 and died. The son's lawsuit alleged that the nursing home failed to take certain preventative measures, including enforcing social distancing among residents and staff, restricting visitors, and mandating cloth face coverings. The nursing home and related employee defendants initially removed the case from state court to federal court by raising two defenses to the claims: 1) that the claims are completely preempted by, or necessarily and significantly implicate, the Public Readiness and Emergency Preparedness ("PREP") Act; and/or 2) they qualify for federal-officer removal under § 1442(a)(1) because the Centers for Medicare and Medicaid Services ("CMS") and the Centers for Disease Control ("CDC") specifically compelled healthcare providers and nursing homes to respond to the COVID-19 pandemic, and therefore, the defendants were acting under specific federal instructions/regulations.

In remanding the case to state court, the Court held that the immunity provided by the PREP Act did not apply to the claims asserted because they did not relate to or result from the administration of "covered countermeasures," i.e. certain drugs, biological products, or devices. In addition, the Court held that the fact that the defendants were "highly regulated" by CMS and the CDC did not create any special relationship that would trigger federal-officer removal.

The opinion of the District Court in *Dupervil v. Alliance Health Operations, LLC*, No. 20-CV-4042 (PKC) (PK) (N.D.N.Y. Feb. 2, 2021) is available at: https://casetext.com/case/dupervil-v-all-health-operations.

***Biden Administration to Increase Supply of Vaccine Doses, Provide Vaccines Directly to Pharmacies***

On February 2, the White House issued a statement on new steps the Biden Administration is taking to increase the speed and efficiency of the COVID-19 vaccination process. The new measures include: increasing the overall vaccine doses supplied to states, Tribes, and territories by 22% to 10.5 million doses weekly; sending vaccine doses directly to over 40,000 pharmacies identified in cooperation with states to assist in vaccinations; and increasing FEMA reimbursements to states, Tribes, and territories.

The White House's announcement, including a list of participating pharmacies receiving vaccine doses, is available at: https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/02/fact-sheet-president-biden-announces-increased-vaccine-supply-initial-launch-of-the-federal-retail-pharmacy-program-and-expansion-of-fema-reimbursement-to-states/.

***OIG Issues Data Snapshot on Medicare Part D Beneficiaries' Opioid Use, Treatment During Early Part of COVID-19 Pandemic***

On February 5, the U.S. Department of Health and Human Services, Office of Inspector General ("OIG") issued a report titled "Opioid Use in Medicare Part D During the Onset of the COVID-19 Pandemic," wherein it presented data on opioid use and deaths in Medicare Part D beneficiaries during the pandemic. The report compares data for the first eight months of 2019 and 2020 to measure the effects, if any, of the pandemic on opioid use. OIG found that about 5,000 Medicare Part D beneficiaries per month suffered an opioid overdose during the first eight months of 2020, as compared to an average of about 5,200 overdoses during the first eight months of 2019. The number of beneficiaries receiving short-term opioid prescriptions declined in the spring of 2020, particularly in April, from about 1.1 million beneficiaries to 727,505. OIG says the decline is likely due to elective surgeries being postponed during the early months of the pandemic, particularly in April. Additionally, the number of beneficiaries receiving drugs for medication-assisted treatment increased by ten percent in the first eight months of 2020 compared to the same period in 2019.

OIG's report is available at: https://oig.hhs.gov/oei/reports/OEI-02-20-00400.pdf.

## STATE DEVELOPMENTS

***NH Legal Assistance, DRC, AARP File Lawsuit Against DHHS Seeking Better Administration of Medicaid Program***

On January 11, New Hampshire Legal Assistance, the Disability Rights Center-NH, the AARP Foundation, and law firm Nixon Peabody filed a lawsuit in federal court against the New Hampshire Department of Health and Human Services ("DHHS") and Commissioner Lori Shibinette, alleging that DHHS has failed to properly administer its Choices for Independence ("CFI") Medicaid waiver program. The CFI program is operated under a Medicaid waiver approved by the Centers for Medicare & Medicaid Services ("CMS") and is intended to allow senior citizens and disabled residents to receive certain personal care and support services in their homes rather than having to enter into a residential facility. In the lawsuit, the plaintiffs allege that DHHS is currently operating the CFI program in a manner that systematically deprives CFI participants of the home and community-based care to which they are entitled to under the provisions of the waiver program.

A Press Release about the lawsuit is available at: https://drcnh.org/litigation/lawsuit-filed-cfi-waiver/.

The Complaint in the lawsuit is available at: https://www.aarp.org/content/dam/aarp/aarp_foundation/litigation/2021/stephanie-p-v-shibinette-complaint.pdf.

## State Legislative Update

Because of the remote nature of the House and Senate proceedings this session, both houses have implemented a remote method by which members of the public and registered lobbyists may communicate their support for or opposition to a bill and may sign up to provide testimony during a public hearing.

Instructions on how to register support/opposition on a bill in the House are available at: http://gencourt.state.nh.us/misc/House%20Remote%20Testimony%20Directions.pdf.

Instructions on how to register support/opposition on a bill in the Senate are available at: http://gencourt.state.nh.us/misc/How%20to%20sign%20in%20and%20testify%20on%20Zoom%20before%20the%20New%20Hampshire%20State%20Senate.pdf.

**HB62 Title: relative to continued in-network access to certain health care providers.**
This bill requires access by a covered person to a provider in the insurer's provider directory at in-network rates for the duration of the contract for health care services. Introduced in the House. Referred to Commerce and Consumer Affairs Committee. Public Hearing 2/2. Executive Session 2/10, 1:15pm.

**HB89 Title: adding qualifying medical conditions to the therapeutic use of cannabis law. Introduced in the House. Referred to HHS Committee.**
This bill adds moderate to severe insomnia to the definition of "qualifying medical condition" for the purposes of the use of cannabis for therapeutic purposes law.

**HB94 Title: relative to licensure renewal dates for certain governing boards under the office of professional licensure and certification**
This bill revises the procedure and timeframe for license renewals of allied health professionals, body art practitioners, podiatrists, chiropractors, acupuncturists, and veterinarians. Introduced in the House. Referred to Executive Departments and Administration Committee. Public Hearing 2/1.

**HB103 Title: establishing a dental benefit under the state Medicaid program.**
This bill requires the Commissioner of Health and Human Services to solicit information and to contract with dental managed care organizations to provide dental care to persons under the Medicaid managed care program. Introduced in the House. Referred to HHS Committee. Public Hearing 2/1.

**HB120 Title: relative to administration of psychotropic medications to children in foster care.**
This bill requires DHHS to provide medication monitoring for children in foster care and to ensure that the use of medication restraint conforms with the limitations of RSA 126-U. Introduced in the House. Referred to Children and Family Law Committee.

**HB131 Title: relative to reporting of health care associated infections.**
This bill clarifies the information that hospitals must report regarding infections. Introduced in the House. Referred to HHS Committee. Public Hearing 1/26.

**HB143 Title: relative to an electronic prescription drug program.**
This bill requires electronic prescribing for controlled drugs under certain circumstances. Introduced in the House. Referred to HHS Committee.

**HB146 Title: requiring health care providers to furnish upon request a list of ingredients contained in an injectable medication that is recommended or administered.**
This bill requires health care providers to furnish upon request a list of ingredients contained in any injectable medication that is recommended or administered. Introduced in the House. Referred to HHS Committee.

**HB149 Title: extending certain civil immunity to public and private entities during major public health emergencies.**
This bill establishes immunity from civil liability for public and private entities during a declared state of emergency due to a public health risk if the entity was acting in good faith and in accordance with public health and safety directives. Introduced in the House. Referred to Judiciary Committee.

**HB163 Title: relative to cannabis use during pregnancy.**
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 in the House. Referred to HHS Committee. Public Hearing 2/2.

**HB165 Title: relative to noncompete agreements for certain mental health professionals.**
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 in the House. Referred to Commerce and Consumer Affairs Committee. Public Hearing 2/2. Executive Session 2/10, 1:25pm.

**HB185 Title: removing the work requirement of the New Hampshire granite advantage health care program.**
This bill removes the work and community engagement requirements of the New Hampshire granite advantage health care program. Introduced in the House. Referred to HHS Committee. Public Hearing 2/2.

**HB187 Title: relative to the emergency powers of the commissioner of health and human services.**
This bill makes various changes to the powers of the commissioner of the department of health and human services during a public health emergency; authorizes the joint legislative oversight committee on health and human services to review, and rescind by a 2/3 vote, emergency orders issued by the commissioner; gives a person subject to a treatment order for a communicable disease a right to a hearing on the order; and amends the membership and duties of the ethics oversight advisory committee. The bill also amends the house membership on the health and human services oversight committee. Introduced in the House. Referred to HHS Committee. Committee Voted Ought to Pass with Amended on 2/3.

**HB191 Title: relative to prior authorizations and interfacility transports under group health insurance policies and managed care.**
This bill adds requirements for prior authorizations under managed care health benefit plans and the administration of patient transfers to another health care facility. Introduced in the House. Referred to Commerce and Consumer Affairs Committee. Public Hearing 2/2. Executive Session 2/10, 1:20pm.

**HB220 Title: establishing the medical freedom act.**
This bill establishes the policy for medical freedom in immunizations for communicable diseases. Introduced in the House. Referred to HHS Committee. Public Hearing 2/28, 9:00am.

**HB221 Title: relative to opting in to the state pediatric and adult vaccine registries.**
This bill makes the state immunization registry an opt-in program rather than an opt-out program. Introduced in the House. Referred to HHS Committee. Public Hearing 2/28, 10:00am.

**HB244 Title: relative to the membership and duties of the joint health care reform oversight committee.**
This bill amends the membership and duties of the joint health care reform oversight committee. Introduced in the House. Referred to HHS Committee. Public Hearing 1/26.

**HB247 Title: relative to treatment alternatives to opioids.**
This bill requires the department of health and human services to create a voluntary nonopioid directive form which may be used for nonopioid treatment options for pain. This bill also establishes insurance coverage for such treatment options. Introduced in the House. Referred to HHS Committee. Public Hearing 1/26.

**HB264 Title: requiring health care providers to provide cost quotes for non-emergency services.**
This bill requires health care providers to provide a cost quote for non-emergency medical services offered to a patient. Introduced in the House. Referred to Commerce and Consumer Affairs Committee. Public Hearing 2/3.

**HB290 Title: relative to policies required for health facilities and special health care service licenses.**
This bill exempts certain health facilities that exclusively provide services to persons making direct payment from requirements on written policies for providing services. Introduced in the House. Referred to HHS Committee. Public Hearing 1/26. Committee voted Inexpedient to Legislate on 2/5.

**HB349 Title: relative to certification requirements for school nurses.**
This bill removes the requirement for school nurses to be certified by the state board of education. Introduced in the House. Referred to Education committee. Public Hearing 2/2. Executive Session 2/9.

**HB350 Title: permitting qualifying patients and designated caregivers to cultivate cannabis for therapeutic use.**

This bill permits qualifying patients and designated caregivers to cultivate cannabis for therapeutic use. Introduced in the House. Referred to HHS Committee. Public Hearing 2/1.

**HB369 Title: relative to the use of physical agent modalities by occupational therapists.**
This bill limits the use of ultrasound and electrical physical agent modalities by occupational therapists and occupational therapy assistants. This bill is a request of the Office of Professional Licensure and Certification. Introduced in the House. Referred to Executive Departments and Administration Committee. Public Hearing 2/4.

**HB430 Title: repealing the prohibition on entering or remaining on a public way or sidewalk adjacent to a reproductive health care facility.**
This bill repeals the prohibition on entering or remaining on a public way or sidewalk adjacent to a reproductive health care facility. Introduced in the House. Referred to the Judiciary Committee. Public Hearing 2/9.

**HB444 Title: relative to the board of pharmacy.**
This bill makes various technical changes to the laws governing pharmacies regulated by the pharmacy board. Introduced in the House. Referred to Executive Departments and Administration Committee. Public Hearing 2/11, 2:00pm.

**HB488 Title: establishing a committee to study the benefits of allowing New Hampshire citizens to purchase health insurance from out-of-state companies.**
This bill establishes a committee to study the benefits of allowing New Hampshire citizens to purchase health insurance from out-of-state companies. Introduced in the House. Referred to Commerce and Consumer Affairs Committee. Public Hearing 2/3.

**HB572 Title: relative to pharmacist administration of vaccines and allowing a licensed advanced pharmacy technician to administer vaccines.**
This bill extends authority for pharmacist administration of vaccines to include vaccines approved by the Centers for Disease Control (CDC) and allows licensed advanced pharmacy technicians to administer vaccines. Introduced in the House. Referred to HHS Committee.

**HB582 Title: relative to prescriptions for the treatment of attention deficit disorder or attention deficit disorder with hyperactivity.**
This bill allows for certain prescriptions for treatment of attention deficit disorder or attention deficit disorder with hyperactivity to be for 90 days. Introduced in the House. Referred to HHS Committee.

**HB599 Title: relative to the therapeutic cannabis medical oversight board.**
This bill requires the medical director of DHHS to conduct a review of qualifying medical conditions under the therapeutic cannabis law. The bill also requires members of the therapeutic cannabis medical oversight board to disclose certain conflicts of interest before participating in matters in which such conflicts of interest exist. Introduced in the House. Referred to HHS Committee.

**HB600 Title: relative to funding for newborn screening.**

This bill instructs the Commissioner of Health and Human Services on the setting of fees for newborn screening tests. Introduced in the House. Referred to HHS Committee. Public Hearing 2/1. Committee voted Ought to Pass on 2/3.

**HB602 Title: relative to reimbursements for telemedicine.**
This bill makes changes to the reimbursement limits for telemedicine. This bill also further defines telemedicine. Introduced in the House. Referred to HHS Committee. Public Hearing 2/2.

**HB604 Title: expanding the New Hampshire vaccine association to include adult vaccines.**
This bill expands the New Hampshire vaccine association to include adult vaccines. Introduced in the House. Referred to HHS Committee. Public Hearing 2/1.

**HB605 Title: relative to the therapeutic cannabis program.**
This bill:
I. Establishes protections for authorized employees of the department of health and human services when possessing or transporting cannabis or cannabis-infused products pursuant to statute.
II. Makes various changes to the law regarding the use of cannabis for therapeutic purposes, including clarifying the information required on the registry identification cards.
III. Adds opioid use disorder to the qualifying medical conditions under the use of cannabis for therapeutic purposes law.
IV. Adds moderate to severe insomnia to the definition of "qualifying medical condition" for the purposes of the use of cannabis for therapeutic purposes law.
V. Permits out-of-state residents qualified in other jurisdictions to purchase therapeutic cannabis at New Hampshire therapeutic dispensaries.
VI. Repeals the therapeutic cannabis advisory council.
VII. Requires alternative treatment centers to prepare information regarding the risk of cannabis use during pregnancy and 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 in the House. Referred to HHS Committee.

**SB29 Title: relative to the health risks associated with dispensing high-concentration marijuana in alternative treatment centers.**
This bill allows a medical provider to request an exemption from the department of health and human services to the limitations on THC content in medical marijuana on behalf of a qualifying patient. Introduced in the Senate. Referred to HHS Committee. Public Hearing 1/20.

**SB37 Title: relative to warning label requirements for marijuana products dispensed in alternative treatment centers.**
This bill requires DHHS to adopt rules that include certain specific information on marijuana product labels dispensed in alternative treatment centers. Introduced in the Senate. Referred to Commerce Committee. Public Hearing 1/19. Committee voted Inexpedient to Legislate 2/4.

**SB38** **Title:** **relative to the organization of alternative treatment centers.**
This bill permits alternative treatment centers to organize as business corporations and limited liability companies, and provides the procedure for alternative treatment centers organized as voluntary corporations to convert to business corporations or limited liability companies. Introduced in the Senate. Referred to Commerce Committee. Public Hearing 1/19. Committee voted Ought to Pass on 2/4. Committee voted to rerefer to Committee on 2/4.

**SB45** **Title:** **relative to the controlled drug prescription health and safety program.**
This bill modifies the administration of the controlled drug prescription health and safety program administered by the office of professional licensure and certification introduced in the Senate. Referred to HHS Committee. Public Hearing 1/20. Committee voted Ought to Pass with Amendment on 1/29.

**SB57** **Title:** **relative to allowing pharmacy technicians and interns to remotely perform non-dispensing tasks**
This bill allows pharmacy technicians and interns to remotely perform non-dispensing tasks. Introduced in the Senate. Referred to Executive Departments and Administration Committee. Public Hearing 1/27.

**SB58** **Title:** **relative to the administration of occupational regulation by the office of professional licensure and certification.**
This bill makes changes to the statutory provisions governing the regulatory boards and commissions for technical professions and health professions in order to conform to oversight and administration by the office of professional licensure and regulation. Introduced in the Senate. Referred to Executive Departments and Administration Committee. Public Hearing 1/27.

**SB59** **Title:** **relative to the collaborative care model service delivery method.**
This bill requires individual and group insurers to reimburse a primary care physician for the treatment of mental health and substance use disorders provided through the psychiatric collaborative care model. Introduced in the Senate. Referred to HHS Committee. Public Hearing 1/28. Committee voted Ought to Pass with Amendment on 1/29.

**SB70** **Title:** **relative to insurance coverage for emergency behavioral health services for children and young adults.**
This bill requires commercial insurance carriers to cover the initial assessment and intervention without prior authorization for children in psychiatric distress. This bill also delays any prior authorization requirements on longer term treatment for children in psychiatric distress for 72 hours. Introduced in the Senate. Referred to Commerce Committee. Public Hearing 2/8.

**SB74** **Title:** **relative to advance directives for health care decisions.**
This bill:
I. Defines "attending practitioner" and "POLST."
II. Redefines "near death" as "actively dying."
III. Further defines the role of a surrogate.
IV. Repeals the applicability of certain advanced directives.

Introduced in the Senate. Referred to HHS Committee. Public Hearing 1/28.

**SB97 Title: adopting omnibus legislation relative to health insurance.**
This bill adopts legislation:
I. Relative to direct primary care referral parity.
II. Relative to in-network retail pharmacies.
Introduced in the Senate. Referred to HHS Committee. Public Hearing 2/3.

**SB121 Title: relative to a state-based health exchange.**
This bill requires the insurance department to examine the implementation of a state health exchange and implement such an exchange upon approval of the joint health care reform oversight committee. Introduced in the Senate. Referred to HHS Committee. Public Hearing 2/10.

**SB123 Title: relative to copayments for COVID-19 testing.**
This bill waives cost-sharing for COVID-19 testing under accident and health insurance policies. Introduced in the Senate. Referred to HHS Committee. Public Hearing 2/10.

**SB133 Title: adopting omnibus legislation relative to occupational licensure.**
This bill adopts legislation relative to:
I. Licensing places of assembly.
II. Establishing a limited plumbing specialist license.
III. Repealing the emergency medical services personnel licensure interstate compact.
IV. Hearings at the board of nursing.
V. Membership of the professional standards board.
VI. Adopting the Audiology and Speech-Language Pathology Compact and the Occupational Therapy Licensure Compact.
VII. Licensure and regulation of music therapists.
VIII. The authority of the office of professional licensure and certification for administration, rulemaking, and enforcement of investigations, hearings, and appeals.
IX. Skilled professional medical personnel.
X. Temporary licensure of certain licensed nursing assistants.
XI. The revocation of licensure for licensed emergency medical service units and emergency medical service vehicles.
XII. Schools for barbering, cosmetology, and esthetics.
XIII. Telemedicine provided by out of state psychologists.
XIV. Sanitary production and distribution of food.
Introduced in the Senate. Referred to Executive Departments and Administration Committee. Public Hearing 2/10.

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

## BIOS

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