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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 Finds 11 Drug Codes Meet Criteria for Price Substitution

On February 11, the U.S. Department of Health and Human Services ("HHS"), Office of the Inspector General ("OIG") issued a report titled: "Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2019." By law, OIG must notify the Secretary of Health and Human Services if the average sales price ("ASP") for a particular drug exceeds the drug's average manufacturer price ("AMP") by 5 percent or more. If that threshold is met, the Secretary may disregard the drug's ASP when setting the reimbursement amount and shall substitute the payment amount with the lesser of either the widely available market price or 103 percent of the AMP. OIG found that in the third quarter of 2019, 11 drug codes met CMS's price substitution criteria by exceeding the 5-percent threshold for 2 consecutive quarters or 3 of the previous 4 quarters, based on complete AMP data. Another seven drug codes had ASPs that exceeded the AMPs by at least 5 percent in the third quarter of 2019, based on complete AMP data, but these drug codes did not meet other CMS price-substitution criteria.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-03-20-00040.pdf.

Department of Justice Launches National Nursing Home Initiative

On March 3, the U.S. Department of Justice ("DOJ") announced a National Nursing Home Initiative, which will "coordinate and enhance civil and criminal efforts to pursue nursing homes that provide grossly substandard care to their residents." The DOJ's announcement identified a number of factors that will guide its decisions to pursue civil and/or criminal enforcement actions against nursing homes, including whether they provide adequate nursing staff, adhere to basic protocols of hygiene and infection control, provide residents without food to eat, and appropriately administer pain medications and physical and chemical restraints. The DOJ is expected to utilize several statutory authorities at its disposal, including the False Claims Act, Anti-

Kickback Statute, and mail and wire fraud statutes. Although the Initiative was announced prior to the declaration of a public health emergency in the United States for the COVID-19 pandemic, experts expect that the Initiative's review of nursing homes will include their response to the pandemic and proper infection control procedures.

DOJ's announcement is available at: https://www.justice.gov/opa/pr/department-justice-launches-national-nursing-home-initiative.

HHS Issues Two Final Rules on Interoperability and Patient Data Access

On March 9, the Centers for Medicare & Medicaid Services ("CMS") and the Office of the National Coordinator for Health Information Technology ("ONC"), both part of the U.S. Department of Health and Human Services, issued Final Rules to implement the interoperability and data access provisions of the 21st Century Cures Act. Changes in the Final Rules include: establishing new rules to prevent "information blocking" by providers, developers of certified health IT, and health information exchanges; requiring electronic health records to provide necessary clinical data, including standards for core data classes and elements; establishing secure, standards-based application programming interface ("API") requirements, which allows patients to access their health data from their smartphones; requiring federal health programs to share claims data electronically with patients; establishing a new Condition of Participation for hospitals that requires sending electronic notifications to certain other providers when a patient is admitted, discharged, or transferred; and requiring states to send Medicaid enrollee data daily beginning April 1, 2022 to improve coordination of care for dual-enrolled beneficiaries. The Final Rules were published in the Federal Register on May 1, 2020 and go into effect on June 30, 2020.

CMS' Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf.

ONC's Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

OIG Recommends Incorporating Additional Program Integrity Safeguards into Part D

On March 10, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report titled: "Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D." In the report, OIG analyzed three safeguards for program integrity that it says are missing from Medicare Part D. First, OIG noted that while pharmacies are required to enroll in Medicare to bill Part B, they are not required to enroll to bill Part D. Second, pharmacies that have their Medicare enrollment revoked for failing to meet Medicare requirements are still permitted to bill Part D. Third, while CMS can use preclusion to bar problem pharmacies from billing Part C, there is no similar mechanism for Part D. All three of these issues result in pharmacies billing Part D without being subject to the same program integrity safeguards that are in place for other part of Medicare. OIG recommends that CMS make changes to incorporate enrollment, revocation, and preclusion into Part D. OIG reported that CMS concurred with its recommendations.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-02-15-00440.pdf.

U.S. Court in Texas Enjoins Government from Recouping Alleged Overpayment Pending ALJ Hearing

On March 11, the U.S. District Court for the Northern District of Texas issued an injunction preventing the government from recouping an alleged overpayment from a home health agency while during the pendency of the home health agency's request for an administrative law judge ("ALJ") hearing. The government claims that the home health agency, Med-Cert, owes nearly $2 million in overpayments to Medicare. Med-Cert appealed the ruling all the way to the ALJ level but has yet to have a hearing. Nevertheless, the government began to recoup the overpayment prior to any hearing being conducted. The court found that Med-Cert would be irreparably harmed by the erroneous deprivation of Medicare funds as a result of the recoupment, as Med-Cert had shown that without the Medicare revenue it would not have sufficient income to sustain its operations. In issuing the injunction, the court joined a number of other courts that have waded into this issue, including the Court of Appeals for the Fourth Circuit, which recently denied a similar injunction request.

The decision in *Med-Cert Home Care v. Azar*, No. 3:18-CV-02372-E (N.D. Tex. Mar. 11, 2020), is available at: https://www.govinfo.gov/content/pkg/USCOURTS-txnd-3_18-cv-02372/pdf/USCOURTS-txnd-3_18-cv-02372-1.pdf.

OIG: CMS Should Do More to Ensure States Comply with Prohibition Against Medicaid Payments for Services Related to Preventable Medical Errors

On March 19, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report titled: "CMS Could Take Actions to Help States Comply with Federal Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions." The report includes the results of OIG's review of nine previous audits of states' efforts to comply with Centers for Medicare & Medicaid Services' ("CMS") rules prohibiting Medicaid payments for services related to provider-preventable conditions ("PPCs"), which are certain reasonably preventable conditions caused by medical accidents or errors in a healthcare setting. The previous audits showed that none of the states audited fully complied with the prohibition. In this report, OIG recommended that CMS verify that all state plans fully comply with the prohibition on Medicaid payments for services related to PPCs and issue clarifying guidance to address specific areas in which states have failed to comply with those requirements. OIG reports that CMS concurred with its recommendations.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region9/91802004.pdf.

CMS Waives Certain Stark Law Referral Prohibitions During COVID-19 Public Health Emergency

On March 30, the Centers for Medicare & Medicaid Services issued blanket waivers of certain self-referral prohibitions contained in the Stark Law in order to provide flexibility to providers during the pendency of the COVID-19 public health emergency. CMS waived sanctions under the Stark law for several financial arrangements that may be unable to comply with the requirements in the Stark Law as a consequence of the COVID-19 pandemic, including: remuneration from an entity to a physician that is above or below the fair market value for services personally performed by the physician to the entity; rental charges paid by an entity to a physician that are below fair market value for the entity's lease of office space and/or equipment from the physician; remuneration from an entity to a physician that is below fair market value for items or services purchased by the entity from the physician; and the referral by a physician in a group practice for medically necessary designated health services furnished by the group practice to a patient in his or her private home, an assisted living facility, or independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes.

Importantly, the waivers only apply to remuneration and referrals related to "COVID-19 Purposes," which include: diagnosis or medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID19; securing the services of physicians and other health care practitioners and professionals to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19, in response to the COVID-19 outbreak in the United States; or ensuring the ability of health care providers to address patient and community needs due to the COVID-19 outbreak in the United States.

The waivers have a retroactive effective date to March 1, 2020.

CMS' communication of the waivers is available at: https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.

OIG Issues Five-Year Strategic Plan Laying out Goals and Enforcement Priorities

On March 30, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued its Strategic Plan for 2020-2025. The Plan focuses on OIG's three clear goals: 1) fight fraud, waste, and abuse; 2) promote quality, safety, and value; and 3) advance excellence and innovation. The Plan also lays out additional specific priorities: protect beneficiaries from prescription drug abuse, including opioids; promote patient safety and accuracy of payments in home and community settings; ensure health and safety of children served by HHS grants; and strengthen Medicaid protections against fraud and abuse.

OIG's report is available at: https://oig.hhs.gov/about-oig/strategic-plan/OIG-Strategic-Plan-2020-2025.pdf.

OIG Finds that Terminated Providers Remain Enrolled in Several States' Medicaid Programs

On March 30, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report titled: "States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries." In accordance with a statutory requirement, OIG undertook to determine: (1) whether providers in the Centers for Medicare & Medicaid Services' ("CMS") termination database are terminated from Medicaid in all States; (2) the amount of Medicaid payments associated with terminated providers; (3) whether State contracts with managed care organizations ("MCOs") included a required provision that prohibits providers terminated from Medicare, Medicaid, or CHIP from participating in Medicaid managed care networks; and (4) the amount of Medicaid payments to MCOs that did not have the required provision in their contracts. OIG found that nearly 1,000 terminated providers—11% of all terminated providers—were inappropriately enrolled in state Medicaid programs or were associated with $50.3 million in Medicaid payments after being terminated. In addition, only eight states' managed care contracts all clearly included a provision that prohibits terminated providers from participating in Medicaid managed care networks, resulting in at least $62.3 billion in capitation payments to plans under contracts that did not include the required provision. OIG recommended that CMS take several actions, including: (1) recover from states the Federal share of inappropriate fee-for-service Medicaid payments associated with terminated providers; (2) implement a method to recover from states the Federal share of inappropriate managed care capitation payments associated with terminated providers; and (3) follow up with states to remove terminated providers that OIG identified as inappropriately enrolled in Medicaid. OIG reports that CMS concurred with all of its recommendations.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-03-19-00070.pdf.

OIG Reports that 23 States Failed to Enroll All Providers Serving Medicaid Beneficiaries

On April 1, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report titled: "Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries." In accordance with a statutory requirement, OIG reviewed survey responses from 49 states and the District of Columbia about the extent to which they had enrolled all Medicaid providers and the amount of federal dollars associated with unenrolled providers. Based on states' responses, OIG found that 23 states had not enrolled all providers serving Medicaid beneficiaries. Of the 27 states that reported enrolling all providers, 16 reported that they were not collecting the required identifying and ownership info or that they lacked enforcement controls to ensure ongoing compliance with federal requirements. OIG recommended that the Centers for Medicare & Medicaid Services ("CMS") take several actions, including taking steps to disallow federal reimbursements for expenditures associated with unenrolled providers and to work with states to ensure that that they are complying with requirements to collect identifying and ownership information. CMS concurred with OIG's recommendations.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-05-19-00060.pdf.

OIG Reports Feedback from Hospitals on Challenges of COVID-19 Pandemic and Government Response; President Trump Publicizes His Disagreement with the Report

On April 6, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report titled: "Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020." Based on hospitals' responses to OIG's survey, OIG reported the following challenges facing hospitals during the COVID-19 public health emergency: severe shortages of testing supplies and extended waits for results; widespread shortages of PPE; difficulty maintaining adequate staffing and support staff; difficulty maintaining and expanding hospital capacity to treat patients; shortages of critical supplies, materials, and logistic support; anticipated shortages of ventilators; increased costs and decreased revenue; and changing and sometimes inconsistent guidance. The report also included some strategies that hospitals had been employing to address these challenges and some recommendations from hospitals of things that the government could do to help. Following its publication, President Trump denounced the report on Twitter as politically motivated, "just wrong," and "Another Fake Dossier!"

The report is available at: https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf.

CMS Issues Proposed Rules Updating Payment Rates for SNFs, IPFs, Hospices, and IRFs

On April 10, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule to update Medicare payment rates and quality programs for Skilled Nursing Facilities ("SNFs"). These updates include routine technical rate-setting updates to the SNF Prospective Payment System ("PPS") payment rates, as well as a proposal to adopt the most recent Office of Management and Budget statistical area delineations and apply a 5% cap on wage index decreases from FY 2020 to FY 2021. The proposed rule includes minor administrative proposals related to the SNF Value-Based Purchasing Program. CMS estimates that the change to the SNF PPS will result in an increase in payments to SNFs of $784 million in FY 2021.

Also, on April 10, CMS issued a proposed rule updating the Inpatient Psychiatric Facility ("IPF") PPS. CMS estimates that the changes to the IPF PPS will result in an increase in payments to IPFs of $75 million in FY 202.

On April 15, CMS published a proposed rule updating the wage index, payment rates, and cap amount for FY 2021. CMS estimates that the changes to the hospice payment rates will result in an increase in payments to hospices of $580 million in FY 2021.

On April 16, CMS issued a proposed rule updating Medicare payments for Inpatient Rehabilitation Facilities ("IRFs"). CMS estimates that the changes to the IRF payments will result in an increase in payments to IRFs of $270 million in FY 2021.

Comments to the SNF, IPF, and hospice proposed rules were due by June 9th. Comments to the IRF proposed rule were due by June 15th.

The SNF proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-04-15/pdf/2020-07875.pdf.

A CMS Fact Sheet on the SNF proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2021-proposed-medicare-payment-and-policy-changes-skilled-nursing-facilities-cms-1737-p.

The IPF proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-04-14/pdf/2020-07870.pdf.

A CMS Fact Sheet on the IPF proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2021-proposed-medicare-payment-and-policy-changes-inpatient-psychiatric-facilities-cms.

The hospice proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-04-15/pdf/2020-07959.pdf.

A CMS Fact Sheet on the hospice proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2021-hospice-payment-rate-update-proposed-rule-cms-1733-p.

The IRF proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-04-21/pdf/2020-08359.pdf.

A CMS Fact Sheet on the IRF proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-inpatient-rehabilitation-facilities-irf-prospective-payment-system-pps-cms-1729.

OIG Review Finds CMS Improperly Paid 87% of IPF Claims With Outlier Payments

On April 13, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report estimating that 87% of Inpatient Psychiatric Facility ("IPF") claims with outlier payments did not meet Medicare's medical necessity of documentation requirements. Under the IPF prospective payment system, in addition to the standard per-diem rate paid for inpatient services, CMS also makes outlier payments in cases with unusually high costs to limit financial losses to IPFs. Due to an increase in outlier payments from FY 2014 to FY 2015, OIG conducted an audit of outlier payments during that period to determine whether IPFs complied with Medicare coverage, payment, and participation requirements for services that resulted in outlier payments. OIG's review of 160 sampled claims revealed that 25 claims did not meet Medicare medical necessity requirements for some or all days of the stay, and 142 claims had missing or inadequate medical record elements. Based on this audit, OIG estimated that 87% of IPF claims paid during

the period did not meet Medicare medical necessity or medical record requirements, resulting in improper payments to IPFs of at least $93 million.

OIG made seven recommendations to CMS, however CMS did not concur with three of the recommendations.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region1/11600508.pdf.

OIG's Review Finds that 96% of South Carolina FFS Medicaid Telemedicine Payments Were Improper

In April, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report of its findings that 96% of Medicaid fee-for-service ("FFS") telemedicine claims in South Carolina during a three-year audit period were improperly paid. Of the 100 sampled claims during the period of July 1, 2014 through June 30, 2017, OIG found that 95 payments were unallowable because the providers documented neither the start and stop times nor the consulting site location of the medical services, and two claims were unallowable because they were actually in-office consultations, not telemedicine services. OIG determined that the noncompliance occurred because South Carolina did not give providers formal training on telemedicine documentation requirements or adequately monitor compliance. Based on the sample results, OIG estimated that 96 percent of South Carolina's Medicaid FFS telemedicine payments were unallowable, resulting in unallowable payments totaling at least $2.1 million ($1.5 million Federal share) during the audit period.

OIG recommended that South Carolina refund $1.5 million to the Federal government, give providers formal training on telemedicine services, and increase its monitoring efforts. South Carolina concurred with OIG's recommendations, except that it believes that refund of a lesser amount is warranted given that the majority of the identified noncompliance was due solely to documentation issues.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region4/41800122.pdf.

CMS and ONC Extend Compliance Deadlines for Interoperability, Information Blocking Rules; OIG Proposed New Authorities to Enforce Information Blocking Rules

On April 21, the U.S. Department of Health and Human Services, Office of the National Coordinator for Health IT ("ONC") and Centers for Medicare & Medicaid Services ("CMS") issued statements that as a result of the COVID-19 pandemic, they are extending the compliance deadlines for the interoperability and information blocking rules that were announced on March 9. CMS is extending the implementation timeline for the admission, discharge, and transfer notification Conditions of Participation by an additional six months, from six months after publication of the final rule to twelve months after publication. In addition, CMS will not enforce the Patient Access API or Provider Directory API for Medicare Advantage, Medicaid, Children's Health Insurance Program, or Qualified Health Plan issuers until July 1, 2021, an increase of six months.

ONC announced that it will exercise enforcement discretion for information blocking rules for an additional three months following initial compliance dates.

In addition to these deadline extensions by CMS and ONC, the Office of Inspector General ("OIG") published a proposed rule including new authorities for enforcing information blocking rules. OIG sought comment from stakeholders on when enforcement should begin. Comments to the proposed rule were due by June 23rd.

CMS' statement is available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.

ONC's statement is available at: https://www.healthit.gov/curesrule/resources/enforcement-discretion.

OIG's proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-04-24/pdf/2020-08451.pdf.

Supreme Court: Federal Government Must Pay ACA Risk Corridor Payments to Insurers

On April 27, the U.S. Supreme Court issued a decision requiring the Federal government to make risk corridor payments to insurers as required under the Affordable Care Act ("ACA"). The risk corridor program was established as part of the ACA to protect against uncertainty in rate setting by qualified health plans sharing risk in losses and gains with the Federal government. It was a temporary program that included payments to health plans. When the Congress failed to fund the program and the Federal government failed to make any payments, several insurers filed suit, with mixed results, including a decision from the Court of Appeals for the Federal Circuit that the payment obligation had been subsequently amended by certain appropriations riders. In its recent decision, the Supreme Court held that neither the failure to fund the program nor the subsequent appropriations riders repealed or discharged the "unique obligation" in the ACA for the Federal government to make the risk corridor payments. The Court held that insurers who are owed payments could seek to collect the payments through civil actions against the government in court.

The Supreme Court's decision in *Maine Community Health Options v United States* is available at: https://www.supremecourt.gov/opinions/19pdf/18-1023_m64o.pdf.

OIG Review Identifies $11.7 Million in Medicare Overpayments to Hospital Outpatient Providers

On May 5, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a report of its findings that Medicare made $11.7 million in overpayments for nonphysician outpatient services provided shortly before or during inpatient stays. OIG conducted an audit of inpatient stays with corresponding nonphysician outpatient services within three days before the date of admission, on the date of admission, or during Inpatient Prospective Payment System ("IPPS") stays for CYs 2016 and 2017. OIG conducted the audit to follow up on previous audits that identified this problem. OIG's latest review found that Medicare made incorrect payments to outpatient providers for 40,984 nonphysician outpatient services provided nation-wide within 3 days before the date of admission, on the date of admission, or during IPPS stays (excluding date of discharge). These incorrect payments occurred because the Common Working File edits were not designed to accurately identify all potentially incorrect claims. As a result, Medicare made $11.7 million in incorrect payments to hospital outpatient providers during CYs 2016 and 2017. This includes claims beyond the 4-year reopening period. In addition, beneficiaries incurred $2.7 million in coinsurance and deductible liabilities related to these incorrect payments.

OIG recommended that the Centers for Medicare & Medicaid Services ("CMS") take action to recoup the $11.7 million in overpayments, direct outpatient providers to refund a portion of the $2.7 million to beneficiaries, and provide education to outpatient providers about appropriately billing for these services. CMS concurred with all recommendations and indicated that it had already begun to address them.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region1/11700508.pdf.

HHS Issues ACA Exchange Final Rule for 2021

On May 7, the U.S. Department of Health and Human Services ("HHS") issued the final Notice of Benefit and Payment Parameters for the 2021 benefit year. According to the Centers for Medicare & Medicaid Services ("CMS"), the final Notice includes several provisions aimed at promoting affordable insurance coverage, "including a blueprint for issuers to design innovative healthcare plans that empower consumers to receive high value services at lower costs." The Notice also includes provisions intended to improve customer access to health coverage and program integrity.

The final Notice is available at: https://www.govinfo.gov/content/pkg/FR-2020-01-23/pdf/2020-01004.pdf.

CMS' Press Release on the Notice is available at: https://www.cms.gov/index.php/newsroom/press-releases/cms-announces-final-payment-notice-2021-coverage-year.

CMS Issues Proposed Rule for Payments to Hospitals, LTCHs

On May 11, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule updating the Hospital Inpatient Prospective Payment System ("IPPS") and Long Term Acute Care Hospital ("LTCH") Prospective Payment System for fiscal year 2021. CMS estimates that the proposed changes to the IPPS will result in a total increase in overall payments of approximately 1.6%, translating to an estimated increase of about $2.07 billion. Additionally proposed changes for hospitals include: a new DRG for chimeric antigen receptor T-cell therapy; a $500 million decrease in uncompensated care payments; changes to the graduate medical education policy related to closing teaching hospitals and residency programs; and changes to the Hospital Readmissions Reduction, Hospital-Acquired Condition, and Hospital Inpatient Quality Reporting programs.

For LTCHs, CMS estimates that overall payments will decrease by0.9%, or $36 million, mainly as a result of continued statutory implementation of the revised LTCH Prospective Payment System.

Comments to the proposed rule were due by July 10.

The proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2020-05-29/pdf/2020-10122.pdf.

CMS' Fact Sheet about the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute.

CMS Restarting Risk Adjustment Transfers Following Federal Court Decision

On May 11, the Centers for Medicare & Medicaid Services ("CMS") announced that beginning in the June 2020 payment cycle, it intends to resume the collection of risk adjustment charges, including overpayments, and distribution of risk adjustment payments for the 2014-2016 benefits years. CMS operates the risk adjustment program pursuant to the ACA for all states that do not operate their own program. In 2018, a federal court in New Mexico issued a decision vacating CMS' use of statewide average premium data in the risk adjustment formula, thereby preventing CMS from further collections. Following this decision, CMS issued final rules ratifying and reissuing the risk adjustment methodology, with an additional explanation of the rationale for the use of statewide average premium data. On December 31, 2019, the Court of Appeals for the

Tenth Circuit reversed the lower court's ruling and held that the use of statewide average premium data was reasonable, and that CMS had adequately explained its rationale for the methodology.

The Court of Appeals' decision is available at: https://cases.justia.com/federal/appellate-courts/ca10/18-2186/18-2186-2019-12-31.pdf?ts=1577811628.

CMS' announcement is available at: https://www.cms.gov/files/document/Update-RA-Transfers-2014-2016.pdf.

GAO Report Highlights Deficiencies in Infection Control at Nursing Homes

On May 20, the Government Accountability Office ("GAO") reported on the prevalence of deficiencies in infection prevention and control at nursing homes, and specifically stating that during the five-year period from 2013 to 2017, 82% of surveyed nursing homes, or 13,299 facilities, violated federal infection prevention and control standards in one or more of those years. Furthermore, half of that number were cited for an infection control deficiency in multiple consecutive years during that period, an indication of "persistent problems," the report noted. In 2018 and 2019, around forty percent (40%) of surveyed nursing homes had deficiencies in infection prevention and control.

The Centers for Medicare & Medicaid Services ("CMS") only implemented enforcement actions in 1% of the instances of violations, as the vast majority (99%) did not show a finding of actual harm to the residents and were therefore not considered "severe." The GAO's report comes in response to inquiries by the U.S. Senate Finance Committee about CMS oversight of infection prevention and control protocols and emergency response standards for emerging infectious diseases at nursing homes in light of the COVID-19 pandemic. The GAO report stated that future reports will address those topics more broadly in nursing homes as well as CMS' response to the COVID-19 pandemic.

The full GAO report can be read here: https://www.gao.gov/assets/710/707069.pdf

CMS Issues Final Rule on MA Plans and Part D Program for Rural Communities

On May 22, the Centers for Medicare & Medicaid Services ("CMS") finalized its proposed rule making changes to the Medicare Advantage ("MA") and Part D programs focusing on increased access to telehealth and increased plan options for beneficiaries in rural communities. The final rule only finalizes certain of the changes proposed in the February proposed rule in order that they would be in place before MA and Part D plan year bids, which were due June 1. Subsequent rulemaking will be issued to finalize the remaining proposals. CMS anticipates the changes from the final rule will reduce Medicare spending over the next ten years by an estimated $3.65 billion.

The final rule as published in the June 2 Federal Register, 85 FR 33796, may be accessed here: https://www.federalregister.gov/documents/2020/06/02/2020-11342/medicare-program-contract-year-2021-policy-and-technical-changes-to-the-medicare-advantage-program

A CMS Fact Sheet on the Final Rule may be accessed here: https://www.cms.gov/newsroom/fact-sheets/contract-year-2021-medicare-advantage-and-part-d-final-rule-cms-4190-f1-fact-sheet

CMS Issues Proposed Rule on Risk Adjustment Data Validation Program

On June 2, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule amending the Department of Health and Human Services' risk adjustment data validation ("HHS-RADV") program. In a CMS fact sheet, the agency explained that the proposed rule takes stakeholder feedback into account and will provide "a more stable and predictable regulatory framework." The HHS-RADV program was created to ensure that issuers are providing accurate and complete data, which is used to calculate the amount of funds transferred among insurers based on the risks of the individuals they enroll. The program is aimed at reducing incentives for insurers to avoid high-cost and high-risk individuals by providing payments to health insurers with higher-than-average risk individuals who often have chronic conditions. The proposed rule would make changes to two technical aspects of the program, the error rate calculation and the application of HHS-RADV results.

The CMS fact sheet on the proposed rule may be found here: https://www.cms.gov/newsroom/fact-sheets/cms-issues-proposed-rule-amend-us-department-health-and-human-services-risk-adjustment-data

The proposed rule as published in the *Federal Register*, 85 Fed. Reg. 33595, may be accessed here: https://www.govinfo.gov/content/pkg/FR-2020-06-02/pdf/2020-11703.pdf

CMS Delays Value-Based Payment Models

On June 3, CMS Administrator Seema Verma announced in a Health Affair's website blog post that because of the COVID-19 pandemic and major disruptions to the health care industry, the Centers for Medicare & Medicaid Services ("CMS") is delaying some new value-based payment models and is offering new flexibilities and adjustments for others. The blog post highlights that the CMS Center for Medicare and Medicaid Innovation ("CMMI") is the "major driver" of value-based models, and that these models can both help providers focus on keeping patients healthy rather than the volume of services provided and also provide stable predictable revenue during the pandemic. Examples of some of the changes include a delay until April 1, 2021 for the first performance period for optional models for patients with late stage chronic kidney disease; a delay until April 1, 2021 for the start of the new direct contracting and primary care first models; and extending performance periods until March 31, 2021 for other established models, including the Comprehensive End-Stage Renal Disease Care and Comprehensive Care for Joint Replacement ("CJR") models.

The June 3 Health Affairs blog post may be read here: https://www.healthaffairs.org/do/10.1377/hblog20200602.80889/full/

CMS created a model flexibilities table describing the changes that may be referenced here: https://www.cms.gov/files/document/covid-innovation-model-flexibilities.pdf

MEDPAC Reports that Medicare Payment Models Need Improvement

In its June 15, 2020 report to Congress, the Medicare Payment Advisory Committee ("MedPAC") stated that Medicare should make serious changes to the way it pays for services and how beneficiary care is organized and delivered so that the cost of the program does not remain on an "unstable trajectory." MedPAC said that Medicare should continue to move to paying for value not volume but that accountable care organizations ("ACOs") and Medicare Advantage ("MA") plans that serve as the foundation for new payment models need improvement to meet that goal. Among other topics, the report addresses challenges in maintaining and increasing savings from ACOs, recommends that the MA quality bonus program ("QBP") be

replaced with the alternative MA value-incentive program ("MA-VIP"), and recommends reforms to Part D to realign plan and manufacturer incentives.

The full MedPAC report may be found here: http://www.medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0

HHS Awards Over $100 Million for Training Workforce in Rural and Underserved Communities

On June 18, the Department of Health and Human Services ("HHS") announced $107.2 million in awards through the Health Resources and Services Administration ("HRSA") for expanding and training the health care workforce in rural and underserved communities. The awards will go to 310 recipients in 45 states and territories. The awards will allow recipients to help develop and retain clinicians in high-need areas, and will support the following programs: the Nurse Faculty Loan Program; Postdoctoral Training in General, Pediatric, and General Health Dentistry; Scholarships for Disadvantaged Students; Nurse Anesthetist Traineeships; Primary Care Training and Enhancement: Residency Training in Primary Care Program; Nurse Education, Practice, Quality, and Retention; Interprofessional Collaborative Practice Program; and Behavioral Health Integration.

A CMS press release on the awards may be read here: https://www.hhs.gov/about/news/2020/06/18/hhs-awards-107.2-million-to-grow-and-train-health-workforce.html

US Court Upholds Price Transparency Rule in Suit by Hospitals

On June 22, the U.S. District Court for the District of Columbia rejected a challenge to a final rule issued by the Centers for Medicare & Medicaid Services ("CMS") in November 2019 related to the requirement that hospitals publicly disclose price information.

The Affordable Care Act ("ACA") requires hospitals to establish and make public "a list of the hospital's standard charges for items and services." 42 U.S.C. § 300gg-18(e) (2018). CMS' final rule defines "standard charges", proscribes publication requirements, and sets forth an enforcement scheme that includes audits, corrective action plans, and civil monetary penalties. The rule requires that by 2021 hospitals post standard charges publicly in a machine-readable file for at least 300 common "shoppable" services in a consumer-friendly and searchable format with annual updates.

The American Hospital Association ("AHA"), the Federation of American Hospitals, the Association of American Medical Colleges, and the National Association of Children's Hospitals, along with several member hospitals, challenged the final rule, arguing it exceeded the agency's statutory authority, violated the First Amendment, and was arbitrary and capricious under the Administrative Procedures Act. Specifically, they argued that "standard charges" unambiguously refer to chargemaster rates ("gross charges"), which are inflated and often "bear little resemblance" to the payments that patients or third-party payors actually pay. In its opinion granting the motion for summary judgement filed by the government, the court found that "standard charges" is not limited to the chargemaster charges and that CMS' decision to define "standard charges" to include gross charges, payer-specific negotiated charges, discounted cash prices, and de-identified minimum and maximum negotiated charges for all items and services was reasonable.

The opinion in *American Hosp. Ass'n v. Azar*, No. 1:19-cv-03619 (CJN) (D.D.C. June 22, 2020) is found here: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2019cv3619-35

CMS Announces New Regulatory Burden Reduction Office

On June 23, 2020, the Centers for Medicare & Medicaid Services (CMS) announced the new Office of Burden Reduction and Health Informatics that will focus on the agency's efforts to reduce regulatory and administrative burdens and putting patients first. The creation of the office comes from CMS' Patients over Paperwork ("PoP") initiative, which resulted from the Trump administration's 2017 executive order directing federal agencies to eliminative duplicative, unnecessary, and costly regulatory requirements. The new office "permanently embeds a culture of burden reduction across all platforms of CMS agency operations," according to a press release. CMS said that estimated cost savings of the PoP so far have saved health care providers $6.6 billion through 2021.

The CMS press release can be read at the following link: https://www.cms.gov/newsroom/press-releases/cms-unveils-major-organizational-change-reduce-provider-and-clinician-burden-and-improve-patient

CMS Proposed Rule on Home Health Increases Rates for CY 2021

On June 25, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule that would increase Medicare rates under the home health prospective payment system by 2.6%, or $540 million, in calendar year 2021. The increase reflects a proposed 2.7% home health payment update less a 0.1% decrease for reductions in the rural add-on percentages mandated by law. Additionally, the proposed rule looks to make regulatory changes outlined in the March 30, 2020 Policy and Regulatory Revisions in Response to the COVID 19 Public Health Emergency Internal Final Rule (85 FR 19230) allowing home health agencies to use telehealth to provide care to beneficiaries permanent beginning January 1, 2021. The benefit would be available for telehealth services so long as it relates to the skilled services being furnished, is outlined on the plan of care, and is tied to a specific patient goal.

Comments on the proposed rule are due August 24, 2020.

A CMS Fact Sheet on the proposed rule is here: https://www.cms.gov/newsroom/fact-sheets/cms-proposes-calendar-year-2021-payment-and-policy-changes-home-health-agencies-and-calendar-year

The proposed rule was published in the *Federal Register* on June 30 and can be read in full here: https://www.federalregister.gov/documents/2020/06/30/2020-13792/medicare-and-medicaid-programs-cy-2021-home-health-prospective-payment-system-rate-update-home

HHS Updated 2020 Regulatory Agenda Includes Changes to HIPAA

On June 30, the Office of Management and Budget ("OMB") Office of Information and Regulatory Affairs posted its spring 2020 Unified Agenda of Regulatory and Deregulatory Actions. Included in the update are plans for a proposed rule from the Office for Civil Rights seeking comments on changes to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules that may impede transforming to a value-based health care system by discouraging coordinated care and case management among hospitals, health care providers, payers, and patients. Proposals would decrease unnecessary compliance burdens while continuing to protect the privacy and security of protected health information ("PHI"). It also would support removing barriers to individuals' ability to engage the healthcare system by strengthening their ability to access their PHI. This proposal comes as part of a four-part framework to coordinated care initiative by HHS, with part one being the changes to 42 C.F.R. Part 2 regulations and parts two and three being changes to the Stark Law and Anti-Kickback Statute proposed rules. The agenda also has a proposed HIPAA enforcement rule, that seeks comments on the distribution of civil money penalty ("CMP") and monetary settlements with individuals

harmed by a HIPAA violation as well as certain annual limits on CMPs under the HITECH Act. The date for the Notice of Proposed Rulemaking for the enforcement changes is April 2021.

The full regulatory and deregulatory action items agenda may be accessed at the following link: https://www.reginfo.gov/public/do/eAgendaMain. Select Department of Health and Human Services from the drop-down menu.

Supreme Court Upholds Exemption for Contraception Coverage

On July 8, the U.S. Supreme Court upheld final rules expanding the exemption from the Affordable Care Act's ("ACA's") contraceptive coverage mandate for employers with religious or moral objections. The Court held that the administration had the authority under the ACA to provide the exemptions to the regulatory contraceptive requirements for employers with religious and conscientious objections and that the rules promulgating the exemptions are free from procedural defects.

The U.S. District Court for the Eastern District of Pennsylvania issued a nationwide injunction blocking the final rules on the same day they were slated to go into effect. (*Pennsylvania v. Trump,* No. 17-450 (E.D. Pa. Jan. 14, 2019)). The Third Circuit affirmed, holding that the plaintiffs (Pennsylvania and New Jersey) were likely to succeed on the merits of their claim that the Departments of Health and Human Services (HHS), Labor, and Treasury exceeded their statutory authority and failed to follow notice-and-comment rulemaking in issuing the exemptions in violation of the Administrative Procedure Act ("APA"). One of the two rules, both issued in 2018, applies to those organizations that object to covering contraceptive items on the basis of sincerely held religious beliefs, while the second applies to organizations that have non-religious moral objections.

The Supreme Court's decision, *Little Sisters of the Poor v. Pennsylvania*, No. 19-431 (U.S. July 8, 2020), may be found here: https://www.supremecourt.gov/opinions/19pdf/19-431_5i36.pdf

The Third Circuit Court's decision, *Pennsylvania v. President United States of Am.,* Nos. 17-3752, 18-253, 19-1129, 19-1189 (3d Cir. June 12, 2019) that was overturned by the Supreme Court case may be found here: https://www2.ca3.uscourts.gov/opinarch/173752p.pdf

The two final rules at issue in the case may be read here: https://www.federalregister.gov/documents/2018/11/15/2018-24512/religious-exemptions-and-accommodations-for-coverage-of-certain-preventive-services-under-the

and here: https://www.federalregister.gov/documents/2018/11/15/2018-24514/moral-exemptions-and-accommodations-for-coverage-of-certain-preventive-services-under-the-affordable

New Updates to Part 2 Regulations; Expect More to Come

On July 13, 2020, the Substance Abuse and Mental Health Services Administration ("SAMHSA") within the U.S. Department of Health and Human Services (HHS) issued a Final Rule that amends 42 CFR Part 2 ("Part 2"). The revisions come as a result of requirements in Section 3221 of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") signed into law on March 27, 2020, with further revisions to the Part 2 regulations required by March 27, 2021.

The final rule is effective August 14, 2020, and it makes a number of significant changes, including (i) treatment records created by a non-Part 2 provider are no covered by Part 2 unless records received from a Part 2 provider are incorporated into the record, while segregating those Part 2 records will ensure that the non-Part 2 provider's records do not become subject to Part 2; (ii) when a SUD patient sends an incidental message to a Part 2 program employee's personal device, the employee can delete the message to fulfill the Part 2 requirement that the device be "sanitized"; (iii) SUD patients can now provide consent to an entity (rather than having to name an individual), allowing disclosure of their Part 2 records; and (iv) disclosures for the purpose of "payment and health care operations" are permitted with written consent, and a list of 18 activities that fall under that category are now provided in the regulation. Additionally, the definition of a "bona fide medical emergency" under Part 2 which allows disclosure of a patient's record without consent, now includes state or federally declared natural disaster emergencies that disrupt treatment facilities and services.

Additional changes required by the CARES Act will come in the first half of 2021 and are primarily intended to better align Part 2 with HIPAA.

A fact sheet from SAMHSA describing the changes in the Final Rule can be found at this link: https://www.samhsa.gov/newsroom/press-announcements/202007131330

The Final Rule as published in the *Federal Register* at 85 FR 42986 can be found here: https://www.federalregister.gov/documents/2020/07/15/2020-14675/confidentiality-of-substance-use-disorder-patient-records

OIG Says that Incorrect Coding Caused Hospitals to Overbill Medicare by More than $1 Billion

On July 15, 2020, the Department of Health and Human Services Office of Inspector General ("OIG") posted a report concluding that hospitals received estimated overpayments of $1 billion for fiscal years (FYs) 2016 and 2017 based on incorrect use of severe malnutrition diagnosis codes. Out of 200 sample Medicare claims the OIG reviewed, it found hospitals correctly billed Medicare for severe malnutrition diagnosis codes for only 27 claims. The remaining claims were incorrectly billed and resulted in net overpayments of $914,128. Extrapolating from that sample review, OIG estimated that hospitals received overpayments of $1 billion for FYs 2016 and 2017. The report explained that the error came when hospitals used severe malnutrition diagnosis codes rather than codes for other forms of malnutrition or no malnutrition diagnosis code at all. The OIG said that the Centers for Medicare & Medicaid Services ("CMS") should collect the portion of the $914,128 for the incorrectly billed hospital claims that are within the reopening period, and notify appropriate providers so that they can exercise reasonable diligence to identify, report, and return any overpayments. OIG also recommend that CMS attempt recovery of the estimated overpayment by reviewing the remaining inpatient claims and that CMS should review how hospitals are using diagnosis code E41 and E43 and work with hospitals to ensure that they correctly bill Medicare when using severe malnutrition diagnosis codes. CMS concurred with the recommendations.

OIG's report, *Hospitals Overbilled Medicare $1 Billion by Incorrectly Assigning Severe Malnutrition Diagnosis Codes to Inpatient Hospital Claims, can be read in full here:* https://oig.hhs.gov/oas/reports/region3/31700010.pdf

COVID-19 RELATED FEDERAL DEVELOPMENTS

CMS Issues Guidance and Waivers to Help Contain the Spread of COVID-19

Since the declaration of the public health emergency ("PHE") by the Federal government, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") has exercised its authority to issue guidance and blanket waivers of various regulatory requirements in order to help providers contain the spread of COVID-19, including the following:

- Blanket Waivers. CMS has issued blanket waivers of various regulatory requirements, including on the following topics: expansion of telehealth; physician supervision; workforce expansion; COVID-19 diagnostic testing and reporting; Stark Law enforcement; signature requirements; changes to the Merit-based Incentive Payment System; and Medicare appeals. Information about the current blanket waivers and flexibilities is available on CMS' website at: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.
- Guidance on Adult Elective Surgery and Procedures Recommendations. Available at: https://www.cms.gov/files/document/31820-cms-adult-elective-surgery-and-procedures-recommendations.pdf
- Guidance on Increased Federal Medical Assistance Percentage (FMAP). Available at: https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-faqs.pdf
- Exceptions and Extensions for Quality Reporting Programs. Available at: https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf
- Guidance for Infection Control and Prevention of COVID-19. Available at: https://www.cms.gov/files/document/qso-20-22-asc-corf-cmhc-opt-rhc-fqhcs.pdf
- Guidance for Processing Attestation Statements from ASCs Temporarily Enrolling as Hospitals during the COVID-19 Public Health Emergency. Available at: https://www.cms.gov/files/document/qso-20-24-asc.pdf
- Toolkit for Expanding Telehealth for Medicaid and Navigating Workforce Issues. Available at: https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf
- Non-Emergent, Elective Medical Services, and Treatment Recommendations. Available at: https://www.cms.gov/files/document/cms-non-emergent-elective-medical-recommendations.pdf.
- Recommendations for Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase I. Available at: https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf
- Recommendations for Re-opening Facilities to Provide Non-emergent Non-COVID-19 Healthcare: Phase II. Available at: https://www.cms.gov/files/document/covid-recommendations-reopening-facilities-provide-non-emergent-care.pdf

- Preliminary Medicare Covid-19 Claims Data Snapshot, as of June 20, 2020. Available at: https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf

All of CMS' COVID-19 related guidance is available on CMS' website at: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page.

CMS Expands Medicare Coverage of Telehealth Services

On March 17, 2020, the U.S. Department of Health and Human Services ("HHS"), Centers for Medicare & Medicaid Services ("CMS") expanded telehealth coverage under Medicare in accordance with its Section 1135 waiver authority and the Coronavirus Preparedness and Response Supplemental Appropriations Act. As of March 6, 2020, Medicare beneficiaries can receive a wider range of telehealth services, including evaluation and management visits, mental health counseling, and preventive health screenings. CMS has also removed the requirements that the patient live in a rural area and travel to a local medical facility to receive the telehealth services. Under this new policy, beneficiaries can receive telehealth services from any "originating site," including their own homes. A range of providers, such as doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers, will be able to offer telehealth to their patients. CMS is also not enforcing any requirement that a beneficiary have an established relationship with the provider providing the telehealth services.

On March 30, CMS released an Interim Final Rule with Comment Period (effective March 1) which implements several changes to the payment rules for services provided via telehealth and clarifies the coding and billing requirements for the new expanded telehealth coverage.

Helpful Resources:

- CMS Fact Sheet: https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
- CMS FAQs: https://www.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf
- CMS List of Telehealth Services: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes
- CMS General Provider Telehealth and Telemedicine Took Kit: https://www.cms.gov/files/document/general-telemedicine-toolkit.pdf
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf

HHS and OCR Issue Guidance and Enforcement Discretion for HIPAA Privacy Rule Application During COVID-19 Public Health Emergency

Since the declaration of the public health emergency ("PHE") by the Federal government, the U.S. Department of Health and Human Services ("HHS"), including its Office for Civil Rights ("OCR"), have issued numerous guidance documents, bulletins, and notices of enforcement discretion regarding the applicability of the HIPAA Privacy Rule during the PHE, including the following:

- Limited Waiver of HIPAA Sanctions and Penalties During a Nationwide Public Health Emergency. Communicates Secretary of Health and Human Services Alex Azar's exercise his authority under the

current public health emergency to waive certain requirements of the HIPAA Privacy Rule for hospitals in an emergency area that have instituted their disaster protocol. Available at: https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf.

- Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency. This Notice announced that OCR will exercise its enforcement discretion to not impose penalties for noncompliance with the HIPAA Rules in connection with covered entities' good faith provision of telehealth using non-public facing audio or video communication products during the COVID-19 nationwide public health emergency. Available at: https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.

- Guidance on Telehealth Remote Communications Following its Notification of Enforcement Discretion. This Guidance includes FAQs on HIPAA and the use of telehealth during the PHE. Available at: https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf.

- Guidance on Disclosures to Law Enforcement, Paramedics, Other First Responders and Public Health Authorities. This Guidance highlights the current flexibilities in the HIPAA Privacy Rule for covered entities to disclose patient information to law enforcement, paramedics, other first responders, and public health authorities as they work to respond to the COVID019 pandemic. Available at: https://www.hhs.gov/sites/default/files/covid-19-hipaa-and-first-responders-508.pdf.

- Notification of Enforcement Discretion to Allow Uses and Disclosures of PHI by Business Associates for Public Health and Health Oversight Activities During the PHE. OCR will exercise its enforcement discretion and will not impose potential penalties for violations of certain provisions of the HIPAA Privacy Rule against covered health care providers or their business associates for uses and disclosures of protected health information by business associates for public health and health oversight activities during the COVID-19 PHE. Available at: https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-hipaa.pdf.

- Notification of Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites. OCR will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers or their business associates in connection with the good faith participation in the operation of a COVID-19 Community-Based Testing Site during the PHE. Available at: https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-community-based-testing-sites.pdf.

- Guidance on Covered Health Care Providers and Restrictions on Media Access to PHI. Provides FAQs about the impact of the PHE on the HIPAA Privacy Rule's restrictions on disclosures of patient PHI to the media. Available at: https://www.hhs.gov/sites/default/files/guidance-on-media-and-film-crews-access-to-phi.pdf.

- Guidance on HIPAA and Contacting Former COVID-19 Patients about Blood and Plasma Donation. Provides information on how the Privacy Rule permits covered entities to use patient PHI to contact former patients to inquire about donating blood and plasma to assist in treatment of COVID-19. Available at: https://www.hhs.gov/sites/default/files/guidance-on-hipaa-and-contacting-former-covid-19-patients-about-blood-and-plasma-donation.pdf.

All guidance and notifications of enforcement discretion are available on OCR's website at: https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html.

OIG Announces Non-Enforcement of Prohibitions Against Waiving Cost-Sharing for Telehealth Services

On March 17, the HHS Office of Inspector General ("OIG") issued a policy statement confirming that it will not subject physicians and other practitioners to administrative sanctions related to the waiver of cost-sharing for telehealth arrangements that satisfy both of the following conditions:

1. A physician or other practitioner reduces or waives cost-sharing obligations (i.e., coinsurance and deductibles) that a beneficiary may owe for telehealth services furnished consistent with the then-applicable coverage and payment rules; and
2. The telehealth services are furnished during the time period subject to the COVID-19 Public Health Emergency Declaration.

Helpful Resources:

- OIG Policy Statement: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf
- OIG Fact Sheet: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/factsheet-telehealth-2020.pdf

President Trump Signs CARES Act

On March 30, President Trump the Coronavirus Aid, Relief, and Economic Security ("CARES") Act into law following the unprecedented $2 trillion stimulus package unanimously clearing both the House and Senate. In a March 31 letter to Department of Health and Human Services ("HHS") Secretary Alex Azar and Centers for Medicare & Medicaid Services ("CMS") Administrator Seema Verma, the American Hospital Association ("AHA") asked the agencies to direct Medicare Administrative Contractors to immediately distribute funds under the CARES Act marked for providers to every type of hospital, including rural and urban short-term acute-care, long-term care, and critical access hospitals, as well as inpatient rehabilitation and inpatient psychiatric facilities, at "the rate of $25,000 per bed, and $30,000 per bed for 'hot spots.'"

The Department of Health and Human Services (HHS) began distributing an initial $30 billion in relief funding of the $100 billion set aside in the CARES Act for health care providers based proportionate to providers' share of Medicare fee-for service reimbursements in 2019. On April 10, $26 billion was delivered to providers' bank accounts and the remaining $4 billion was delivered April 17. The remaining funds went out on a weekly rolling basis beginning April 24. The aid will be used to support health care expenses or lost revenue resulting from the coronavirus and to pay for testing and treatment provided to uninsured Americans.

On July 22, HHS announced it will devote $5 billion of the Provider Relief Fund authorized by the CARES Act to Medicare-certified long term care facilities and state nursing homes to build nursing home skills and enhance nursing homes' response to COVID-19, including enhanced infection control. Nursing homes must participate in the Nursing Home COVID-19 Training in order to be qualified to receive the funding.

The March 31 letter from the AHA can be read here: https://www.aha.org/lettercomment/2020-03-31-aha-urges-hhs-and-cms-distribute-funds-hospitals-and-health-systems

HHS' press release about additional allocations of health care provider funds available under the CARES Act may be read here: https://www.hhs.gov/about/news/2020/04/22/hhs-announces-additional-allocations-of-cares-act-provider-relief-fund.html

The CMS announcement of additional provider relief funds under the CARES Act is found here: https://www.cms.gov/newsroom/press-releases/trump-administration-announces-new-resources-protect-nursing-home-residents-against-covid-19

OIG Institutes Enforcement Discretion for Remuneration Related to COVID-19

On April, 2020, the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") issued a policy statement announcing that it will exercise its enforcement discretion not to impose administrative sanctions under the Federal anti-kickback statute with respect to remuneration that is covered by 11 of the 18 the Blanket Waivers of Section 1877(g) of the Social Security Act issued by the Secretary on March 30, 2020 (the "Blanket Waivers"). The OIG stated that all of the conditions and definitions that apply to the Blanket Waivers apply to the Policy Statement, and that the Policy Statement applies to conduct on or after April 3, 2020, and will terminate the same day as the Blanket Waivers terminate.

Helpful Resources:

- https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf
- https://oig.hhs.gov/coronavirus/authorities-faq.asp
- https://oig.hhs.gov/coronavirus/index.asp?utm_source=web&utm_medium=web&utm_campaign=covid19-landing-page

SAMHSA Issues Guidance on Disclosure of Substance Use Disorder Records Without Written Consent of the Patient

On March 19, HHS' Substance Abuse and Mental Health Services Administration ("SAMHSA") issued guidance on the applicability of the substance use disorder confidentiality provisions at 42 C.F.R. Part 2 to the provision of telehealth services. SAMHSA noted that provider office closures and compliance with social distancing recommendations is likely to result in the interruption of in-person substance use disorder treatment. SAMHSA acknowledged that if providers are turning to telehealth options to provide treatment, they may face difficulty obtaining prior written patient consent for disclosure of substance use disorder records. SAMHSA confirmed that obtaining the patient's written consent is not required to the extent that providers determine that the disclosure of information without written consent is necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained, pursuant to 42 C.F.R. § 2.51.

Helpful Resources:

- SAMHSA Guidance: https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf

DEA Confirms Providers Can Prescribe Controlled Substances via Telehealth

The U.S. Drug Enforcement Administration ("DEA") has confirmed that, pursuant to HHS Secretary Azar's declaration of a Public Health Emergency, prescribers may prescribe schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

1. The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
2. The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
3. The practitioner is acting in accordance with applicable Federal and State laws.

DEA has also exercised its authority to provide flexibility to ensure authorized practitioners may admit and treat new patients with opioid use disorder ("OUD") during the public health emergency. DEA, along with SAMHSA, announced that practitioners may prescribe buprenorphine to new and existing patients with OUD via telephone without requiring such practitioners to first conduct an examination of the patient in person or via telemedicine.

Helpful Resources:

- DEA's COVID-19 Information Page: https://www.deadiversion.usdoj.gov/coronavirus.html
- DEA's Guidance on Prescribing Buprenorphine: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf

FCC Adopts Programs to Support Providers' Use of Telehealth in Responding to COVID-19 Pandemic

On April 2, the Federal Communications Commission ("FCC") adopted a $200 million telehealth program to support healthcare providers responding to the COVID-19 pandemic. Through the COVID-19 Telehealth Program, the FCC will help healthcare providers purchase telecommunications, broadband connectivity, and devices necessary for providing telehealth services. Funding applications from healthcare providers will be processed on a rolling basis. The FCC also adopted final rules to stand up a Connected Care Pilot Program. This separate three-year Pilot Program will provide up to $100 million of support from the Universal Service Fund ("USF") to help defray health care providers' costs of providing connected care services and to help assess how the USF can be used in the long-term to support telehealth. The FCC started accepting applications for the COVID019 Telehealth Program. No deadline has been set for filing applications, but the program is first come, first served.

The FCC's announcement of the new programs is available at: https://docs.fcc.gov/public/attachments/DOC-363498A1.pdf.

CDC Issues Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic

The Centers for Disease Control and Prevention ("CDC") recently released its "Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic." The Framework is intended to guide healthcare systems in the delivery of non-COVID-19 care during the pandemic, and is based on a few important considerations for providers to keep in mind: 1) be prepared to rapidly detect and respond to an increase of COVID-19 cases in the community; 2) provide care in the safest way possible; and 3) consider that services may need to expand gradually.

The CDC's Framework is available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html.

Senators Urge Leadership to Make Telehealth Expansion Permanent

On June 15, several United States Senators sent a joint letter to Senators McConnell and Schumer urging them to make permanent the temporary expansions to telehealth that are in place during the COVID-19 pandemic. They also recommended taking advantage of the current expansion of telehealth to collect and analyze data to inform future decision about the provision of care via telehealth.

On June 17, the Senate Committee on Health, Education, Labor & Pensions ("HELP") held a hearing to discuss the telehealth lessons that are being learned during the pandemic.

The letter to Senate leadership is available at: https://www.schatz.senate.gov/imo/media/doc/Letter%20to%20leadership_CONNECT%20for%20Health%20Act_06.12.20.pdf

The HELP Committee hearing can be viewed at: https://www.help.senate.gov/hearings/telehealth-lessons-from-the-covid-19-pandemic

HHS's "Operation Warp Speed" Aims to Have 300 Million Doses of COVID-19 Vaccine Available by January 2021

On June 16, the U.S. Department of Health and Human Services ("HHS") announced "Operation Warp Speed" ("OWS"), with a goal of delivering 300 million doses of a safe, effective vaccine for COVID-19 by January 2021. According to HHS, this goal will be accomplished by "investing in and coordinating countermeasure development."

In keeping with the OWS' goal, on July 22 HHS announced that it has engaged Pfizer to produce at least 100 million and up to 600 million doses of a COVID-19 vaccine.

HHS' initial OWS announcement is available at: https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html

HHS' announcement about the deal with Pizer is available at: https://www.hhs.gov/about/news/2020/07/22/us-government-engages-pfizer-produce-millions-doses-covid-19-vaccine.html

STATE DEVELOPMENTS

U.S. District Court in NH Declines to Issues Temporary Order to Allow Hospitals to Immediately Transfer Involuntarily Admitted Patients out of Emergency Rooms

On June 16, 2020, the U.S. District Court for the District of New Hampshire declined to issue a temporary restraining order to hospitals that had asked for the order so they could immediately transport involuntarily admitted patients experiencing mental health crises out of their emergency rooms. As a result of numerous lawsuits against hospitals by involuntarily admitted patients for false imprisonment and other related charges, the New Hampshire Hospital Association and twenty New Hampshire hospitals have intervened in a class action lawsuit filed against the Commissioner of the New Hampshire Department of Health and Human Services. According to the plaintiffs, involuntary emergency admission ("IEA") patients are not being transported to designated receiving facilities as required by statute, which results in IEA patients being boarded at the hospitals. The hospitals sought a temporary restraining order and preliminary injunction to transport IEA patients out of the hospitals' emergency departments "upon the signing of an IEA certificate immediately (but in no event more than three days after the signing of the IEA certificate)." However, the court said the harm faced by the hospitals did not rise to the standard required for a temporary restraining order. "To the extent the hospitals are seeking a temporary restraining order to prevent circumstances that would lead to IEA patients filing new suits for false imprisonment against the hospitals, that possibility does not clearly present an immediate and irreparable harm justifying a temporary restraining order," the court said.

Doe v. Commissioner, New Hampshire Dep't of Health and Human Servs., No. 18-cv-1039-JD (D.N.H. June 16, 2020).

LEGISLATIVE UPDATE

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. Awaiting action 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=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.

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.

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.

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

COVID-19 RELATED STATE DEVELOPMENTS

Fueled by Governor Sununu's Emergency Orders, New Hampshire Launches Robust Response to COVID-19 Epidemic

On March 13, 2020, Governor Sununu issued Executive Order 2020-04, declaring a state of emergency for New Hampshire. The Order contained several measures that the state will implement to address the growing COVID-19 epidemic, including the ability of hospitals and health care facilities to obtain emergency waivers for certain facility licensing or credentialing requirements.

Under the authority of the state of emergency, Governor Sununu has since issued over fifty Emergency Orders, including the following Emergency Orders impacting health care providers:

Emergency Order #8	Requiring private insurers and Medicaid to cover services provided via all modes of telehealth.
Emergency Order #9	Establishing the Emergency healthcare System Relief Fund of up to $50 Million to provide grants or loans to hospitals and other healthcare providers. Modified by Emergency Order #44.
Emergency Order #14	Authorizing out-of-state pharmacies to act as mail-order facilities.
Emergency Order #15	Allowing out-of-state providers to perform medically necessary services in New Hampshire under certain conditions, including that they obtain an emergency license.
Emergency Order #30	Requiring insurers and Medicaid to cover services provided at alternative settings as a result of patients being diverted away from acute care hospitals.
Emergency Order #31	Establishing the COVID-19 Long Term Care Stabilization Program to provide monetary stipends to qualifying front line workers. Modified by Emergency Order #45 and extended by Emergency Order #55.
Emergency Order #33	Activating the Crisis Standards of Care Plan.
Emergency Order #34	Establishing additional temporary requirements for insurers to facilitate the provision of COVID-19 related health care services.
Emergency Order #36	Establishing eligibility of First Responders to worker's compensation coverage in the event they contract COVID-19.
Emergency Order #41	Establishing Medicaid coverage for COVID-19 testing for uninsured individuals.
Emergency Order #42	Establishing the position of "temporary health partner" to work in skilled nursing facilities under the supervision of an RN, APRN, or LPN.
Emergency Order #46	Authorizing the Office of Professional Licensure and Certification to issue emergency licenses to providers whose NH or out-of-state licenses changed to inactive status in the last three years and fellows enrolled in a GME program.
Emergency Order #47	Authorizing pharmacists to administer COVID-19 tests.

The Emergency Orders are maintained on the Governor's website at: https://www.governor.nh.gov/news-and-media/covid-19-emergency-orders-2020.

In addition to the above Emergency Orders, the N.H. Department of Health and Human Services maintains a website containing COVID-19 resources and guidance for healthcare providers at: https://www.nh.gov/covid19/resources-guidance/healthcare-providers.htm.

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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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