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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

OIG Issues Advisory Opinion Approving Charitable Organization's Proposal to Purchase and Forgive Medical Debt

On July 24, 2020, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") posted an advisory opinion concerning approving a request from a 501(c)(3) tax-exempt organization to purchase or receive donations of unpaid medical debt owed by qualifying patients from certain types of providers and then forgive that debt. In its Advisory Opinion, OIG noted that the proposal implicates both the anti-kickback statute and the prohibition against beneficiary inducements, but ultimately concluded that it would be sufficiently low risk and OIG would not impose penalties. The OIG's opinion was based on several factors, including that: 1) the providers' waiver of cost-sharing would not be routine but rather would be made based on objective criteria; 2) the providers' selling or donating the medical debt to the requestor would agree not to publicize the arrangement; 3) the proposal would not lead to increased costs to Federal health care programs because the only uncollected debt would be forgiven.

The advisory opinion is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-04.pdf.

OCR Announces $1 Million Settlement with Health System to Resolve Potential HIPAA Violations

On July 27, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") announced a $1 million settlement with Lifespan Health System Affiliated Covered Entity ("Lifespan") to resolve potential violations of the Health Insurance Portability and Accountability Act ("HIPAA") related to the theft of a Lifespan employee's unencrypted laptop. In April, Lifespan reported the breach of patient's names, medical record numbers, demographic information, and medication information affecting 20,431 individuals. OCR

investigated the report and found that there was systemic noncompliance with HIPAA including a failure to encrypt ePHI on laptops after Lifespan determined it was reasonable and appropriate to do so. OCR also uncovered a lack of device and media controls, and a failure to have a business associate agreement in place. In addition to the monetary settlement, Lifespan agreed to a corrective action plan that includes two years of monitoring.

OCR's announcement of the settlement agreement is available at: https://www.hhs.gov/about/news/2020/07/27/lifespan-pays-1040000-ocr-settle-unencrypted-stolen-laptop-breach.html.

The corrective action plan is available at: https://www.hhs.gov/sites/default/files/lifespan-ra-cap-signed.pdf.

HHS Reports Significant Increase in Medicare Primary Care Telehealth Visits During COVID-19 Pandemic

On July 28, the U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation ("ASPE") issued a report titled "Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic." The report contains the following key findings about the increase in the use of telehealth by Medicare beneficiaries during the pandemic:

- Medicare fee-for-service ("FFS") in-person visits for primary care fell precipitously in mid-March at the start of the COVID-19 public health emergency ("PHE") and began to rise again in mid-April through May.
- 43.5% of Medicare primary care visits were provided via telehealth in April, compared with less than one percent before the PHE in February.
- As in-person visits started to resume from mid-April thru May, the use of telehealth in primary care declined somewhat but appears to have leveled off at a persistent and significant level by the beginning of June.
- Beneficiaries dually enrolled in Medicare and Medicaid and high-cost Medicare beneficiaries had similar patterns in the use of primary care in-person and telehealth visits as other Medicare beneficiaries.
- Providers in rural counties had smaller increases in Medicare primary care telehealth visits compared with providers in urban areas who had much greater use of telehealth visits early in the PHE.
- Among major urban areas, the proportion of total primary care visits delivered by telehealth in April ranged from one third in Phoenix to nearly two-thirds in Boston. Cities with more COVID-19 hospitalizations like New York City, Detroit and Boston had higher uptake of telehealth in primary care visits along with San Francisco, which largely avoided the early COVID-19 surge. This suggests telehealth is partly driven by concerns with COVID-19, but also patient and provider readiness for telehealth.

ASPE's report is available at: https://aspe.hhs.gov/system/files/pdf/263866/HP_IssueBrief_MedicareTelehealth_final7.29.20.pdf.

HHS Report Urges Congress to Enact Legislation to Address Surprise Billing

On July 28, the U.S. Department of Health and Human Services ("HHS"), Assistant Secretary for Planning and Evaluation ("ASPE") issued a report addressing surprise medical billing and urging Congress to enact legislation. The report was issued in compliance with a requirement in President Trump's Executive Order 13877, "Improving Price and Quality Transparency in American Healthcare to Put Patients First" from 2019. The report provides an overview of surprise billing—where patients receive bills from out-of-networks providers in addition to the bill they receive from a hospital—and of recent measures taken by states and the federal government to address surprise billing. The report recommends that Congress enact legislation that would direct HHS, the U.S. Department of Labor, and the Internal Revenue Service to regulate and control the use of surprise billing by providers and insurers.

ASPE's report is available at: https://aspe.hhs.gov/system/files/pdf/263871/Surprise-Billing.pdf.

DOJ Charges Chiropractor with Fraudulently Obtaining COVID Funds, Health Care Fraud

On July 29, the U.S. Department of Justice announced that Dennis Nobbe, a Florida chiropractor, had been charged regarding allegations that he fraudulently obtained a Paycheck Protection Program loan and an Economic Injury Disaster Loan, and that he orchestrated a conspiracy to submit false and fraudulent claims for reimbursement to Medicare and CareCredit, and to defraud his own patients by charging them thousands of dollars for chiropractic services under false pretenses. The complaint alleges that Nobbe orchestrated a scheme to exploit his patients for financial gain through a credit card program intended to help patients pay for out-of-pocket medical expenses. To conceal his role in the scheme, Nobbe paid bribes to other physicians to open credit card merchant accounts in their names. Nobbe then encouraged patients at his chiropractic business, Dynamic Medical Services Inc., many of whom were low-income and did not speak English, to apply for the credit cards.

The DOJ announcement is available at: https://www.justice.gov/opa/pr/florida-man-charged-covid-relief-fraud-health-care-fraud-and-money-laundering.

D.C. Circuit Upholds Cuts to 340B Drug Reimbursement

On July 31, the Court of Appeal for the D.C Circuit upheld significant planned cuts to the 340B drug program by the U.S. Department of Health and Human Services ("HHS"). The cuts, which have been included in hospital outpatient prospective payment system final rules since 2018, were challenged by hospital groups who said they would severely negatively impact hospitals' financial health. In its decision, the Court of Appeals held that the cuts did not exceed HHS' statutory authority. The hospital plaintiffs requested that the court reconsider this decision, but the request was denied on October 19.

The Court's opinion is available at: https://www.cadc.uscourts.gov/internet/opinions.nsf/B8E3F76510742B95852585B600531146/$file/19-5048-1854504.pdf.

Medicare Payments to Psychiatric Facilities to Increase by $95 Million

On August 4, the Centers for Medicare & Medicaid Services ("CMS") published a Final Rule updating the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities ("IPFs"). CMS estimates that the changes in the Final Rule will result in an increase in payments to IPFs of 2.3%, or $95 million. The Final Rule also adopts recent Office

of Management and Budget statistical area delineations, and applies a 2-year transition for all providers negatively impacted by wage index changes, among other updates.

The Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-08-04/pdf/2020-16990.pdf.

Hospice Final Rule Includes 2.4% Increase in FY 2021 Medicare Payments

On August 4, the Centers for Medicare & Medicaid Services ("CMS") published a Final Rule updating the hospice wage index, payment rates, and cap amount for fiscal year 2021. The Final Rule also revises the hospice wage index to reflect the current Office of Management and Budget area delineations, with a 5 percent cap on wage index decreases. CMS estimates that the Final Rule will result in an increase in Medicare payments to hospices of 2.4%, or $540 million, which is slightly less than the .6% estimated in the proposed rule.

The Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-08-04/pdf/2020-16991.pdf.

SNF Final Rule Boosts Medicare Payments by 2.2%

On August 5, the Centers for Medicare & Medicaid Services ("CMS") published a Final Rule updating the payment rates used under the prospective payment system for skilled nursing facilities ("SNFs") for fiscal year 2021. CMS estimates that under the Final Rule SNFs will see an increase in Medicare reimbursement of 2.2%, or $750 million. The Final Rule also adopts the most recent Office of Management and Budget statistical area delineations and updates the Value-Based Purchasing Program that affects Medicare payment to SNF, among other changes.

The Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-08-05/pdf/2020-16900.pdf.

CMS Approves New Hampshire's Waiver to Establish Reinsurance Program

On August 5, the Centers for Medicare & Medicaid Services ("CMS") approved New Hampshire's request to implement a section 1332 State Relief and Empowerment waiver. With the waiver, New Hampshire intends to run a state-based reinsurance program for plan years 2021 through 2025 to partially reimburse insurers for certain high-cost claims for consumers in the individual health insurance market. According to CMS, the reinsurance program reduces costs for some enrollees in the individual market and is projected to reduce premiums by approximately 16 percent in New Hampshire in plan year 2021.

A CMS Press Release on the waiver approval is available at: https://www.cms.gov/newsroom/press-releases/cms-approves-new-hampshires-state-relief-and-empowerment-waiver.

IRF Final Rule Boosts Medicare Payments by $260 Million

On August 10, the Centers for Medicare & Medicaid Services ("CMS") published a Final Rule updating the prospective payment rates for inpatient rehabilitation facilities ("IRFs") for Federal fiscal year 2021. The Final Rule also adopts recent Office of Management and Budget statistical area delineations and applies a 5 percent cap on any wage index decreases compared to FY 2020 in a budget neutral manner. The Final Rule also amends the IRF coverage requirements to remove the post-admission physician evaluation requirement and codifies existing documentation instructions and guidance. CMS estimates that the payment updates in the Final Rule will result in an increase in Medicare payments to IRFs of 2.4%, or $260 million.

The Final Rule is available at: https://www.americanhealthlaw.org/content-library/health-law-weekly/article/2ab1e9f5-0277-48d8-95da-ef7f95ba7255/IRF-Final-Rule-Boosts-Medicare-Payments-to-IRFs-by.

OIG Identifies $267 Million in Medicare Overpayments Connected to Post-Acute Transfers to Home Health

On August 10, the Department of Health and Human Services Office of Inspector General ("OIG") reported its findings that Medicare improperly paid most of the hospital inpatient claims subject to Medicare's post-acute care transfer policy for home health care services. OIG said that improper coding resulted in an estimated $267 million in overpayments during a two-year audit period. Out of 150 inpatient claims subject to the audit, OIG found Medicare properly paid only three, while the remaining 147 claims should have been paid using a graduated per diem rate. OIG recommended that CMS direct Medicare contractors to: (1) recover a portion of the overpayments in its sample; (2) reprocess the remaining claims to recover a portion of the estimated overpayments; and (3) analyze the remaining claims to recover a portion of the estimated $40.6 million in potential overpayment. OIG also recommended that CMS correct its related systems edits, improve provider education, and use data analytics to identify hospitals with disproportionate us of condition code 42. Finally, OIG said CMS should reduce the need for clinical judgment when processing claims under the policy, including seeking legislative authority, to deem any home health service occurring within three days of discharge to be "related."

The report titled *Inadequate Edits and Oversight Caused Medicare To Overpay More Than $267 Million for Hospital Inpatient Claims With Post-Acute-Care Transfers to Home Health Services* may be read in full here: https://oig.hhs.gov/oas/reports/region4/41804067.pdf

CMS Unveils New Payment Model for Rural Health Care

On August 11, the Centers for Medicare & Medicaid Services ("CMS") announced a new payment model for rural health care. CMS stated that the Community Health Access and Rural Transformation Model, or "CHART," will allow rural communities to deliver high quality care that is supported through new seed funding and payment structures, operational and regulatory flexibilities and technical and learning support. The CHART Model is the result of President Trump's August 3rd Executive Order on *Improving Rural Health and Telehealth Access* as well as the President's Medicare Executive Order and CMS's *Rethinking Rural Health* initiative.

CMS describes that the CHART Model will offer two tracks, one for rural communities and one for accountable care organizations ("ACO"s). The Community Transformation Track will start in summer 2021 and participating communities will receive $75 million in upfront investments to empower communities to implement care delivery reform, provide predictable capitated payments, and offer operational and regulatory flexibilities like telehealth and waivers of certain Medicare hospital conditions of participations. The model also will allow participating hospitals to waive cost sharing for certain Part B services and provide transportation support and gift cards for chronic disease management. On September 15, CMS issued a Notice of Funding Opportunity for the Community Health Access and Rural Transformation (CHART) Model Community Transformation Track.

Under the ACO Transformation Track, providers will enter into two-sided risk arrangements under the Medicare Shared Savings Program. CMS plans to select up to 20 rural ACOs and to request applications for the model in spring 2021, with the track starting in January 2022.

The CMS press release on the CHART Model is here: https://www.cms.gov/newsroom/press-releases/trump-administration-announces-initiative-transform-rural-health

The CMS announcement of the Notice of Funding Opportunity may be found here: https://www.cms.gov/newsroom/press-releases/cms-releases-chart-model-notice-funding-opportunity-encourages-rural-communities-apply

The Notice of Funding Opportunity itself may be found here: https://www.grants.gov/web/grants/search-grants.html?keywords=93.624

OIG Issues Annual Report on Unimplemented Recommendations for Reducing Fraud, Waste, and Abuse

On August 11, the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") released its annual report on unimplemented recommendations for reducing fraud, waste, and abuse in HHS programs. It includes the top 25 unimplemented recommendations based on audits and evaluations through December 31, 2019, but also includes an appendix of all unimplemented recommendations that require legislative action and a broader list of significant unimplemented recommendations through June 1, 2020. OIG acknowledged that the COVID-19 response is the top priority for HHS at this time.

Highlighted unimplemented recommendations for Medicare Parts A and B include that the Centers for Medicare & Medicaid Services ("CMS") take action to ensure that incidents of potential abuse or neglect of Medicare beneficiaries are identified and reported and that CMS reevaluate the inpatient rehabilitation facility ("IRF") payment system. For Medicare Part C, OIG recommended that CMS review Medicare Advantage Organizations that had high risk-adjusted payments based on unlinked chart reviews for beneficiaries who have no service records. OIG also stated that CMS should make sure reports by states on national Medicaid data are complete, accurate, and timely. Additionally, CMS should develop policies and procedures to improve the timeliness of recovering Medicaid overpayments and recover uncollected amounts identified by OIG's audits.

OIG's report may be read in full here: https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2020.pdf

CMS Issues Medicare Physician Fee Schedule Proposed Rule for 2021

On August 17, the Centers for Medicare & Medicaid Services ("CMS") published a Proposed Rule proposing changes to the Physician Fee Schedule ("PFS"), as well as: changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program requirements for Eligible Professionals; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; Medicare enrollment of Opioid Treatment Programs; payment for office/outpatient evaluation and management services; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA–PD plan and Medicare Diabetes Prevention Program.

The Proposed Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-08-17/pdf/2020-17127.pdf.

Former Cardiologist Agrees to Pay $2 Million to Settle Allegations of False Claims

On August 21, the Acting U.S. Attorney for the Eastern District of New York announced that Ghanshyam Bhambhani, a former Queens cardiologist, will pay a total of $2 million to settle civil claims that he paid kickbacks to other physicians for referrals of patients insured by Medicare, Medicaid and the Federal Employees' Health Benefits Program. Under the terms of the settlement, Bhambhani will pay the United States $1,370,294.50. In addition, he will pay the State of New York $629,705.50. An investigation by the Office, the FBI and OPM-OIG revealed that, from 2010 through 2017, Bhambhani paid other doctors compensation disguised as rent for patient referrals in violation of the Anti-Kickback Statute and the False Claims Act. The investigation also revealed that Bhambhani falsified records to justify cardiac procedures. Bhambhani admitted engaging in this conduct and has agreed to cooperate with the Government.

The U.S. Attorney's announcement is available at: https://www.justice.gov/usao-edny/pr/former-queens-cardiologist-settles-civil-fraud-allegations.

Chiropractor and Medical Practice Ordered to pay over $5 Million to Resolve False Claims Case

On August 21, the U.S. Attorney for the Southern District of Georgia announced that a judgment obtained in District Court awards the United States more than $4.3 million against Heller Family Medicine, LLC and $700,000 against its owner, Dr. Jennifer Heller, D.C. in connection with allegations that Dr. Heller and her medical practice violated the False Claims Act by submitting claims to the Medicare Program for hundreds of surgical procedures involving implantable neurostimulators, when in actuality the practice used an acupuncture device commonly referred to as a "P-Stim." While Medicare pays thousands of dollars for the surgical neurostimulator procedure, it does not cover acupuncture services. In court documents, the United States alleged the medical practice falsely certified that they were performing the surgical procedure, rather than using the acupuncture device.

The U.S. Attorney's announcement is available at: https://www.justice.gov/usao-sdga/pr/government-obtains-more-5-million-judgments-resolve-healthcare-fraud-allegations.

Pain Management Doctor Pays $530,000 to Settle Medicare Fraud Allegations

On August 25, the U.S. Attorney for the Southern District of Texas announced that Dr. Syed Nasir, a pain management physician, had paid $530,000 to resolve allegations he falsely billed Medicare for the use of electro-acupuncture devices. The announcement stated that from March 1, 2019, to Oct. 31, 2019, Dr. Nasir billed Medicare for the implantation of neurostimulator electrodes–a surgical procedure that usually requires use of an operating room, however, Nasir did not perform these surgeries. Instead, he applied a device used for electro-acupuncture which Medicare does not reimburse as implantable neurostimulators.

The U.S. Attorney's announcement is available at: https://www.justice.gov/usao-sdtx/pr/pain-doctor-pays-settle-allegations-deceptive-medicare-billing.

DOJ Announces Charges Against Teva for Generic Drug Price-Fixing

On August 26, the U.S. Department of Justice ("DOJ") announced that it was charging Teva Pharmaceuticals USA Inc. ("Teva") with conspiring to fix prices, rig bids, and allocate customers for generic drugs. The indictment against Teva charges that the company participated in three conspiracies from at least as early as May 2013 until at least in or around Dec. 2015. Teva is the seventh company to be charged for its participation in conspiracies to fix prices, rig bids, and allocate customers for generic drugs. Five previous corporate cases were resolved by deferred prosecution agreements, and one co-conspirator is awaiting trial.

Four executives have also been charged; three have entered guilty pleas, and one is awaiting trial. Each of the charged offenses carry a statutory maximum penalty of $100 million for companies. The maximum fine may be increased to twice the gain derived from the crime or twice the loss suffered by the victims of the crime if either amount is greater than $100 million.

DOJ's announcement is available at: https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrust-investigation.

CMS Extends Deadline for Publishing Stark Final Rules

On August 27, the Centers for Medicare & Medicaid Services ("CMS") published a notice in the Federal Register extending the timeline for publication of the final rule implementing changes to the Stark Law. CMS previously published a proposed rule in October 2019 and had announced in the Spring 2020 Unified Agenda that it would issue a final rule in August 2020. In this latest notice, CMS stated that it is "still working through the complexity of the issues raised by comments received on the proposed rule and therefore [it is] not able to meet the announced publication target date." The expected publication timeline is extended until August 31, 2021.

CMS' notice if available at: https://www.govinfo.gov/content/pkg/FR-2020-08-27/pdf/2020-18867.pdf.

OIG Report: Medicare Contractors Need More Guidance on Reviewing Extrapolated Overpayment Appeals

On August 27, the Office of the Inspector General ("OIG") issued a report titled "Medicare Contractors Were Not Consistent in How They Reviewed Extrapolated Overpayments in the Provider Appeals Process." The report contained OIG's findings from its review of how contractors review overpayment extrapolations during the appeal process. OIG found that although contractors generally reviewed appealed extrapolated overpayments in a manner that conforms with existing Centers for Medicare & Medicaid Services ("CMS") requirements, CMS did not always provide sufficient guidance and oversight to ensure that these reviews were performed in a consistent manner. OIG stated that the most significant inconsistency involved the use of a type of simulation testing by a subset of contractors that was associated with at least $42 million in extrapolated overpayments that were overturned in 2017 and 2018. OIG had several recommendations for CMS to provide additional guidance to contractors to increase consistency. CMS concurred with all recommendations.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region5/51800024.pdf.

CMS Issues FY 2021 IPPS Final Rule

On September 2, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule that is expected to increase Medicare payments to hospitals under the inpatient prospective payment system ("IPPS") by approximately $3.5 billion, or 2.7%, in fiscal year ("FY") 2021. The final rule includes a decrease of 1.1% or $40 million in payment rates for long term care hospitals ("LTCHs") in FY 2021. CMS said the decrease reflects the continued implementation of the revised LTCH PPS site-neutral payment rate. The new rates will apply to roughly 3,200 acute care hospitals and 360 LTCHs as of October 1.

CMS finalized its proposal to collect a summary of hospitals' median payer-specific negotiated inpatient services charges for Medicare Advantage Organizations and third-party payers on Medicare cost reports ending on or after January 1, 2021. Starting FY 2024, CMS will use this data in a new market-based

methodology to set the Medicare Severity Diagnostic Related Group (MS-DRG) relative weights used to determine Medicare payment rates for inpatient hospital stays. In November 2019, CMS issued a final rule requiring hospitals, by 2021, to publicly post "standard charges" for all items and services.

CMS is also finalizing a separate new Medicare Severity-Diagnosis Related Group ("MS-DRG") for Chimeric Antigen Receptor ("CAR") T-cell therapy, which utilizes a patient's own immune system to fight cancer. CMS states in a fact sheet that the new MS-DRG for CAR-T will provide a predictable payment rate for hospitals administering new CAR T-cell therapies as they become available in the future.

CMS also approved 13 technologies that applied for new add-on payments for FY 2021, including two under the alternative pathway for new medical devices as part of the FDA's Breakthrough Devices Program and five under the alternative pathway for products that received FDA Qualified Infectious Disease Product (QIDP) designation. CMS also is continuing add-on payments for 10 of 18 technologies currently receiving them. CMS predicts Medicare spending on new technology add-on payments to be roughly $874 million in FY 2021, an increase of 120% over FY 2020.

CMS is projecting that Medicare uncompensated care payments to hospitals will decrease by roughly $60 million in FY 2021 to $8.3 billion, which estimate incorporates the impact of the COVID-19 pandemic. CMS will use a single year of data on uncompensated care costs from FY 2017 to distribute the funds in FY 2021.

The final rule as published in the *Federal Register* on September 18 may be accessed here: https://www.federalregister.gov/documents/2020/09/18/2020-19637/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

The CMS fact sheet may be read here: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0

HHS Releases Rural Health Action Plan

On September 3, the U.S. Department of Health and Human Services ("HHS") released its Rural Action Plan, which is intended to provide a roadmap for HHS to strengthen departmental coordination to better serve the millions of Americans who live in rural communities across the United States. In particular, the Rural Health Plan examines certain challenges facing rural communities related to issues such as emerging health disparities, chronic disease burden, high rates of maternal mortality and limited access to mental health services. The plan lays out a four-point strategy to transform rural health and human services, with a number of actions that can be launched within weeks or months. The four points of the strategy are: building a sustainable health and human services model for rural communities; leveraging technology and innovation; focusing on preventing disease and mortality; and increasing rural access to care.

The Rural Action Plan is available at: https://www.hhs.gov/sites/default/files/hhs-rural-action-plan.pdf.

Owner, Managers of North Carolina Health Care Practice Agree to Pay $900,000 to Settle Allegations of Medically Unnecessary Testing

On September 9, the U.S. Attorney for the Western District of North Carolina announced that two former managers and the owner of the defunct North-Carolina based Carolina Comprehensive Health Network, PA ("CCHN") have agreed to pay $900,000 to resolve allegations that they violated the False Claims Act by

causing CCHN to bill claims for medically unnecessary diagnostic tests and procedures to the Medicare and Medicaid programs. The settlement resolves allegations that from May 1, 2015 through November 30, 2015, CCHN billed the Medicare and Medicaid programs for unnecessary diagnostic procedures including positional nystagmus testing, rotational axis testing, nerve conduction testing, and autonomous nervous system testing.

The announcement is available at: https://www.justice.gov/usao-wdnc/pr/owner-and-two-managers-health-care-practice-agree-pay-900000-resolve-allegations-0.

CMS Launches Hospital Price Transparency Website

In September, the Centers for Medicare & Medicaid Services ("CMS") launched a "Hospital Price Transparency" website outlining the requirements that hospitals must meet in posting their standard charges in both a machine readable file and in a consumer-friendly display of shoppable services. These requirements for hospitals will go into effect on January 1, 2021; CMS says that "[f]or hospitals that do not comply, we may issue a warning notice, request a corrective action plan, and impose a civil monetary penalty and publicize the penalty on a CMS website." The CMS final rule implementing this requirement has already withstood a legal challenge from the American Hospital Association and other hospital groups, however the federal court's decision upholding the rule is currently on appeal.

CMS new Hospital Price Transparency Website is available at: https://www.cms.gov/hospital-price-transparency/hospitals.

Fifth Circuit Holds That Medicare Recoupment Before ALJ Hearing Does Not Deprive Provider of Due Process

On September 18, the federal Court of Appeals for the Fifth Circuit upheld a lower court's ruling that the Department of Health and Human Services' ("HHS") actions in recouping alleged overpayments from a provider while the overpayments were on appeal to an administrative law judge ("ALJ") did not deprive the provider of due process. Following a 2017 audit in which it was found to have been overpaid roughly $3.6 million, Sahara Health Care began the appeal process, which resulted in a reduction in the alleged overpayment to $2.4 million by the time Sahara sought a hearing before an ALJ. While Sarah waited several years for a hearing, HHS began recouping the overpayment. Sarah sued, claiming that the recoupment deprived it of due process because it had a property interest in the Medicare payments. In rejecting Sarah's argument, the Fifth Circuit noted that Sahara has already been heard at two appeal levels and held that "the sufficiency of the current procedures and the minimal benefit of the live hearing weighs so strongly against Sahara that we reject its due process claim."

The court opinion in *Sahara Health Care v. Azar,* No. 18-41120 (5th Cir. Sept. 18, 2020) is available at: http://www.ca5.uscourts.gov/opinions/pub/18/18-41120-CV0.pdf.

CMS Finalizes ESRD Treatment Choices Payment Model

On September 18, the Centers for Medicare & Medicaid Services ("CMS") finalized its new End-Stage Renal Disease ("ESRD") Treatment Choices ("ETC") payment model to incentivize home dialysis and kidney transplants for Medicare beneficiaries with ESRD.

The payment model is part of the Advancing American Kidney Health initiative under an executive order issued in July 2019 to improve care for patients with kidney disease. According to a CMS press release, 20% of dollars in traditional Medicare—$114 billion a year—are spent on beneficiaries with kidney disease. CMS also

stated that of the "more than 100,000 American who begin dialysis to treat end-stage renal disease each year, one in five will die within a year."

The model will apply payment adjustments to the adjusted ESRD Prospective Payment System ("PPS") per treatment base rate to selected ESRD facilities, as well as the monthly capitation payment ("MCP") to selected Managing Clinicians to encourage participating ESRD facilities and Managing Clinicians to ensure that ESRD beneficiaries have access to and receive education about their kidney disease treatment options. CMS will positively adjust certain Medicare payments to participating ESRD facilities and Managing Clinicians for the first three years of the model for home dialysis and dialysis-related services. The second adjustment will be based on a participant's home dialysis rate and transplant waitlist rate and living donor transplant rate and could be either positive or negative.

The payment adjustments for the ETC Model will apply to select Medicare claims with dates from January 1, 2021 through June 30, 2027.

The CMS press release can be found here: https://www.cms.gov/newsroom/press-releases/cms-announces-transformative-new-model-care-medicare-beneficiaries-chronic-kidney-disease

A CMS fact sheet on the final rule is available here: https://www.cms.gov/newsroom/fact-sheets/end-stage-renal-disease-treatment-choices-etc-model-fact-sheet

OIG Determines CMS Should Improve Monitoring of ACO Quality Data Reporting

On September 22, the Department of Health and Human Services Office of Inspector General ("OIG") released a report that it found the Centers for Medicare & Medicaid Services ("CMS") should improve its monitoring activities to ensure Accountable Care Organizations ("ACOs") in the Medicare Shared Savings Program ("MSSP") report complete and accurate data on quality measures.

For performance year ("PY") 2017, ACOs were required to report data on 31 quality measures through three methods of submission: a patient survey, claims and administrative data, and the designated CMS web portal. Although CMS' monitoring activities were generally effective for ensuring that ACOs report complete and accurate data through claims and administrative data and the web portal, OIG identified some weaknesses that could lead to ACOs reporting incomplete or inaccurate data through the patient survey. One issue was that the CMS contractor did not request documentation from the survey vendors to verify that issues directly related to the collection or reporting of data were corrected. Also, the contractor did not provide feedback reports in time for survey vendors to include all the changes that were implemented into their Quality Assurance Plans ("QAPs"). Finally, CMS also did not ensure that its contractor reviewed survey instruments translated into other languages.

OIG recommended that CMS update the Statement of Work to require its contractor to: (1) verify that survey vendors have corrected identified issues that directly relate to the collection or reporting of data; (2) confirm that all implemented changes to address the identified issues are included in QAPs before they are approved; and (3) review the translated survey templates, mail survey packages, and telephone survey scripts to ensure that they are consistent with the English versions. CMS concurred with the recommendations.

OIG's report can be found here: https://oig.hhs.gov/oas/reports/region9/91803033.asp

OIG Report: States Failing to Timely Investigate Serious Nursing Home Complaints

On September 25, the Office of the Inspector General ("OIG") issued a report titled "States Continued To Fall Short in Meeting Required Timeframes for Investigating Nursing Home Complaints: 2016-2018," in which it stated its findings from a review of nursing home complaints over a three year period. OIG found that the rate of nursing home complaints per 1,000 nursing home residents increased from 45 in 2015 to 52 in 2018 and that 21 states failed to meet the Centers for Medicare & Medicaid's ("CMS") timeliness threshold for the second most serious level of complaints in all 3 years from 2016 through 2018, and 10 of these states did not meet the threshold for 8 consecutive years, from 2011 through 2018. OIG recommended that CMS ensure that all states receive training on updated triage guidance and identify new approaches to address states that are consistently failing to meet required timeframes for investigating the most serious nursing home complaints. CMS concurred with both recommendations.

OIG's report is available at: https://oig.hhs.gov/oei/reports/OEI-01-19-00421.pdf.

DOJ Charges 345 Defendants for Alleged $6 Billion in Health Care Fraud Schemes

On September 30, the Department of Justice announced a nationwide enforcement action involving 345 charged defendants across the country, including more than 100 doctors, nurses and other licensed medical professionals. The defendants were charged with submitting more than $6 billion in false and fraudulent claims to federal health care programs and private insurers, including more than $4.5 billion connected to telemedicine, more than $845 million connected to substance abuse treatment facilities, or "sober homes," and more than $806 million connected to other health care fraud and illegal opioid distribution schemes across the country. The telemedicine claims involved certain defendant telemedicine executives allegedly paying doctors and nurse practitioners to order unnecessary durable medical equipment, genetic and other diagnostic testing, and pain medications, either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen. The "sober homes" schemes involved the payment of illegal kickbacks and bribes for the referral of scores of patients to substance abuse treatment facilities; those patients were subjected to medically unnecessary drug testing – often billing thousands of dollars for a single test – and therapy sessions that were frequently not provided, and which resulted in millions of dollars of false and fraudulent claims being submitted to private insurers.

DOJ's announcement is available at: https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants.

Anthem Agrees to $39.5 Million Multi-State Data Breach Settlement

On September 30, it was announced that Anthem had agreed to pay approximately $40 billion to resolve state claims relating to a massive data breach the company experienced in 2014 that exposed private information of current and former members. The settlement included 41 states and the District of Columbia, and is in addition to the $16 million settlement that Anthem reached with the Office for Civil Rights to resolve associated HIPAA violations and a $115 million class action settlement. The data breach was caused by malware installed through a phishing email and resulted in the exposure of names, dates of birth, Social Security numbers, and other identifying data.

The NY Attorney General's announcement of the settlement is available at: https://oag.ca.gov/news/press-releases/attorney-general-becerra-announces-869-million-settlement-against-anthem-inc.

CMS Report: Next Generation ACO Model's First Years Saw Gross Medicare Spending Decrease, Non-Significant Net Spending Increase

In October, the Centers for Medicare & Medicaid Services ("CMS") issued a report on is evaluation of the first three Performance Years (2016-2018) of the Next Generation Accountable Care Organization ("NGACO") Model. The NGACO model tests whether strong financial incentives, flexible payment options, and tools to support care management improve value and lower expenditures for Medicare fee-for-service ("FFS") beneficiaries. Participating ACOs assume 80% or 100% up- and down-side financial risk and select from one of four payment mechanisms that allow FFS or prospective payments for services delivered to their aligned population of beneficiaries. CMS found that in the first three of five total Performance Years, the NGACO Model decreased gross Medicare spending by 0.9%, or $349 Million, but increased net spending by 0.3% after shared savings and other incentive payments were taken into account. The model was associated with reduced post-acute care and professional services spending but saw no appreciable declines in hospital utilization and spending.

The NGACO was scheduled to end after 2020, but has been extended for another year due to COVID-19.

CMS' report is available at: https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-ataglance.

Supreme Court Declines Review of DSH Payments Final Rule

On October 5, the U.S. Supreme Court declined to review a D.C. Circuit Court decision upholding a Centers for Medicare & Medicaid Services ("CMS") final rule that changed the payment calculation for Medicaid disproportionate share hospital ("DSH") payments.

In their petition for *certiorari*, plaintiff children's hospitals argued that they lose "tens of millions of dollars" treating huge numbers of children, who make up the largest portion of Medicaid enrollees and they challenged the final rule as contrary to the Medicaid Act and arbitrary and capricious, according to their petition for certiorari. The D.C. Circuit in August 2019 reversed a nationwide injunction of the final rule, which included payments from Medicare and private insurers in calculating the hospital-specific limit on Medicaid DSH payments. *Children's Hosp. Ass'n of Tex. v. Azar*, No. 18-5135 (D.C. Cir. Aug. 13, 2019). The D.C. Circuit found the Medicaid statute did not exclusively specify which payments could be considered in calculating "costs incurred" and that the rulemaking was not arbitrary and capricious because CMS sufficiently explained its reasoning.

The petition to the Supreme Court (petition for certiorari) can be read here: https://www.supremecourt.gov/DocketPDF/19/19-1203/140967/20200406165334281_Petition%20for%20a%20Writ%20of%20Certiorari.pdf

The D.C. Circuit opinion can be accessed here: https://www.cadc.uscourts.gov/internet/opinions.nsf/48CE86E8510F330585258455004EE247/$file/18-5135.pdf

OCR Settles Ninth Enforcement Action Under HIPAA Right of Access Initiative

On October 9, the Office for Civil Rights ("OCR") of the U.S. Department of Health and Human Services announced that it had settled its ninth enforcement action in its HIPAA Right of Access Initiative. OCR began

its Right of Access Initiative in 2019 as an enforcement priority to support individuals' right to timely access to their health records at a reasonable cost under the HIPAA Privacy Rule. In this latest enforcement action, NY Spine Medicine, a neurology and pain management office, agreed to take corrective action and pay $100,000 to settle potential violations of the Privacy Rule's right of access standard. OCR began this enforcement action based on a complaint from a patient in July of 2019 alleging that in response to her request in June of that year, NY Spine produced some, but not all of her requested medical records, including that it failed to produce diagnostic films. Following the initiation of OCR's investigation, NY Spine finally produced all of the patient's records to her in October of 2020. In addition to the monetary settlement, NY Spine will undertake a corrective action plan that includes two years of monitoring.

Earlier settlements in the Right of Access Initiative include:

- $38,000 with the New York-based Housing Works, Inc., which provides services to those affected by HIV/AIDS.
- $15,000 with All Inclusive Medical Services, Inc., a multi-specialty family medicine clinic in California.
- $70,000 with Beth Israel Lahey Health Behavioral Services, a network of mental health and substance use disorder services in Massachusetts.
- $3,500 with King MD, a small psychiatric services provider in Virginia.
- $10,000 with Wise Psychiatry, a small psychiatric services provider in Colorado.

OCR's announcements of the settlements can be found at:
https://www.hhs.gov/about/news/2020/10/09/ocr-settles-ninth-investigation-hipaa-right-access-initiative.html

https://www.hhs.gov/about/news/2020/09/15/ocr-settles-five-more-investigations-in-hipaa-right-of-access-initiative.html

NY Spine's resolution agreement and corrective action plan are available at:
https://www.hhs.gov/sites/default/files/ny-spine-ra-cap.pdf.

CMS Announces Approval of Georgia's Partial Medicaid Expansion with Work Requirements

On October 15, the Centers for Medicare & Medicaid Services ("CMS") announced that it has approved Georgia's new Medicaid section 1115 demonstration called "Pathways to Coverage," which intended to create a pathway for working-age Georgia adults who are ineligible for Medicaid to opt into Medicaid coverage by participating in qualifying activities like work and education, as well as meeting premium and income requirements. Pathways to Coverage applies to individuals who are between the age of 19 and 64, with income up to and including 100 percent of the federal poverty level ("FPL")and is effective through September 30, 2025, with implementation beginning July 1, 2021. In order to qualify for this program, individuals must comply with specific requirements, including participating in 80 hours a month of work or other qualifying activities. Most individuals with income between 50 and 100 percent of the FPL will be required to make initial and ongoing monthly premium payments.

CMS' announcement is available at: https://www.cms.gov/newsroom/press-releases/trump-administration-approves-innovative-state-led-health-reform-expand-and-strengthen-coverage.

CMS Finalizes Rule on Insurer Price Transparency

On October 29, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule setting forth requirements for group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee, including an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider. This requirement will go into effect on January 1, 2023 for 500 specific services, with the remainder of covered services being added on January 1, 2024. In addition, beginning in 2022, insurers must make available on the internet three machine-readable files disclosing disclose in-network provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information.

The Final Rule is available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CMS-Transparency-in-Coverage-9915F.pdf.

CMS Proposes 2022 Rates for Medicare Advantage and Part D

On October 30, the Centers for Medicare & Medicaid Services ("CMS") released Part II of a proposed rule that would result in increases i to Medicare Advantage ("MA") plan payments of 2.8% in calendar year ("CY") 2022. Part I of the CY 2022 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies was released on September 14. CMS is proposing a 5/9% coding pattern adjustment, which is a required adjustment to plan payments to reflect differences in diagnosis coding between MA organizations and fee-for-service Medicare providers. CMS is also proposing to implement an updated Part D risk adjustment model using 2017 diagnoses to predict 2018 costs. The model includes an update to better simulate catastrophic threshold coverage and is calibrated based on ICD-10 diagnoses.

The Advance Notice announces updates that the CY 2019 and CY 2020 Final Rules required for changes in payment and risk adjustment policies. CMS is asking for feedback on several different measurement concepts, including provider directory accuracy and COVID-19 vaccination.

CMS is accepting comments on Part I and II of the CY 2022 Advance Notice through November 30. The final Rate Announcement to be published by April 5, 2021.

Part II of the Advance Notice can be read here: https://www.cms.gov/files/document/2022-advance-notice-part-ii.pdf

A CMS Fact Sheet on the proposal can be read here: https://www.cms.gov/newsroom/fact-sheets/2022-medicare-advantage-and-part-d-advance-notice-part-ii

HHS Appeals Decision on Final Rule Rolling Back LGBTQ Protections

On October 31, the Department of Health and Human Services ("HHS") appealed a U.S. District Court for the District of Columbia decision that preliminary enjoined parts of a final rule that removed nondiscrimination protections for LGBTQ individuals under Affordable Care Act ("ACA") regulations. The HHS Office for Civil Rights issued the final rule in June, which eliminated gender identity from the definition of "on the basis of sex" under Section 1557 of the ACA. In September, the court held that HHS failed to provide either "good reasons" or a "reasoned analysis" for changing the definition of sex discrimination under Section 1557. It also held that the final rule's incorporation of Title IX's religious exemption was arbitrary and

capricious because HHS "failed to sufficiently consider the implications" on access to health care. *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health and Human Servs*., 20-1630 (JEB) (D.D.C. Sept. 3, 2020).

The final rule was issued three days before (and published four days after) the Supreme Court delivered a decision ruling that Title VII protects workers from discrimination in employment on the basis of their sexual orientation or gender identity. In *Bostock v. Clayton County, Ga.*, Nos. 17-1618, 17-1623 and 18-107 (U.S. June 15, 2020), the Court held that an employer who fires an individual merely for being transgender or homosexual violates Title VII's prohibition on sexual discrimination. The court noted that the principles set forth in *Bostock* "plainly have implications for Title IX's prohibition on sex discrimination and, by extension, Section 1557." The court said that at a minimum, *Bostock's* reasoning "suggests the possibility that this provision encompasses discrimination based on transgender status" and that the agency's failure to take the obvious step of considering the import of the *Bostock* decision on the final rule "prevents the Court from finding its policy change was supported by 'reasoned analysis' and compels the conclusion that its action was arbitrary and capricious."

The District Court's decision may be read here: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2020cv1630-56

CMS Issues Final ESRD Payment Rule

On November 2, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule that will increase Medicare payments under the End-Stage Renal Disease ("ESRD") Prospective Payment System ("PPS") for equipment and supplies used for home dialysis treatments. The final rule makes changes to reduce the need for ESRD patients to travel from home. In a fact sheet, CMS said that more than 85% of Medicare beneficiaries with ESRD travel to dialysis facilities at least three times a week. CMS Administrator Seema Verma stated that "Medicare beneficiaries with ESRD have long been ill-served by a system that too often fails to incentivize the types of care that yield the best health outcomes for their quality of life." The rule expands the transitional add-on payment adjustment for new and innovative equipment and supplies to qualifying new dialysis machines when used in the home. Under the final rule, the ESRD PPS base rate is set at $253.13, an increase of $13.80. Final payment policies for the ESRD PPS are effective January 1, 2021.

The final rule as published in the November 9 *Federal Register* may be read here: https://www.federalregister.gov/documents/2020/11/09/2020-24485/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis

The CMS fact sheet on the final rule may be found here: https://www.cms.gov/newsroom/fact-sheets/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-renal-dialysis-services

CMS Proposed Rule Aims to Streamline Coverage, Payment of New DMEPOS

On November 4, the Centers for Medicare & Medicaid Services ("CMS") published a Proposed Rule that would make the following changes concerning durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"): establish methodologies for adjusting the Medicare DMEPOS fee schedule amounts using information from the Medicare DMEPOS competitive bidding program; establish procedures for making benefit category and payment determinations for new items and services that are durable medical equipment ("DME"), prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B;

classify continuous glucose monitors as DME under Medicare Part B and establish fee schedule amounts for these items and related supplies and accessories; and expand the scope of the Medicare Part B benefit for DME by revising the interpretation of the ‘‘appropriate for use in the home’’ requirement in the definition of DME specifically for certain drugs or biologicals infused in the home using an external infusion pump. According to CMS, these changes are intended to codify CMS sub-regulatory guidance that streamlines of the DMEPOS approval process from the 18 months it used to take down to a 6-month timeframe.

Comments on the Proposed Rule must be received by January 4, 2021.

The Proposed Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24194.pdf.

CMS Estimates Home Health Final Rule Will Increase Payments by $390 Million in 2021

On November 4, the Centers for Medicare & Medicaid Services (“CMS”) published a Final Rule updating the home health prospective payment system (“HHPPS”) payment rates and wage index for calendar year 2021 and implementing changes to the home health regulations regarding the use of telecommunications technology in providing services under the Medicare home health benefit, among other changes. CMS estimates that the updates to the HHPPS will result in an increase in the aggregate payments by 1.9%, or $390 million, based on a 2% home health payment update percentage and a 0.1% decrease in payments due to reductions in the rural add-on percentages.

The Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24146.pdf.

ONC Extends Compliance Deadlines for Information Blocking Rule

On November 4, the Office of the National Coordinator for Health Information Technology (“ONC”) published an Interim Final Rule with Comment Period extending certain compliance dates and timeframes for the information blocking provisions that were finalized in March. ONC previously extended the compliance deadlines in April due to the ongoing COVID-19 pandemic. The Interim Final Rule extends compliance deadlines for the information blocking provisions and certain conditions and maintenance of certification requirements from November 2, 2020 to April 5, 2021.

Comments to the Interim Final Rule must be received by January 4, 2021.

The Interim Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.

OCR Settles Two Additional HIPAA Right of Access Violations

On November 6 and 12, the Office for Civil Rights (“OCR”) announced two new settlements in its HIPAA Right of Access Initiative, which aims to enforce patients’ right to access their medical information. The first involved the payment of $25,000 by a California psychiatric practice following OCR’s investigation of multiple complaints by a patient that the practice had failed to provide her medical records. The second involved a New York otolaryngologist agreeing to pau $15,000 to settle an OCR investigation of the failure to provide a patient’s requested records for almost two years.

OCR’s November 6 announcement is available at: https://www.hhs.gov/about/news/2020/11/06/ocr-settles-tenth-investigation-hipaa-right-access-initiative.html?language=en.

OCR's November 12 announcement is available at: https://www.hhs.gov/about/news/2020/11/12/ocr-settles-eleventh-investigation-hipaa-right-access-initiative.html

U.S. Attorneys Announce Multiple Health Care Fraud Enforcement Actions

During the first two weeks of November, U.S. Attorneys' offices around the country announced multiple health care fraud enforcement actions against providers, including:

- A Tennessee podiatrist indicted on 40 counts for billing Medicare for services not rendered, resulting in excess billings of over $1 million: https://www.justice.gov/usao-edtn/pr/podiatrist-indicted-health-care-fraud
- A New York family physician agreeing to pay $150,000 to settle allegations of kickbacks and false claims related to claims to Medicare for services not rendered: https://www.justice.gov/usao-edny/pr/medical-doctor-settles-civil-fraud-allegations-adult-homes-investigation-0
- A Pennsylvania physicians agreeing to pay $850,000 to settle claims that she submitted to Medicare over 23,000 false and inflated travel reimbursement claims through her laboratory company for specimen collection and testing over a three-year period: https://www.justice.gov/usao-mdpa/pr/mechanicsburg-physician-pay-850000-resolve-potential-liability-under-false-claims-act
- A Virginia OBGYN convicted by a jury on 52 counts related to his performance of and billing private and government insurers for unnecessary surgeries: https://www.justice.gov/usao-edva/pr/jury-convicts-doctor-scheme-perform-unnecessary-surgeries-women
- A New Jersey pain management doctor charged with three counts of fraud concerning his longstanding billing fraud scheme, including billing more than $24.6 million to Medicare and Medicaid for services not rendered: https://www.justice.gov/usao-nj/pr/south-jersey-doctor-charged-health-care-fraud-billing-scheme
- A New Jersey medical office employee who pleaded guilty to conspiracy to violate the anti-kickback statute by accepting kickbacks in exchange for collecting DNA samples of Medicare beneficiaries: https://www.justice.gov/usao-nj/pr/doctor-s-employee-admits-role-genetic-testing-kickback-and-bribery-scheme
- A Delaware cardiology practice agreeing to pay $500,000 to settle allegations that it billed for cardiology procedures without generating the corresponding interpretive reports that are required for payment: https://www.americanhealthlaw.org/content-library/health-law-weekly/print-all/bd18ffa3-54b1-44cd-b0e8-c13a2ec2c7cc

Federal COVID-19 Updates

Funding Available to Providers for Counseling Patients to Self-Isolate After COVID-19 Testing

On July 30, the Centers for Medicare & Medicaid Services ("CMS") and the Centers for Disease Control and Prevention ("CDC") announced that payment is available to physicians and health care providers to counsel patients, at the time of COVID-19 testing, about the importance of self-isolation after they are tested and prior to the onset of symptoms. Provider counseling to patients, at the time of their COVID-19 testing, should include the discussion of immediate need for isolation, even before results are available, the importance to inform their immediate household that they too should be tested for COVID-19, and the review of signs and symptoms and services available to them to aid in isolating at home. CMS will use existing evaluation and management (E/M) payment codes to reimburse providers who are eligible to bill CMS for counseling services no matter where a test is administered, including doctor's offices, urgent care clinics, hospitals and community drive-thru or pharmacy testing sites.

The joint CMS and CDC announcement is available at: https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19.

HHS Enters into Deals with Pharmaceutical Manufacturers as Part of Operation Warp Speed

Since announcing Operation Warp Speed in May, the U.S. Department of Health and Human Services ("HHS") has entered into several agreement with pharmaceutical manufacturers to guarantee the availability of a COVID-19 vaccine as soon as possible:

- July 31: HHS announced a $2.1 billion deal with Sanofi and GlaxoSmithKline to secure 100 million doses of a COVID-19 vaccine currently under development, with the ability to acquire up to 500 million additional doses.
- August 5: HHS announced a $1 billion agreement with Janssen Pharmaceutical Companies to secure 100 million doses of its COVID-19 vaccine, with an option to acquire up to an additional 300 million doses.
- August 11: HHS announced a $1.5 billion agreement with Moderna to secure 100 million doses of its COVID-19 vaccine, with the option to acquire more.
- August 23: HHS announced an agreement with AstraZeneca for late-stage development and large-scale manufacturing of the company's COVID-19 investigational product AZD7442, a cocktail of two monoclonal antibodies, that may help treat or prevent COVID-19.
- October 28: HHS announced a $375 million agreement with Eli Lilly and Company to purchase the first doses of the company's COVID-19 investigational antibody therapeutic bamlanivimab, also known as LY-CoV555.

Information on Operation Warp Speed, including the vaccines currently being developed, is available at: https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html.

FDA: Provider May Extend In-Use Time of Injectable COVID-19 Drugs in Short Supply

On August 4, the Food & Drug Administration ("FDA") issued guidance to providers who are considering using certain drugs to treat COVID-19 cases beyond the drugs' labeled "in-use times" in order to ensure access to the drugs for patients. According to the FDA, "[w]hen an injectable drug product is prepared for administration per labeling instructions, and where FDA-approved labeling describes an in-use time for that drug product, the Agency has not necessarily evaluated data to support a longer in-use time." FDA's new guidance states that any period of extended use time be as short as possible, and not exceed 4 hours for a refrigerated storage condition, or 2 hours for any labeled room temperature in-use time.

FDA's guidance is available at: https://www.fda.gov/drugs/coronavirus-covid-19-drugs/information-health-care-facilities-and-providers-use-time-covid-19.

HHS Releases State Testing Plan

On August 10, the U.S. Department of Health & Human Services ("HHS") publicly posted the July through December COVID-19 Testing Plans from all states, territories, and localities on HHS.gov. The State Testing Plans serve as a roadmap developed in partnership with the Federal government for each jurisdiction's monthly 2020 testing strategy for SARS-CoV-2, the virus that causes COVID-19. Each state plan is required to include details of critical parameters for state testing strategies, including target numbers of tests per month.

State testing plans are available at: https://www.hhs.gov/coronavirus/testing-plans/index.html.

CMS: Increased Reimbursement for COVID-19 Cases Requires Documentation of Positive Test Result

On August 17, the Centers for Medicare & Medicaid Services ("CMS") updated guidance on increased reimbursement for COVID-19 cases under the CARES Act to Inpatient Prospective Payment System hospitals, Long-Term Care Hospitals, and Inpatient Rehabilitation Facilities. The update clarified that effective with admissions occurring on or after September 1, 2020, claims eligible for the 20 percent increase in the Medicare Severity-Diagnosis Related Group weighting factor will also be required to have a positive COVID-19 laboratory test documented in the patient's medical record. Positive tests must be demonstrated using only the results of viral testing (i.e., molecular or antigen), consistent with CDC guidelines. The test may be performed either during the hospital admission or prior to the hospital admission.

In a letter to CMS on August 26, the American Hospital Association urged CMS to provide additional flexibility regarding the COVID-19 test documentation requirement for the add-on payment, arguing that "[the] new requirement will put substantial administrative burden on hospitals at a time when they are focusing their efforts and resources on critical patient care." AHA requested that CMS allow provider documentation to suffice if a test result is not available.

The updated guidance is available at: https://www.cms.gov/files/document/se20015.pdf.

The AHA's letter is available at: https://www.aha.org/system/files/media/file/2020/08/aha-to-cms-on-drg-add-on-requirement-letter-8-26-20.pdf.

CMS Imposes New Reporting and Testing Requirements for Providers

On September 2, the Centers for Medicare & Medicaid Services ("CMS") published an Interim Final Rule with Comment Period which revises regulations to strengthen CMS' ability to enforce compliance with Medicare and Medicaid long-term care ("LTC") facility requirements for reporting information related to COVID-19, establishes a new requirement for LTC facilities for COVID-19 testing of facility residents and staff, establishes new requirements in the hospital and critical access hospital Conditions of Participation for tracking the incidence and impact of COVID-19 to assist public health officials in detecting outbreaks and saving lives, and establishes requirements for all CLIA laboratories to report COVID-19 test results to the Secretary of Health and Human Services.

The Interim Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-09-02/pdf/2020-19150.pdf.

HHS Authorizes Pharmacists to Order and Administer COVID-19 Vaccines

On September 3, the U.S. Department of Health & Human Services ("HHS") issued guidance authorizing State-licensed pharmacists to order and administer, and State-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, to persons ages three or older COVID-19 vaccinations that have been authorized or licensed by the Food and Drug Administration. The guidance sets forth several requirements that must be met in order for pharmacists or pharmacy interns to qualify as "covered persons" under the PREP Act and therefore able to administer vaccines, including: the vaccine must be FDA-authorized or FDA-issued; the vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices' COVID-19 vaccine recommendation; and the licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination

provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s). HHS issued additional guidance for covered pharmacists and pharmacy interns on October 20.

HHS' September 3 guidance is available at: https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf.

HHS' October 20 guidance is available at: https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf.

EEOC: Mandating COVID-19 Testing of Employees Does Not Violate the ADA

On September 8, the Equal Employment Opportunity Commission ("EEOC") issued updated guidance for employers concerning COVID-19 and compliance with federal anti-discrimination laws. The updated guidance confirms that employers may require employees to undergo COVID-19 testing before entering the workplace without violating the American's with Disabilities Act ("ADA"). The EEOC has taken the position that such testing satisfies the ADA standard that requires that any mandatory medical test of employees be "job related and consistent with business necessity."

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

HHS Releases COVID-19 Vaccine Strategy "Playbook"

On September 16, the U.S. Department of Health and Human Services ("HHS") released several documents outlining the Trump Administration's strategy to deliver COVID-19 vaccines to the American people once one becomes available. The documents, developed by HHS in coordination with the Department of Defense and the Centers for Disease Control and Prevention , provide a strategic distribution overview along with an interim playbook for state, tribal, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their respective jurisdictions. The strategic overview lays out four tasks necessary for the COVID-19 vaccine program: 1) engage with state, tribal, territorial, and local partners, other stakeholders, and the public to communicate public health information around the vaccine and promote vaccine confidence and uptake; 2) distribute vaccines immediately upon granting of Emergency Use Authorization/ Biologics License Application, using a transparently developed, phased allocation methodology and CDC has made vaccine recommendations; 3) ensure safe administration of the vaccine and availability of administration supplies; and 4) monitor necessary data from the vaccination program through an information technology system capable of supporting and tracking distribution, administration, and other necessary data.

HHS' announcement and the strategy documents are available at: https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html.

CMS Issues Guidance on Nursing Home Visitation

On September 17, the Centers for Medicare & Medicaid Services ("CMS") issued revised guidance on safely expanding nursing home visitation during the COVID-19 pandemic. The guidance encourages outdoor visitation for all nursing homes, and indoor visitation for nursing homes in areas with limited community spread of COVID-19. The guidance also includes information about visitor testing and compassionate care visitation.

CMS' guidance is available at: https://www.cms.gov/files/document/qso-20-39-nh.pdf.

CDC to Provide Funding to Help Jurisdictions Prepare for COVID-19 Vaccine

On September 23, the U.S. Department of Health and Human Services ("HHS") announced that the Centers for Disease Control and Prevention ("CDC") would provide $200 million to 64 jurisdictions around the country or COVID-19 vaccine preparedness. The funding comes from the CARES Act and will be awarded through the existing Immunizations and Vaccines for Children cooperative agreement. The funding has since been distributed, and New Hampshire received over $800,000.

HHS' announcement is available at: https://www.hhs.gov/about/news/2020/09/23/administration-announces-200-million-from-cdc-jurisdictions-covid-19-vaccine-preparedness.html.

Information on financial assistance the CDC has provided to states is available at: https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/funding-update.pdf.

GAO Issues Report on Federal Response to COVID-19

On September 21, the Government Accountability Office ("GAO") issued a report to Congressional committees titled "Federal Efforts Could Be Strengthened by Timely and Concerted Actions." The report, which is required by the CARES Act, details several findings the GAO made about the federal government's response to the COVID-19 pandemic, including both successes and remaining challenges. The report provides sixteen recommendations to federal agencies, including that the Secretary of Health and Human Services should immediately document roles and responsibilities for supply chain management functions transitioning to the Department of Health and Human Services, including continued support from other federal partners, to ensure sufficient resources exist to sustain and make the necessary progress in stabilizing the supply chain, and address emergent supply issues for the duration of the COVID-19 pandemic.

The GAO's report is available at: https://www.gao.gov/assets/710/709492.pdf.

CMS Reports Significant Declines in Childhood Vaccination and Primary and Preventative Care

On September 23, the Centers for Medicare & Medicaid Services released information revealing that during the COVID-19 public health emergency (PHE), rates for vaccinations, primary, and preventive services among children in Medicaid and CHIP have steeply declined. Specifically, between March and May, there were 22 percent fewer (1.7 million) vaccinations received by CHIP beneficiaries up to age 2, 44 percent fewer (3.2 million) child screening services that assess physical and cognitive development and can provide early detection of autism and developmental delay, among other conditions, even after accounting for the increased use of telehealth, and 69 percent fewer (7.6 million) dental services. CMS cites this data in urging schools, families, and providers to catch up on well-child visits and services.

CMS' information is available at: https://www.cms.gov/newsroom/press-releases/cms-issues-urgent-call-action-following-drastic-decline-care-children-medicaid-and-childrens-health.

CMS Reports Significant Increase in Medicaid, CHIP Enrollment During Public Health Emergency

On September 30, the Centers for Medicare & Medicaid Services ("CMS") released a data presentation titled "Medicaid and CHIP Enrollment Trends Snapshot through June 2020." The presentation reported that from July 2019 through June 2020, national Medicaid and CHIP enrollment increased by 5.1%, or roughly 3.6 million individuals. This includes an increase of 3.4 million Medicaid enrollments and over 150,000 CHIP enrollments.

CMS' presentation is available at: https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/june-medicaid-chip-enrollment-trend-snapshot.pdf.

CMS Adds 11 New Services to the Medicare Telehealth Services List

On October 14, the Centers for Medicare and Medicaid Services ("CMS") announced that it had added 11 new services to the telehealth services list for the first time using a new expedited process. CMS had previously added 134 new services to the list in May. The new telehealth services include certain neurostimulator analysis and programming services, and cardiac and pulmonary rehabilitation services. In making the announcement, CMS also reported that between mid-March and mid-August 2020, over 12.1 million Medicare beneficiaries – over 36 percent – of people with Medicare Fee-For-Service have received a telemedicine service.

CMS' list of telehealth services is available at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.

Medicare Beneficiaries to Receive COVID-19 Vaccines at No Cost

On November 6, the Centers for Medicare & Medicaid Services published an Interim Final Rule with Comment Period implementing several requirements from the CARES Act concerning Medicare Part B coverage and payment for an eventual COVID-19 vaccine and its administration. The Interim Final Rule ensures that Medicare beneficiaries will pay nothing for COVID-19 vaccines and that Medicaid and CHIP beneficiaries will pay nothing during the public health emergency. The rule also requires that most private health plans cover a vaccine and its administration with no cost sharing, and provides a mechanism for providers to be reimbursed for administrating the COVID-19 vaccine to individuals without insurance. The Medicare payment rates will be $28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of two or more doses, the initial dose(s) administration payment rate will be $16.94, and $28.39 for the administration of the final dose in the series. The rates will be geographically adjusted.

Comments to the Interim Final Rule must be received by January 4, 2021.

The Interim Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-11-06/pdf/2020-24332.pdf.

CMS' Fact Sheet on the Interim Final Rule is available at: https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-coverage-life-saving-covid-19-vaccines-therapeutics.

Pfizer Announces COVID-19 Vaccine Candidate Is More Than 90% Effective

On November 9, Pfizer announced that early analysis of its COVID-19 vaccine candidate showed that is it more than 90% effective at preventing infection. Pfizer states that it plans to ask the U.S. Food and Drug Administration for emergency use authorization the following week after it has the required two months of safety data. It reported that there have been no serious safety concerns yet, however the trial will continue in the meantime. Pfizer said that based on current projections, it expects to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses in 2021. While Pfizer did not take any funding from the Trump Administration's Operation Warp Speed, it has entered into an agreement for the federal government to pay $1.95 billion for production and delivery of the first $100 million doses, with an option to acquire another 500 million.

Pfizer's press release on the vaccine news is available at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against.

Moderna Announces Vaccine with 94.5% Preliminary Effective Rate

On November 16, pharmaceutical manufacturer Moderna announced that the Phase 3 study of its mRNA-1273 COVID-19 vaccine had met the statistical criteria pre-specific in the study protocol for efficacy, with a vaccine efficacy of 94.5%. The results were obtained from a trial of 30,000 participants, half who received the vaccine and half who received a placebo. Among the placebo group, 90 participants developed COVID-19, with eleven developing severe symptoms, while among the vaccine group only 5 developed COVID-19, with none becoming seriously ill. Following accumulation of more safety data later in November, Moderna intends to seek FDA authorization. One potential advantage of Moderna's vaccine over Pfizer's previously announced vaccine with a similar efficacy rate is that Moderna's vaccine does not need to be kept as cold (-20 degrees Celsius vs. -75 degrees Celsius), which makes it easier for providers to maintain the vaccine with existing available technology.

Moderna's announcement is available at: https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy.

STATE DEVELOPMENTS

DHHS Reduces COVID-19 Contact Tracing Efforts

On November 12, the New Hampshire Department of Health and Human Services, ("DHHS") announced that it will no longer be conducting contract tracing for all new COVID-19 cases, instead contact tracing will be conducted only for those who are considered high risk populations, such as individuals under 18 or over 65, health care workers, communities of color, and people living in group living spaces. DHHS Commissioner Lori Shibinette stated that the state's contact tracers have only been reaching about 40-50% of positive cases on the first call, and the primary responsibility for contract tracing will be pushed to health care providers and individuals. State Epidemiologist Benjamin Chan added: "Contact tracing is part of a containment strategy to stop the spread of COVID-19, but it is one and only one layer or intervention for helping to prevent the spread of COVID-19—as community transmission increases, it becomes a less effective strategy of identifying and breaking the chains of transmission." DHHS' announcement comes as the state has been reporting record numbers of new daily cases.

DHHS' website of COVID-19 information is available at: https://www.nh.gov/covid19/.

2020 Legislative Session

Due to closure of the State House as a result of COVID-19, the legislature undertook a revised process for addressing pending legislation. Many bills which had received bipartisan support coming out of the House or Senate, were combined into omnibus bills. Others which were acted on remained as stand-alone bills. There was an opportunity for public input and bills were voted on during in-person sessions of the House and Senate respectively. A summary of the health care related bills that were acted on through this process is set forth below.

OMNIBUS BILLS

HB 1280: Prescription Drug Omnibus Bill (includes HB 1280, HB 1281, SB 685, SB 687, SB 688, SB 691)

This is an act relative to copayments for insulin, establishing a wholesale prescription drug importation program, establishing a New Hampshire prescription drug affordability board, establishing the prescription drug competitive marketplace, relative to the pricing of generic prescription drugs, relative to prior authorization for prescription drug coverage, and requiring insurance coverage for epinephrine auto-injectors.

Passed by the House and Senate. Signed into law by the Governor.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_Status/billText.aspx?sy=2020&id=1143&txtFormat=pdf&v=current

HB 1623: Telehealth Bill (includes HB 1623, SB 555, SB 647)

This bill:

I. Ensures reimbursement parity, expands site of service, and enables all providers to provide services through telehealth for Medicaid and commercial health coverage.

II. Enables access to medication assisted treatment (MAT) in specific settings by means of telehealth services.

III. Amends the Physicians and Surgeons Practice Act to expand the definition of telemedicine.

IV. Amends the relevant practice acts to expand the definition of telemedicine.

V. Enables the use of telehealth services to deliver Medicaid reimbursed services to schools.

Passed by the House and Senate. Signed into law by the Governor.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_Status/billText.aspx?sy=2020&id=1180&txtFormat=pdf&v=current

HB 1639: Health Care Omnibus Bill (combines HB 1287,HB 1639, SB 447, SB 476 SB 507, SB 519, SB 531, SB 546, SB 597, SB 598, SB 619, SB 620, SB 645, SB 693, SB 718, SB 744, SB 762, SB 749)

This bill:

I. Requires the department of health and human services to amend the income standard used for eligibility for the "in and out" medical assistance policy.

II. Clarifies the prior authorization procedures under group health insurance policies and managed care.

III. Clarifies non-covered dental services under the managed care law.

IV. Requires the commissioner of the department of health and human services to develop a state health assessment and a state health improvement plan and establishes the state health assessment and state health improvement plan advisory council to assist the commissioner with the plan.

V. Requires that boards regulating practitioners prescribing, administering, and dispensing controlled substances adopt rules for management of chronic pain.

VI. Defines chronic pain for the purposes of the controlled drug prescription health and safety program.

VII. Requires insurance coverage for long-term antibiotic therapy for tick-borne illness.

VIII. Adds physician assistants to the law governing advance directives.

IX. Clarifies the licensure of physician assistants and provides for biennial renewal of physician assistant licenses.

X. Establishes the New Hampshire drug overdose fatality review commission to review information and data related to drug overdose fatalities in New Hampshire.

XI. Establishes an opioid abatement trust fund. The department of health and human services, in consultation with the New Hampshire opioid abatement advisory commission, shall use the fund to support programs associated with the prevention, treatment, and recovery of substance use disorders.

XII. Authorizes pharmacists to administer a COVID-19 vaccine if one is available.

XIII. Clarifies the deposits to be made into the New Hampshire granite advantage health care trust fund.

XIV. Requires the superintendent of a county correctional facility to provide a prisoner with medication-assisted treatment for substance use disorders where medically appropriate.

XV. Clarifies the patients' bill of rights.

XVI. Prohibits a physician, surgeon, nurse, physician assistant, APRN, or student undertaking a course of professional instruction from performing certain examinations on an anesthetized or unconscious patient without consent unless such examination meets certain specific criteria.

XVII. 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. 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.

Passed by the House and Senate. Signed into law by the Governor.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_Status/billText.aspx?sy=2020&id=1620&txtFormat=pdf&v=current

HB 578: Long Term Care Omnibus Bill (combines SB 545, SB 715)

This bill:

I. Establishes a committee to study the safety of residents and employees in long-term care facilities.

II. Clarifies the cost controls for long-term care services.

III. Requires the commissioner of the department of health and human services to amend the state Medicaid plan amendment and adopt rules for reimbursement of the costs of training nursing assistants.

Passed by the House and Senate. Signed into law by the Governor.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_status/billText.aspx?sy=2020&id=608&txtFormat=pdf&v=current

HB 1491: Licensing Omnibus Bill (includes HB 1188, HB 1491, HB 1599, SB 432, SB 576, SB 676)

This bill:

I. 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.

II. Expands the professions in the allied health governing boards which grant temporary licensure to licensees from other states.

III. Authorizes the department of health and human services to access certain data and information from the controlled drug prescription health and safety program under certain circumstances.

IV. 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.

V. Amends the definition of licensing agency to include the state fire marshal for purposes of licensing places of assembly under RSA 155:18.

VI. Establishes a special marriage officiant license to temporarily authorize an individual to solemnize a marriage. A portion of the license fee shall be deposited in the fund for domestic violence programs.

Passed by the House. Passed by the Senate with amendment. The House non-concurred with the Senate's amendment.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_Status/billText.aspx?sy=2020&id=1748&txtFormat=pdf&v=current

STAND-ALONE BILLS

HB 685: This bill requires insurance plans which cover maternity benefits to provide coverage for emergency or elective abortion services.

Passed by the House and Senate. Vetoed by the Governor. House failed to override the veto.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_Status/billText.aspx?sy=2020&id=512&txtFormat=pdf&v=current

HB 250: This bill requires the commissioner of the department 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.

Passed the House and Senate. Vetoed by the Governor. House failed to override the veto.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_Status/billText.aspx?sy=2020&id=336&txtFormat=pdf&v=current

HB 1166: An act relative to unemployment compensation, certain sanitary protections for COVID- 19, extending the federal Family and Medical Leave Act for certain COVID-19 protections, and waiving cost sharing for testing and treatment for COVID-19.

Passed by the House and Senate. Vetoed by the Governor. House failed to override the veto.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_status/billText.aspx?sy=2020&id=1343&txtFormat=pdf&v=current

HB 1246: An act relative to reporting of health care associated infections, establishing a COVID-19 nursing home and long-term care fund, relative to an independent COVID-19 nursing home and long-term care review, needs assessment, and recommendations, authorizing pharmacists to administer a COVID-19 vaccine, and relative to the reimbursement of costs of training nursing assistants.

Passed by the House and Senate. Vetoed by the Governor. House failed to override the veto.

The full text of the bill may be found at:
http://gencourt.state.nh.us/bill_status/billText.aspx?sy=2020&id=1653&txtFormat=pdf&v=current

2021 Legislative Session

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 into 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.

2021-0181 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.

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

BIOS

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