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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.

FEDERAL DEVLEOPMENTS

CMS Issues Final Rule for Medicare Parts C & D That Expands Medicare Advantage Telehealth Benefits

On April 5, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule updating the Medicare Advantage ("MA") and Medicare Prescription Drug Benefit ("Part D") programs. The final rule makes several changes, including integrating requirements and unifying grievance and appeals procedures for MA Dual Eligible Special Needs Plans and updating the measures and methodology for Star Ratings for MA and Part D plans.

One of the most significant changes in the final rule is the implementation of a provision of the Bipartisan Budget Act of 2018 that will allow MA plans to cover certain telehealth benefits beyond what are covered under Medicare Plan B. CMS believes that the additional telehealth benefits will increase access to patient-centered care by giving beneficiaries more control to determine when, where, and how they access benefits.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf.

A CMS Fact Sheet about the final rule is available at: https://www.cms.gov/newsroom/fact-sheets/contract-year-2020-medicare-advantage-and-part-d-flexibility-final-rule-cms-4185-f.

CMS Communicates Transition Plan and Guidance to Part D Sponsors Regarding Proposed Change to Drug Rebate Safe Harbor; CBO Says Change Will Increase Federal Spending

On April 5, Seema Verma, Administrator of the Centers for Medicare & Medicaid Services ("CMS"), issued a memorandum to sponsors of Medicare Part D plans offering guidance about how plan sponsors should address potential changes to the prescription drug rebate safe harbor to the Anti-Kickback Statute ("AKS"). Earlier this year, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published a proposed rule that would remove the safe harbor that protects the payment of rebates from drug manufacturers to pharmacy benefit managers, Medicare Part D plans, and Medicaid managed care organizations.

CMS received questions from plan sponsors about how plans should account for the possibility of a change in the safe harbor when submitting bids for calendar year 2020 ("CY2020"). The memo confirms that plan sponsors should submit bids for CY2020 in a form and manner that is consistent with the AKS and regulations in effect as of the bid submission deadline, including, for the purposes of bid development, the treatment of manufacturer rebates per existing rules and guidance related to what constitutes remuneration under the AKS. The memo also states that CMS

will "conduct a demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program."

OIG's proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf.

Administrator Verma's memo is available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2019-Apr-5th.pdf.

On May 2, the Congressional Budget Office ("CBO") released a report analyzing the effect of the proposed safe harbor removal on the federal budget. The CBO estimates that implementing the proposed change will result in a $177 billion increase in Medicare and Medicaid spending over the next ten years, owing largely to an increase in Part D premiums, and, consequently, an increase in federal premium subsidies.

The CBO's report is available at: https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf.

Fifth Circuit Affirms CMS' Revocation of Physicians' Medicare Privileges for Improper Billing of "Incident to" Services

On April 12, the Court of Appeals for the Fifth Circuit upheld a decision by the Centers for Medicare & Medicaid Services ("CMS") to revoke the Medicare privileges of two physicians who improperly billed 190 "incident to" services performed during periods when the physicians were traveling outside of the country and unable to provide the required direct supervision. The physicians appealed CMS' decision to the courts and argued that the "incident to" services were not billed improperly because they were performed by nurse practitioners acting on the physicians' orders, and the services were performed with other "covering" physicians available. Both the Fifth Circuit, and the District Court below, held that the services were improperly billed because they failed to meet the requirements for billing services "incident to" the physicians' services; namely, that they were not performed "under the direct supervision of the physician[s]." Accordingly, the Fifth Circuit affirmed CMS' three-year revocation of the physicians' billing privileges.

The Fifth Circuit's decision is available at http://www.ca5.uscourts.gov/opinions/pub/17/17-40897-CV0.pdf

CMS Issues IRF Proposed Rule, Increasing Payments by $195 Million and Implementing Other Changes

On April 17, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule updating Medicare reimbursement under the Inpatient Rehabilitation Prospective Payment System ("IRF PPS") and the Inpatient Rehabilitation Facility Quality Reporting Program ("IRF QRP") for fiscal year ("FY") 2020. CMS estimates that changes to the payment methodology for the IRF PPS will result in a 2.3% increase in payments to IRFs, or approximately $195 million. Other changes in the proposed rule include amending IRF regulations to clarify that the determination as to whether a physician qualifies as a rehabilitation physician is made by the IRF, removing the Functional Independence Measure items from the patient assessment instrument beginning October 1, 2019, and adopting two new quality measures for the IRF QRP that address the transfer of health information.

Comments on the proposed rule must be received by June 17, 2019.

The proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-04-24/pdf/2019-07885.pdf.

A CMS Fact Sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/proposed-fiscal-year-2020-payment-and-policy-changes-medicare-inpatient-rehabilitation-facilities.

CMS Issues Final Rule Regarding Health Plans Sold on the ACA Exchanges

On April 18, the Centers for Medicare & Medicaid Services issued a final rule setting forth payment parameters and other provisions for health insurance marketplaces under the Affordable Care Act ("ACA"). Changes include: reducing the user fee rate for plans sold on the federal and state exchanges by 0.5 percentage points; changing the prescription drug benefit to encourage enrollees' use of lower-cost generic drugs; recalibrating the risk adjustment for the 2020 benefit year based on data from 2015-2017; changing the risk adjustment validation process; increasing the annual limits on cost-sharing; and making changes to the enrollment process. The changes in the final rule are effective June 24.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf.

A CMS Fact Sheet on the final rule is available at: https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/CMS-9926-F-Fact-Sheet.pdf.

Medicare Inpatient Psychiatric Facilities Proposed Rule Increases Payments by 1.7%

On April 18, the Centers for Medicare & Medicaid Services issued a proposed rule updating Medicare payment policies and rates for the Inpatient Psychiatric Prospective Payment System ("IPF PPS") and the IPF Quality Reporting ("IPFQR") program for fiscal year 2020. CMS estimates that the updates to the IPF PPS payment methodologies will result in a 1.7% increase in payments in FY 2020, or $75 million. Additionally, CMS proposed to adopt a new claims-based measure for the IPFQR—"Medication Continuation Following Inpatient Psychiatric Discharge"—which will assess whether patients admitted to IPFs with certain diagnoses fill at least one evidence-based medication within two days prior to discharge or 30 days post-discharge.

Comments to the proposed rule must be received by CMS by June 17.

The proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-04-23/pdf/2019-07884.pdf.

A CMS Fact Sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fy-2020-proposed-medicare-payment-and-quality-reporting-updates-inpatient-psychiatric-facilities-cms.

ONC Issues Second Draft of the Trusted Exchange Framework and Common Agreement

On April 19, the Office of the National Coordinator for Health Information Technology ("ONC") issued a second draft of the Trusted Exchange Framework and Common Agreement ("TEFCA"). This draft follows a first draft that was issued in January of 2018. According to ONC, the second draft of the TEFCA "outlines a common set of principles, terms, and conditions to support the development of a Common Agreement that

would help enable nationwide exchange of electronic health information (EHI) across disparate health information networks (HINs)" and "is designed to scale EHI exchange nationwide and help ensure that HINs, health care providers, health plans, individuals, and many more stakeholders have secure access to their electronic health information when and where it is needed." ONC is soliciting comments to this draft of the TEFCA by June 17.

ONC is also soliciting applications for a Recognized Coordinating Entity to "develop, implement, and maintain the Common Agreement." Interested entities must submit applications by June 17.

The text of the second draft of the TEFCA is available at ONC's website: https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.

HHS Announces Five New Primary Care Payment Models

On April 22, the Centers for Medicare & Medicaid Services ("CMS") announced the "CMS Primary Cares Initiative," which it describes as "a new set of payment models that will transform primary care to deliver better value for patients throughout the healthcare system." The Primary Cares Initiative includes five new payment models: Primary Care First; Primary Care First – High Need Populations; Direct Contracting – Global; Direct Contracting – Professional; and Direct Contracting – Geographic.

The two Primary Care First ("PFC") models are voluntary five-year options for smaller practices that will pay them a per-patient revenue stream and, beginning in 2020, reward practices based on their performance. PFC practices will also bear downside risk up to 10% of revenue. CMS anticipates releasing a Request for Applications sometime this spring; selected practices will begin participating in January 2020.

The three Direct Contracting ("DC") models are voluntary payment model options for larger practices and other entities like accountable care organizations and Medicare Advantage plans. The three DC models allow participating practices to take on risk and earn rewards, and provide them with choices related to cash flow, beneficiary alignment, and benefit enhancements. The professional model offers a 50% risk-sharing arrangement, while the global model offers a 100% risk-sharing arrangement. CMS sought comments on the third model – geographic – which offers entities an opportunity to assume risk for beneficiaries in a defined target region. Comments were due by May 30. Prior to releasing a Request for Application for the DC models, CMS is currently accepting Letters of Intent from interested organizations through August 2.

Information about the PCF models is available at: https://innovation.cms.gov/initiatives/primary-care-first-model-options/.

Information about the DC models, including the Letter of Intent submission information, is available at: https://innovation.cms.gov/initiatives/direct-contracting-model-options/.

CMS Issues Proposed Payment Rule for Acute and Long-Term Care Hospitals

On April 23, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule that would revise the Medicare hospital inpatient prospective payments system ("IPPS") and long-term care hospital prospective payment system ("LCTH PPS") and implement other substantive changes, including: changes relating to Medicare graduate medical education (GME) for teaching hospitals and payments to critical access hospital (CAHs); addressing wage index disparities between high and low wage index hospitals; providing an alternative IPPS new technology add-on payment pathway for certain transformative

new devices; revising the calculation of the IPPS new technology add-on payment; and establishing new requirements or revise existing requirements for quality reporting by specific Medicare providers.

CMS estimates that the payment methodology changes will result in a 3.7%, or $4.7 billion, increase in payments to hospitals under the IPPS, and a 0.9% increase to payments under the LCTH PPS.

Comments on the proposed rule must be received by CMS by June 24.

The proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-05-03/pdf/2019-08330.pdf.

A CMS Fact Sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2020-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute.

CMS' Proposed Rule for SNF PPS Set to Increase Payments by $887 for FY 2020

On April 25, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule updating the skilled nursing facility prospective payment system ("SNF PPS") and implementing other changes, including: revising the definition of group therapy under the SNF PPS; implementing a subregulatory process for updating ICD-10 code lists used under the Patient Driven Payment Model ("PDPM"); updating requirements for the SNF quality reporting program, including the proposal of two Transfer of Health Information quality measures as well as standardized patient assessment data elements; and expanding data collection for SNF QRP quality measures to all SNF residents.

CMS estimates that the proposed changes to the SNF PPS will result in a 2.5%, or $887 million, increase in payments to SNFs.

Comments on the proposed rule must be received by June 18.

The proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08108.pdf.

A CMS Fact Sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/proposed-fiscal-year-2020-payment-and-policy-changes-medicare-skilled-nursing-facilities-cms-1718-p.

CMS Proposes 2.7% Increase in Hospice Payments and Increased Transparency to Beneficiaries About Hospice Election

On April 25, the Centers for Medicare & Medicaid Services issued a proposed rule updating the hospice wage index, payment rates, and cap amount for fiscal year 2020. Additionally, the proposed rule would modify the hospice election statement by requiring an addendum with information coverage under the hospice election, and would make changes to the Hospice Quality Reporting Program. CMS estimates that the 2.7% hospice payment rate increase will result in a payment increase of $540 million in fiscal year 2020. Application of the same 2.7% increase to the statutory cap on annual per-patient hospice payments results in a FY 2020 cap of $29,993.99.

Comments on the proposed rule must be received by June 18.

The proposed rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08143.pdf.

A CMS Fact Sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2020-hospice-payment-rate-update-proposed-rule-cms-1714-p.

HHS Exercises Enforcement Discretion to Lower CMP Cap Amounts for HIPAA Violations

On April 30, the U.S. Department of Health and Human Services published notice of enforcement discretion announcing that it would be exercising its discretion to apply different cumulative annual limits on civil monetary penalties applied to four different penalty ("CMP") tiers under the Health Insurance Portability and Accountability Act ("HIPAA"), as such provision was amended by the Health Information Technology for Economic and Clinical Health ("HITECH") Act. Previously, a cumulative annual limit of $1.5 million was applied to all violation types. Effective as of April 30, the limits will be as follows: $25,000 for a no knowledge violation; $100,000 for reasonable cause; $250,000 for corrected willful neglect; and $1.5 million for uncorrected willful neglect.

The notice of enforcement discretion is available at: https://www.govinfo.gov/content/pkg/FR-2019-04-30/pdf/2019-08530.pdf.

DOJ Issues Revised Corporate Compliance Program Guidance

On April 30, the U.S. Department of Justice ("DOJ") issued an updated version of its guidance document entitled "Evaluation of Corporate Compliance Programs," which was last updated in February 2017. This updated version emphasizes the three "fundamental questions" that a prosecutor should ask when analyzing a corporation's compliance program in the context of investigating and negotiating resolutions of criminal charges: 1) "Is the corporation's compliance program well designed?"; 2) "Is the program being applied earnestly and in good faith?"; and 3) "Does the corporation's compliance program work" in practice? In looking at program design, prosecutors should analyze the risk-management process, policies and procedures, training and communications, and the confidential reporting structure and investigation process. For effective implementation of the program, prosecutors are advised to look for commitment to the program by senior and middle management, autonomy and resources of internal compliance personnel, and incentives for compliance and disincentives for non-compliance. Finally, in analyzing how the program works in practice, prosecutors should look for continuous improvement and testing of the program and the historical results of the program in identifying and managing misconduct. In all things, the guidance emphasizes that the adequacy of the program is what matters, not just that a program is in place.

The revised guidance is available at: https://www.justice.gov/criminal-fraud/page/file/937501/download.

OCR Issues Final Rule on Conscience-Based Objections to Health Care Services

On May 2, the U.S. Department of Health and Human Services ("HHS"), Office for Civil Rights ("OCR") issued a final rule revising existing regulations "to ensure vigorous enforcement of Federal conscience and anti-discrimination laws applicable to the Department, its programs, and recipients of HHS funds, and to delegate overall enforcement and compliance responsibility to [OCR]." The final rule clarifies the scope of the protection of individuals with conscience and religious-based objections to health care

services, such as abortion, sterilization, and assisted suicide, and sets forth various procedures for OCR's enforcement of the protections and ongoing obligations of recipients of federal funds.

On the same day, the San Francisco City Attorney filed a lawsuit in federal court challenging the final rule on the basis that it exceeds the HHS Secretary's authority and violates the Administrative Procedure Act and numerous provisions of the U.S. Constitution. The complaint is available at: https://www.sfcityattorney.org/wp-content/uploads/2019/05/1_Complaint.pdf.

The final rule is available at: https://www.hhs.gov/sites/default/files/final-conscience-rule.pdf.

An HHS Factsheet on the final rule is available at: https://www.hhs.gov/sites/default/files/final-conscience-rule-factsheet.pdf.

CMS Issues Draft Guidance Clarifying Hospital Co-Location Compliance Expectations

On May 3, the Centers for Medicare & Medicaid Services issued a draft of a guidance document entitled "Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities." The draft guidance is intended to communicate to state surveyors how they should evaluate a hospital that shares space with another health care entity in determining compliance with Medicare Conditions of Participation ("CoPs"). Previously, CMS had made it clear that hospitals and entities that co-locate and share space are separately responsible for demonstrating compliance, however CMS did not provide additional information about how they should demonstrate separate compliance. The draft guidance provides clarity around how entities may and may not share certain spaces—such as public paths of travel—and how the entities may share services and staff through written agreements.

Comments on the draft guidance must be received by July 2.

The draft guidance is available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-13-Hospital.pdf.

CMS Seeks Public Comment on Ideas for Potential ACA Waivers

On May 3, the Centers for Medicare & Medicaid Services ("CMS") issued a request for information ("RFI"), seeking ideas from states on potential "waiver concepts" under the Affordable Care Act's "innovation waivers." According to CMS, the RFI is intended to address the Trump Administration's priority of "empower[ing] states by providing tools to address the serious problems that have surfaced in state individual health insurance markets with the implementation of the Patient Protection and Affordable Care Act." CMS previously communicated four waiver ideas in November of 2018: account-based subsidies; state-specific premium assistance; adjusted plan options; and risk stabilization strategies. This new RFI seeks public comments on "ideas for other innovative waiver concepts," including "ideas that states may be able to use to develop innovative waiver programs that meet the section 1332 guardrails," "waiver concepts that states could potentially use alone or in combination with other waiver concepts, state proposals, or policy changes," and "ideas for waiver concepts that could advance some or all of the principles outlined [in previous CMS guidance]."

Comments in response to the RFI must be received by July 2.

The RFI is available at: https://www.govinfo.gov/content/pkg/FR-2019-05-03/pdf/2019-09121.pdf.

CMS Removes Medicaid Direct Payment Exception for Certain Third-Party Provider Payments, Prompting Lawsuit

On May 6, the Centers for Medicare & Medicaid Services ("CMS") published a final rule removing the regulatory provision that allows states to make Medicaid payments to third parties on behalf of an individual provider for benefits like health insurance, skills training, and other benefits customary for employees. The final rule explains CMS' position that the statutory provision that establishes exceptions to the general requirement that payments be made directly to providers does not explicitly or implicitly authorize these third-party payments, nor does it authorize CMS to create new exceptions. The final rule is scheduled to go into effect on July 5.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-05-06/pdf/2019-09118.pdf.

On May 13, five states filed a lawsuit seeking to enjoin CMS' removal of the third-party payment rule "on the grounds that the manner and substance of [CMS'] new policy guidance violates the Administrative Procedure Act." The complaint credits the third-party payment rule with allowing for voluntary payroll deductions and benefit contributions in connection with the extension of public-sector bargaining to the homecare workforce.

The complaint is available at: https://oag.ca.gov/system/files/attachments/press-docs/ca-v-azar-complaint-medicaid-provider-payments.pdf.

DOJ Issues Guidance on Credit for Defendant Cooperation in False Claims Act Investigations

On May 7, the U.S. Department of Justice ("DOJ") issued guidance explaining the manner in which DOJ awards credit to defendants who cooperate during False Claims Act investigations. The guidance states that defendants can obtain credit for voluntarily disclosing misconduct, cooperating in an ongoing investigation, or undertaking remedial measures in response to a violation. In the context of cooperation with an ongoing investigation, the company must do more than simply respond to subpoenas; it must take some other action beyond its legal obligations. The guidance states that credit for cooperation will most likely take the form of a reduction in penalties or damages sought, but may also include DOJ communicating the cooperation to other agencies for their consideration in taking action against the company.

The guidance is available at: https://www.justice.gov/jm/jm-4-4000-commercial-litigation#4-4.112.

CMS Issues Final Rule of Revising Medicare Appeal Regulations to Increase Efficiency, Clarity

On May 7, the Centers for Medicare & Medicaid Services published a final rule revising the regulations governing the Medicare appeals process to streamline the process and reduce administrative burden on providers, suppliers, beneficiaries, and appeal adjudicators. The final rule also includes technical corrections to increase the regulations' clarity. Specific changes include removing the requirement that appellants sign appeal requests and changing the timeframe for vacating dismissals. The final rule is effective July 8.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-05-07/pdf/2019-09114.pdf.

CMS Publishes Final Rule Requiring Drug Manufacturers to Advertise List Prices

On May 10, the Centers for Medicare & Medicaid published a final rule that requires direct-to-consumer television advertisements of prescription drugs and biological products covered by Medicare or Medicaid to include the list price of the drug or product. The final rule states that the intended effect of the rule is to "improve the efficient administration of the Medicare and Medicaid programs by ensuring that beneficiaries are provided with relevant information about the costs of prescription drugs and biological products so they can make informed decisions that minimize their out-of-pocket costs…and expenditures borne by Medicare and Medicaid." The rule will apply to drugs and products for which the list price for a month's supply or the usual course of therapy is more than $35. According to CMS, "[t]he 10 most commonly advertised drugs have list prices ranging from $488 to $16,938 per month or usual course of therapy." The final rule is scheduled to take effect July 9.

The final rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-05-10/pdf/2019-09655.pdf.

A CMS Fact Sheet on the final rule is available at: https://www.hhs.gov/about/news/2019/05/08/cms-drug-pricing-transparency-fact-sheet.html.

On May 8, after the final rule was announced, the president and CEO of the Pharmaceutical Research and Manufacturers of America ("PhRMA") released a statement expressing concern over the final rule's potential to "discourage [patients] from seeking needed medical care" and suggesting that a legal challenge could be filed.

PhRMA's statement is available at: https://www.phrma.org/press-release/phrma-responds-to-hhs-dtc-rule-launches-website-providing-patients-with-cost-information.

SCOTUS Holds that Longer Statute of Limitations Applies in False Claim Act Qui Tam Actions Where Government Declines to Intervene

In a unanimous decision published May 13, the U.S. Supreme Court resolved a split amongst the federal Courts of Appeals concerning the applicable statute of limitations for qui tam actions brought under the False Claims Act ("FCA") where the government declines to intervene. Under the FCA, private citizens may bring qui tam action on behalf of the United States. The United States can then decide whether to intervene and prosecute the case on its own behalf. The FCA contains two statutes of limitations: the first requires that the action be brought within six years after the violation occurred; the second requires that the action be brought within three years after the United States knows or should know about the violation, but not more than ten years after the violation. In the case before the Supreme Court, the plaintiff brought a qui tam action over six years after the alleged violation occurred, but within three years of an interview during which the plaintiff relayed the facts of the violation to federal officials. The Supreme Court held that both statutes of limitations apply to a qui tam claim in which the United States declines to intervene, such that the longer of the two will control. Accordingly, the plaintiff in the case had brought the action within the applicable statute of limitations.

The Supreme Court's decision is available at: https://www.supremecourt.gov/opinions/18pdf/18-315_1b8e.pdf

HHS Spring Regulatory Agenda Released, Including HIPAA, Anti-Kickback and Stark Changes

On May 22, the Office of Management and Budget, Office of Information and Regulatory Affairs posted the 2019 spring regulatory agenda for the U.S. Department of Health and Human Services ("HHS"). Notable items on HHS' agenda include: proposed rules to reform the Anti-Kickback Statute and Stark Law (expected in July); proposed rule to revise provisions of the Health Insurance Portability and Accountability Act ("HIPAA") to remove "barriers that limit or discourage coordinated care and case management (including care coordination challenges arising from the opioid crisis)" (July); final rule on "information blocking" and the Office of the National Coordinator for Health Information Technology ("ONC") Health IT certification program (November); final rule on removing safe harbor protection for drug rebates (November); and final rule revising discharge planning requirements (November).

The regulatory agenda is available at: https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900.

OIG Report: ACOs Have Made Progress with Health IT and Care Coordination, But Work Remains to Be Done

On May 22, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published a report titled "Using Health IT for Care Coordination: Insights from Six Medicare Accountable Care Organizations." In the report, OIG relayed the results of visits it conducted with six Medicare Accountable Care Organizations ("ACOs") to evaluate their use of health IT tools to coordinate care for their patients. Overall, OIG found that all six of the ACOs had used health IT in ways that allowed them to better coordinate care, including use of a single electronic health record ("EHR") system across provider networks, access to robust health information exchanges, and use of data analytics to inform care coordination. However, OIG also found that challenges in care coordination continue to exist, including: struggles with multiple different EHR systems; provider frustration and burnout with technology; and incomplete data. OIG concluded: "Achieving the interoperability needed for seamless care coordination places burdens on ACOs to either invest in a single EHR system or use other methods, such as non-health IT means, to communicate health information."

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-01-16-00180.pdf.

HHS Proposes to Remove Gender Identity and Termination of Pregnancy from Category of Prohibited Sex-Based Discrimination under ACA Nondiscrimination Rule

On May 24, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") issued a proposed rule that would revise the nondiscrimination rules promulgated under the Affordable Care Act ("ACA") to remove gender identity and termination of pregnancy from the definition of discrimination "on the basis of sex." According to OCR, the proposed rule would "return[] to the government's longstanding interpretation of 'sex' under the ordinary meaning of the word Congress used" in the ACA.

When the current rule—which includes discrimination on the basis of gender identity and termination of pregnancy as forms of discrimination on the basis of sex—was promulgated in 2016, it prompted a federal lawsuit by several states and health care providers. A federal court in Texas granted a nationwide injunction against the enforcement of the rule. Following the change of administration in 2017, HHS sought and was granted a stay of the litigation.

The recent proposed change has resulted in backlash from several LGBT rights groups, including Lambda Legal and the National Center for Transgender Equality, who have indicated that legal action may follow if the proposed rule is made final.

Comments will be due 60 days after the date of publication in the Federal Register.

The proposed rule is available at: https://www.hhs.gov/sites/default/files/1557-nprm-hhs.pdf.

A Fact Sheet on the proposed rule is available at: https://www.hhs.gov/sites/default/files/factsheet-section-1557.pdf.

OCR Issues Fact Sheet Reminding Business Associates About HIPAA Liability

On May 24, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") issued a fact sheet outlining actions that would constitute violations of the Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health ("HITECH") Act, and for which business associates would be directly liable, including: failure to cooperate with OCR investigations; taking retaliatory action against an individual for filing a HIPAA complaint; failure to comply with the requirements of HIPAA's Security Rule; failure to provide breach notification to a covered entity or another business associate; and failure to provide a required accounting of disclosures. The fact sheet also identifies OCR's lack of authority to enforce the "reasonable, cost-based fee" limitation for fulfilling individuals' requests for access to their protected health information ("PHI"). In the event that a business associate is responsible for making PHI available in response to such a request and charges more than the allowable fee, OCR is limited to taking enforcement action against only the covered entity.

The fact sheet is available at: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html.

CMS Publishes Final Rule Updating PACE

On June 3, the Centers for Medicare & Medicaid Services published a final rule updating the requirements for the Programs for All-Inclusive Care for the Elderly ("PACE"). Included in the final rule are changes to the application and waiver procedures, sanctions, enforcement actions, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, payment, federal and state monitoring, data collection, record maintenance, and reporting. CMS expects that the changes will "provide greater operational flexibility, remove redundancies and outdated information, and codify existing practice."

PACE provides comprehensive care to beneficiaries who qualify for nursing home care but can still reside safely in their community.

The final rule is available at: https://www.cms.gov/newsroom/fact-sheets/programs-all-inclusive-care-elderly-pace-final-rule-cms-4168-f.

A CMS Fact Sheet on the Final Rule is available at: https://www.cms.gov/newsroom/fact-sheets/programs-all-inclusive-care-elderly-pace-final-rule-cms-4168-f.

OIG Issues Semiannual Report Touting Auditing and Investigative Results

On June 3, the U.S. Department of Health and Human Services ("HHS"), Office of the Inspector General ("OIG") issued its semiannual report to Congress on its work identifying risks, abuses, remedies, and investigative outcomes relating to HHS programs during the semiannual reporting period from October 1, 2018 through March 31, 2019. The report states that during the audit period, OIG issued 71 audits and 10 evaluations, resulting in 212 recommendations issued to HHS operating divisions. OIG's audit work identified $496 million in expected recoveries, $247 million in questioned costs, and $777 million in potential savings for HHS. OIG's investigative activities resulted in $2.3 billion in expected investigative recoveries, 421 criminal actions, 1,293 individuals and entities excluded from Federal healthcare programs, and monetary penalties assessed against 331 individuals or entities.

OIG's report is available at: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2019/2019-spring-sar.pdf.

Supreme Court Holds CMS Failed to Follow Rulemaking Requirements in Change to DSH Payments

On June 3, the U.S. Supreme Court issued a 7-1 ruling holding that the Centers for Medicare & Medicaid ("CMS") is required to follow notice-and-comment rulemaking when it adopts any "statement of policy" that has the effect of changing or creating a "substantive legal standard." The case concerned CMS' decision to adopt a policy changing the calculation of disproportionate share hospitals ("DSH") payments by including Medicare Part C inpatient days. CMS argued that the policy change was a "statement of policy" that is explicitly exempt from the notice-and-comment rulemaking requirement of the Administrative Procedure Act. However, the Court held that the Medicare Act imposes a similar but independent notice-and-comment rulemaking requirement for any "rule, requirement, or other statement of policy . . ." that establishes or changes a "substantive legal standard," and does not contain a similar exception for statements of policy. The Court vacated the DSH payment change and held that the change to DSH payment calculations was a change to a "substantive legal standard" and therefore CMS is required to submit the change to notice-and-comment rulemaking.

The Court's decision is available at: https://www.supremecourt.gov/opinions/18pdf/17-1484_4f57.pdf.

CMS Requests Public Input on Cutting "Red Tape" in Health Care Delivery

On June 6, the Centers for Medicare & Medicaid Services ("CMS") issued a Request for Information ("RFI") seeking public comment on ideas for regulatory, subregulatory, policy, practice, and procedural changes that reduce unnecessary administrative burdens for clinicians, providers, patients and their families. CMS' stated goal in soliciting comments is to "increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible." Specific areas highlighted for comment include: modification and streamlining of reporting requirements and documentation requirements; aligning of requirements across payors; and enabling of operational flexibility, feedback mechanisms, and data sharing.

Responses to the RFI must be received by August 12.

The RFI will be published in the Federal Register on June 11. It is available at: https://www.federalregister.gov/documents/2019/06/11/2019-12215/request-for-information-reducing-administrative-burden-to-put-patients-over-paperwork.

STATE DEVELOPMENTS

NH Attorney General's Office Seeks to Intervene in Dispute Among North Country Hospitals

The Charitable Trusts Unit of the NH Attorney General's Office ("CTU") has moved to intervene in the dispute among North Country Hospitals arising out of Littleton Hospital's announcement in February of its intent to withdraw from the hospital affiliation between Littleton Regional Hospital, Androscoggin Valley Hospital, Weeks Medical Center and Upper Connecticut Valley Hospital. In choosing to intervene, the CTU stated it was intervening in the exercise of its general supervisory authority over charitable organizations and specific statutory responsibility over transactions involving charitable health care organizations.

LEGISATIVE UPDATES (as of June 7, 2019)

House Bills

HB 113: An Act relative to qualifications for and exceptions from licensure for mental health practice. This bill allows experience as a master licensed alcohol and drug counselor to qualify as experience for licensure as a clinical social worker or clinical mental health counselor. The bill also clarifies the mental health license exemption for psychotherapy activities and services of psychologists and master licensed alcohol and drug counselors. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee. Amendment adds additional requirements related to the substitution of training hours. House voted Ought to Pass with Amendment. Referred to Executive Departments and Administration. Voted Ought to Pass by House. **Introduced and referred to Executive Departments and Administration. Voted Ought to Pass by Committee (5-0) and by full Senate.**

HB 118: AN ACT requiring a child's primary health care provider to be notified of a report of suspected abuse or neglect and relative to access to the department of health and human services case record. This bill requires the department of health and human services to notify a child's primary health care provider of a report of suspected abuse or neglect regarding the child. The bill also permits a child's primary health care provider to access the child's case record if such access is necessary to provide treatment or services or to determine the status of a report under investigation by the department. Introduced and referred to House Children and Family Law Committee. Voted Ought to Pass with Amendment by Committee (15-2). The amended bill directs DHHS to develop a methodology for notifying the child's primary health care providers of a report of abuse and neglect and clarifies immunity and confidentiality requirements in such cases. Introduced in the Senate and referred to Judiciary Committee. **Voted Ought to Pass by Committee and by full Senate.**

HB 127: AN ACT relative to the board of medicine and the medical review subcommittee. This bill clarifies the service of the medical director on the board of medicine and the employment of the medical review subcommittee investigator. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee. Amendment provides that physician to serve as medical review subcommittee investigator shall be contracted. Voted Ought to Pass with Amendment by the House**.** Introduced in the Senate and referred to Executive Departments and Administration Committee. **Voted Ought to Pass with Amendment by the Committee (5-0) and the full Senate. The amendment adds an entire new section to the bill requiring certain health care professionals to complete a survey or an opt-out form for collecting data on the primary care workforce.**

HB 233: AN ACT relative to the group and individual health insurance market. This bill establishes the provisions of the Patient Protection and Affordable Care Act of 2009, Public Law 111-148, as amended in statute. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by the House. The Amendment prohibits health carriers from establishing lifetime or annual limits on the dollar value of essential health benefits, but not for health benefits that are not essential. **Introduced in the Senate and referred to Commerce Committee. Committee voted to re-refer the bill to Committee.**

HB 239: AN ACT relative to license requirements for certain mental health and drug counselors. This bill reduces the number of hours or work experience required for licensure as a master licensed alcohol and drug counselor, a licensed alcohol and drug counselor, a licensed clinical supervisor, a clinical social worker, and a clinical mental health counselor. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the House. The amendment deletes all of the originally proposed language and instead proposes changes to the statute to provide that the location of the supervision of mental health and drug counselors take place in a location that is convenient to both the supervisor and the candidate for licensure. Introduced in the Senate and referred to Executive Departments and Administration. **Voted Ought to Pass with Amendment by the Committee and passed by the full Senate with further amendment. The amendments serve to further clarify that the supervision will take place in a mutually convenient location.**

HB 250: AN ACT relative to oral prophylaxis for dental patients. This bill allows a dental patient to have an oral prophylaxis performed even if the supervising dentist determines that a dental procedure or surgery is required. Introduced and referred to House HHS Committee**. Bill retained in Committee.**

HB 277: AN ACT establishing a commission to study a public option for health insurance. This bill establishes a commission to study a public option program for health insurance in New Hampshire. Introduced and referred to House Commerce Committee. Voted Ought to Pass by Committee (11-7) and by the full House. Introduced in the Senate and referred to the Commerce Committee. **Voted Ought to Pass with Amendment by Committee and full Senate. The amendment completely eliminates the language of the bill as passed by the House. The bill as amended authorizes the insurance commissioner to enforce the federal Mental Health Parity and Addiction Act of 2008.**

HB 278: AN ACT relative to the New Hampshire insurance department's annual hearing requirement. This bill updates the insurance commissioner's annual public hearing requirement relative to premium rates. This bill is a request of the insurance department. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by Committee and House. The Amendment changes the report to look at variations in premium rates, rather than only increases. Introduced in the Senate and referred to Commerce Committee. Voted Ought to Pass by Committee. **Voted Ought to Pass by the full Senate and Signed by the Governor. The bill will be effective July 9, 2019.**

HB 284: AN ACT relative to biennial controlled substance inventories conducted under the Controlled Drug Act. This bill requires persons required by federal law to conduct biennial controlled substance inventories to conduct them every odd-numbered year. Current law provides specific dates for such inventories. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee. Amendment permits the pharmacy board to enact rules to ensure compliance. Voted Ought to Pass with Amendment by House. Introduced in the Senate and referred to Health and Human Services Committee. Voted Ought to Pass by Committee and Senate. **Signed by the Governor. The bill will be effective July 9, 2019.**

HB 335: AN ACT relative to therapeutic cannabis dispensary locations. This bill clarifies where a second dispensary may be geographically located for the purposes of the use of cannabis for therapeutic purposes law. Introduced and referred to House HHS Committee. Voted Ought to Pass by Committee and House. Introduced in the Senate and referred to Executive Departments and Administration. **Voted Ought to Pass by Committee (5-0) and by the full Senate.**

HB 350: AN ACT relative to licensed prescribers of medical marijuana. This bill adds physician assistants as prescribing providers for purposes of the use of cannabis for therapeutic purposes law. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee and House. The Amendment requires the physician assistant to have express consent of the supervising physician to prescribe cannabis for therapeutic purposes. Introduced in the Senate and referred to Health and Human Services. **Voted Ought to Pass with Amendment by Committee and full Senate. The amendment changes the title of the bill. The House concurred with the Senate Amendment.**

HB 359: AN ACT relative to warning labels on prescription drugs containing opiates. This bill requires any drug which contains an opiate dispensed by a health care provider or pharmacy to have a red cap and a warning label regarding the risks of the drug. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by the Committee and House. The Amendment changes the bill to require a red sticker with the word "opioid" on the cap or dispenser rather than requiring a red cap. Introduced in the Senate and referred to Health and Human Services. **Voted Ought to Pass with Amendment by the Senate. The amendment changes the color of the required sticker to orange and text of the warning label to state "Risk of addiction and overdose." The bill also requires the health care provider or pharmacist to provide a handout which shall include guidance on the risks of opioid use and how to mitigate them.**

HB 366: AN ACT adding opioid addiction, misuse, and abuse to qualifying medical conditions under therapeutic use of cannabis. This bill adds opioid addiction, misuse, and abuse to the qualifying medical conditions under therapeutic use of cannabis. Introduced and referred to House HHS Committee. **Retained in Committee.**

HB 369-FN: AN ACT relative to the controlled drug prescription health and safety program. This bill clarifies the rule regarding querying the controlled drug prescription health and safety program when writing an initial opioid prescription for a patient's pain or substance use disorder. Introduced and referred to House HHS Committee. Voted Ought to Pass by Committee and House. Introduced in the Senate and referred to Health and Human Services Committee. **Voted Ought to Pass with Amendment by Committee (5-0), however full Senate voted Ought to Pass as introduced. Bill was signed by the Governor and is effective July 14, 2019.**

HB 461-FN: AN ACT adding qualifying medical conditions to the therapeutic use of cannabis law. This bill adds certain medical conditions to the definition of "qualifying medical condition" for the purposes of the use of cannabis for therapeutic purposes law**. Introduced and referred to House HHS Committee. Retained in Committee.**

HB 463-FN: AN ACT relative to voluntary licensure of pharmacist assistants. This bill establishes voluntary licensure of pharmacist assistants to allow persons working as pharmacist assistants for supervising pharmacists to be licensed to perform certain pharmacist tasks. Introduced and referred to House Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by

Committee and House. The Amended bill establishes the duties of and requirements for the licensure of pharmacist assistants working in a pharmacy under a supervising pharmacist. Introduced in the Senate and referred to Executive Departments and Administration. Voted Ought to Pass with Amendment by Committee. The Amendment changes all references to pharmacist assistant to "licensed advanced pharmacy technician." **House concurred with Senate Amendment.**

HB 483-FN: AN ACT adopting the psychology interjurisdictional compact (PSYPACT). This bill enacts the adoption of the psychology interjurisdictional compact (PSYPACT). Introduced and referred to House HHS Committee. **Retained in Committee.**

HB 490: AN ACT relative to testing for Lyme disease. This bill requires health care providers to provide certain information to persons being tested for Lyme disease. Introduced and referred to House HHS Committee. Voted Ought to Pass by Committee and House. The amended bill establishes a commission to study the use of limitations of serological diagnostic tests to determine the presence or absence of Lyme and other tick-borne diseases and the development of appropriate methods to education physicians and the public with respect to the inconclusive nature of prevailing test methods. Introduced in the Senate and referred to Health and Human Services Committee. **Bill was re-referred to Committee.**

HB 508: AN ACT relative to direct primary care. This bill declares that primary care providers providing direct primary care pursuant to a primary care agreement are not subject to the insurance laws, provided that certain conditions are met. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee. Amendment makes minor changes to conditions. Voted Ought to Pass with Committee Amendment by House. Re-referred to Commerce Committee. Voted Ought to Pass with Amendment by Commerce Committee and full House. The Amendment completely changes the language of the bill and now establishes a study committee to study direct primary care. **Introduced in the Senate and referred to HHS Committee. Voted Ought to Pass with Amendment by Committee (5-0) and Senate. The amendment returns the bill to its original subject matter with some deleted language and eliminates the establishment of a study committee.**

HB 528-FN: AN ACT relative to insurance reimbursement for emergency medical services. This bill requires insurers to consider the presenting symptoms rather than the final diagnosis when determining whether to cover and pay for emergency services. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by Committee and House. The Amendment is a significant change to the bill as introduced and requires that the insurer's retrospective review of a claim for emergency services include consideration of the presenting symptoms along with the final diagnosis. It eliminates the proposed prudent layperson standard for defining emergency medical conditions. Introduced in the Senate and referred to Commerce Committee. Voted Ought to Pass by Committee (5-0) and Senate. **Signed by the Governor. Bill is effective July 9, 2019.**

HB 546-FN: AN ACT relative to the regulation of art therapists. This bill establishes the regulation and licensure of persons engaged in the practice of professional art therapy by the office of professional licensure and certification and includes licensed professional art therapists in certain insurance coverage provisions. Introduced and referred to House Executive Departments and Administration Committee. **Bill retained in committee.**

HB 552-FN: AN ACT relative to transparency and standards for acquisition transactions in health care. This bill clarifies the standards for acquisition transactions involving health care charitable trusts and the

review required by the director of charitable trusts. Introduced and referred to House Judiciary Committee. Voted Ought to Pass with Amendment by Committee and House. The amendment allows the Charitable Trusts Unit to obtain certain confidential information from other state agencies when reviewing the acquisition transactions of health care charitable trusts and amended the applicability to make it clear it would apply only to health care transactions filed on or after the effective date. **Introduced in the Senate and referred to Judiciary Committee. Voted Ought to Pass with Amendment by Committee and Senate. Amendment requires a health care charitable trust to demonstrate an acquisition transaction is in the best interest of communities it serves rather than the entire state and postpones the effective date until January 1, 2020.**

HB 604: AN ACT establishing a commission to assess benefits and costs of a "health care for all" program for New Hampshire. This bill establishes a commission to study the benefits and cost of a "health care for all" program for New Hampshire. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by Committee and House. The amendment added additional factors to be considered by the study commission including to study the creation of a health access corporation and fund, and the feasibility of New England states entering into a compact for a single payer health care program. Introduced in the Senate and referred to Commerce Committee. **Voted Inexpedient to Legislate by Committee (5-0) and Senate.**

HB 615: AN ACT relative to the regulation of pharmacies and pharmacists. This bill makes various changes to the regulation of pharmacies and pharmacists by the board of pharmacy, including procedures of the board, exceptions to possessing prescription drugs, license expirations and renewals, and establishing the licensure of drug distribution agents. Introduced and referred to House Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by Committee (20-0) and full House. The amendment makes technical changes to the bill. Introduced in the Senate and referred to Executive Departments and Administration Committee. **Voted Ought to Pass by Committee (5-0) and Senate.**

HB 656: AN ACT establishing a commission to study the impact of financial initiatives for commercially insured members by drug manufacturers on prescription drug prices and health insurance premiums. This bill establishes a commission to study the impact of financial initiatives for commercially insured members by drug manufacturers on prescription drug prices and health insurance premiums. Introduced and referred to House Commerce Committee. Voted Ought to Pass by House. Introduced in the Senate and referred to Commerce Committee. **Voted to be Re-referred by Committee. Motion to re-refer failed on Senate floor. Voted Ought to Pass with Amendment by Senate. Senate changes the establishment of a commission to the establishment of a study committee.**

HB 670-FN: AN ACT relative to the cost of prescription drugs. This bill requires health insurance carriers to maintain certain information relative to prescription drug costs within their data systems for purposes of the managed care law. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by House. The amendment provides that carriers either maintain or have access to the prescription information. Introduced in the Senate and referred to Commerce Committee. **Voted Ought to Pass by Committee (5-0) and Senate.**

HB 671-FN: AN ACT relative to pharmacy benefit manager business practices, licensure, and transparency. This bill establishes an RSA chapter governing pharmacy benefit managers. Introduced and referred to House Commerce Committee. **Retained in Committee.**

HB 685-FN: AN ACT relative to ambulance billing, payment for reasonable value of services, and prohibition on balance billing. This bill clarifies ambulance billing under the law governing emergency and medical trauma services. Introduced and referred to House Commerce Committee. **Retained in Committee.**

HB 690-FN: AN ACT removing the work requirement of the New Hampshire granite advantage health care program. This bill removes the work and community engagement requirements of the New Hampshire granite advantage health care program. Introduced and referred to House HHS Committee. **Retained in Committee.**

HB 703-FN: AN ACT relative to providing notice of the introduction of new high-cost prescription drugs. This bill requires prescription drug manufacturers to provide certain notice to the office of the attorney general if they are introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by Committee (13-7) and House. The Amendment requires reporting to the Insurance Department rather than the Office of the Attorney General. Introduced in the Senate and referred to Commerce Committee. **Committee (5-0) and Senate voted to Re-Refer the bill.**

HB 717-FN: AN ACT prohibiting prescription drug manufacturers from offering coupons or discounts to cover insurance copayments or deductibles. This bill prohibits with limited exceptions, prescription drug manufacturers from offering coupons or discounts to cover insurance copayments, or deductibles. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by Committee (12-8) and House. The Amendment changes the prohibition from prohibiting manufacturers from offering discounts, repayments, product vouchers, etc. to prohibit pharmacies from accepting them as payment from a patient on behalf of a person who manufactures a prescription drug. It also adds a parallel section prohibiting contracts between a health carrier and a pharmacy to permit the pharmacy to accepting the discounts, repayments, vouchers, etc. as payment. Introduced in the Senate and referred to Commerce Committee. **Voted by Committee (5-0) and Senate to Re-refer bill to Committee.**

HB 725-FN: AN ACT including Medicaid managed care organizations under the managed contractor requirements for provider care law. This bill includes Medicaid managed care organizations for the purposes of the managed care law pursuant to RSA 420-J. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by Committee (19-1) and by the House. As amended, the bill does not include Medicaid managed care organizations under the Managed Care Law but does establish certain credentialing standards and quality assurance standards for Medicaid managed care organizations. Introduced in the Senate and referred to Commerce Committee. **Voted Ought to Pass by Committee (5-0) and Senate.**

Senate Bills

SB 4: AN ACT relative to the group and individual health insurance market. This bill establishes the provisions of the Patient Protection and Affordable Care Act of 2009, Public Law 111-148, as amended in statute. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. The Amendment prohibits health carriers from establishing lifetime or annual limits on the dollar value of essential health benefits, but not for health benefits that are not essential and

adds a non-discrimination provision. Introduced in the House and referred to Commerce Committee. **Voted Ought to Pass (11-8) by Committee and House.**

SB 11-FN-A: AN ACT relative to mental health services and making appropriations therefor. This bill: I. Authorizes the department of health and human services to use general surplus funds for designated receiving facilities and for voluntary inpatient psychiatric admissions. II. Makes an appropriation to the department of health and human services for the purpose of renovating certain existing facilities. III. Provides for rulemaking for involuntary admission hearing requirements. IV. Makes an appropriation to the affordable housing fund, established in RSA 204-C:5, for transitional housing for persons leaving mental health treatment facilities. V. Requires insurers to reimburse certain facilities for emergency room boarding. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. Rereferred to the Senate Finance Committee. Voted Ought to Pass with Amendment by Committee and Senate. As amended, the bill removes the provision related to appropriations to the Affordable Housing Fund but increases amounts available to HHS to contract with programs to provide affordable, supported housing. It also directs HHS to solicit RFPs for a fourth mobile crisis team of second behavioral health crisis treatment center. Voted Ought to Pass with Amendment by Finance Committee and Senate. The Amendment changes the appropriation amounts, modifies the required period insurers must pay for boarding mental health patients in hospital emergency rooms and add a new appropriation for a new mobile crisis team of behavioral health crisis treatment center. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (19-0) and House. Signed by the Governor. The section requiring insurers to reimburse for emergency room boarding of patient subject to involuntary admission is effective July 1, 2019. All other provisions were effective upon passage, May 21, 2019.**

SB 26: AN ACT relative to the New Hampshire health care quality assurance commission. This bill changes the name of the New Hampshire health care quality assurance commission to the New Hampshire health care quality and safety commission. This bill also removes the prospective repeal of the commission. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by Committee and Senate. Amendment changes composition of Commission to include one representative of each licensed hospital rather than each acute care and specialty care hospital and adds the CEO of NH Hospital or his designee to the Commission. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass with Amendment (22-0) and by House. The amendment adds language to allow the state epidemiologist to designate someone to serve in his place on the commission.**

SB 33: AN ACT relative to the therapeutic use of cannabis. This bill authorizes the department of health and human services to collect certain data regarding the therapeutic use of cannabis. This bill also requires the commissioner of the department of health and human services to adopt rules regarding disclosure of information resulting from inspections and investigations under RSA 126-X. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee (5-0) and Senate. The Amendment changes the bill to permit HHS to release collected data with the approval of the Commissioner consistent with HIPAA standards. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (21-1) and House.**

SB 58: AN ACT relative to reimbursement rates for low-dose mammography coverage. This bill clarifies the reimbursement rates for low-dose mammography. Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee (5-0) and Senate. Introduced in the House and referred to Commerce**.**

Voted Ought to Pass with Amendment by Committee (14-6) and House. The amendment requires that the payment include distinct recognition and additional payment for industry standard coding for mammography using 3-D tomosynthesis.

SB 88-FN: AN ACT relative to registry identification cards under the use of cannabis for therapeutic purposes law. This bill makes certain changes in the use of cannabis for therapeutic purposes law, including: I. Eliminating the time frame for a provider-patient relationship. II. Repealing the requirement for a photograph of an applicant's face for purposes of the registry identification card. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by House. The Amendment eliminates the originally proposed repeal of the requirement for a photograph of the applicant's face for the registry identification card. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass with Amendment by Committee and House. The amendment specifies information to be included on the written certification.**

SB 90-FN: AN ACT relative to certain disclosures by health care provider facilities. This bill extends immunity to staff licensed by the division of health professions, office of professional licensure and certification, to disclose certain employment information. Introduced and referred to Senate Judiciary Committee. **Rereferred to Committee.**

SB 97: AN ACT relative to licensure of health facilities near a critical access hospital. This bill requires an applicant seeking to construct certain health care facilities for licensure under RSA 151 to submit a report showing how the proposed project will affect certain health care services. This bill is a request of the department of health and human services. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by the Senate. The Amendment completely changes the bill. As amended the bill clarifies rulemaking regarding special health care services licensing and establishes a study committee to study providing certain health care services while ensuring increased access to affordable health care services in rural areas of the state. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (21-0) and House.**

SB 111: AN ACT relative to the collection of health care data. This bill clarifies the collection of health care data. This bill is a request of the department of health and human services. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment. The Amendment adds a provision allowing data to be released to the Insurance Department, the Department of Justice land other state and federal agencies. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (13-7) and House.**

SB 119: AN ACT directing hospitals to develop an operational plan for the care of patients with dementia. This bill requires hospitals licensed under RSA 151 to complete and implement an operational plan for the recognition and management of patients with dementia or delirium in acute-care settings. Under this bill, each hospital shall keep the plan on file and make it available to the bureau of health facilities administration, department of health and human services, upon request. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. Amendment provides hospitals with two additional years, until January 1, 2023 to comply. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (19-2) and House.**

SB 145: AN ACT relative to the organization of alternative treatment centers. This bill permits alternative treatment centers to organize as business corporations and limited liability companies and provides the

procedure for alternative treatment centers organized as voluntary corporations to convert to business corporations or limited liability companies. Introduced and referred to Senate Commerce Committee. Voted Ought to Pass with Amendment. The Amendment clarifies the intent of the bill by affirmatively stating that alternative treatment centers may be operated on a for-profit or not-for-profit basis. Introduced in the House and referred to Commerce Committee. **Voted Ought to Pass by Committee (16-3) and House.**

SB 175: AN ACT relative to qualifying medical conditions for therapeutic cannabis. This bill changes the definition of qualifying medical condition for the purposes of the law governing the use of cannabis for therapeutic purposes. Introduced and referred to Senate HHS Committee. **The bill was rereferred to Committee.**

SB 177: AN ACT relative to the use of physical restraints on persons who are involuntarily committed. This bill clarifies when physical restraints may be used to transport a person being admitted to New Hampshire hospital or a designated receiving facility. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee (5-0) and Senate. The amendment repeals the entire current statute governing the delivery of individuals to designated receiving facility after completion of an inpatient admission. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass with Amendment by Committee (21-0) and House. The amendments make minor modifications to the requirements for determining the means of transport and the use of physical restraints.**

SB 178: AN ACT relative to telemedicine for spectacle and contact lenses. This bill clarifies the procedure for health care providers who prescribe spectacle lenses and contact lenses by telemedicine. Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee and Senate. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (21-0) and House.**

SB 179: AN ACT relative to pharmacist administration of vaccines. This bill modifies the authority for pharmacists and pharmacy interns to administer vaccinations by including vaccines listed in the recommended adult immunization schedule by the Centers for Disease Control and Prevention. Introduced and referred to Senate HHS Committee. **The bill was rereferred to Committee.**

SB 182: AN ACT relative to a duty to report when another person has suffered grave physical harm. This bill establishes a duty to report when another person has suffered grave physical harm. Introduced and referred to Senate Judiciary Committee. **The bill was rereferred to Committee.**

SB 210: AN ACT relative to emergency medical and trauma services. This bill makes certain reference changes and adds a definition of "telecommunicators" to the law governing emergency medical and trauma services. Introduced and referred to Senate Executive Departments and Administration Committee**.** Voted Ought to Pass with Amendment by the Committee and Senate. The Amendment changes the bill so that it is effective upon passage rather than 60 days after passage. Introduced in the House and referred to Executive Departments and Administration Committee. **Voted Ought to Pass with Amendment by Committee (19-0) and House. The amendment adds a definition of "local dispatcher."**

SB 222-FN: AN ACT relative to licensure of pharmacy benefits managers. This bill establishes the licensure and regulation of pharmacy benefits managers by the insurance commissioner. Introduced and referred to Senate Executive Departments and Administration Committee. **Re-referred to Committee**

SB 226-FN: AN ACT relative to registration of pharmacy benefit managers and reestablishing the commission to study greater transparency in pharmaceutical costs and drug rebate programs. This bill establishes the registration and regulation of pharmacy benefits managers by the insurance commissioner. This bill also reestablishes the commission to study greater transparency in pharmaceutical costs and drug rebate programs. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by Committee. The Amendment changes the section of the RSA where the bill will be codified, adds contracting standards for PBMs, changes the effective date for certain sections of the bill from November 2019 to November 2020, and makes other technical changes. Voted Ought to Pass with Amendment by Senate. Introduced in the House and referred to Commerce Committee**. Voted Ought to Pass with Amendment by Committee (12-8) and House. Amendment expands the definition of pharmacy benefits manager and makes numerous other changes.**

SB 232: AN ACT adopting the model psychology interjurisdictional compact. This bill enacts the adoption of the psychology interjurisdictional compact (PSYPACT). Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass by Committee and Senate. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by HHS Committee (13-8) and referred to Executive Departments and Administration Committee. Voted Ought to Pass by Executive Departments and Administration Committee (12-6) and by House.**

SB 255-FN: AN ACT relative to dementia training for direct care staff in residential facilities and community-based settings. This bill requires dementia training for direct care staff in residential facilities and community-based settings. The bill grants rulemaking authority to the commissioner for the purposes of the bill. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by Committee (5-0) and the Senate. The Amendment eliminates the requirement for the Department to identify and designate approved trainings and makes other technical changes. Introduced in the House and referred to HHS Committee. **Bill retained in Committee.**

SB 258: AN ACT relative to telemedicine and telehealth services. This bill adds definitions to and clarifies the statute governing telemedicine and Medicaid coverage for telehealth services. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. The Amendment does not significantly change the substantive purpose of the bill. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (21-0) and by House. Amendment changes the effective date so that designated sections are effective January 1, 2020.**

SB 259-FN: AN ACT expanding eligibility for the Medicaid for employed adults with disabilities (MEAD) program. This bill directs the department of health and human services to submit an amendment to the state Medicaid plan to expand coverage under the MEAD program, which provides Medicaid for employed adults, to individuals 65 years of age and older. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by HHS Committee and Senate. Referred to Finance Committee and voted Ought to Pass. **Bill laid on table by Senator Feltes.**

SB 260-FN: AN ACT relative to a program for prescription drug costs for certain seniors and making an appropriation therefor. This bill directs the department of health and human services to develop a prescription drug assistance program to pay out-of-pocket prescription drug costs for seniors who have

reached the gap in standard Medicare Part D coverage. The bill also makes an appropriation to the department of health and human services to fund the program. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee. As amended the bill no longer directs HHS to develop a prescription drug assistance program but establishes a pharmaceutical assistance pilot program for seniors and makes an appropriation to HHS to fund the pilot program. Voted Ought to Pass with further amendment by the Senate. The amendment limits the number of participants in the pilot to the first 1000 applicants and limits the timeframe for assistance under the program to January 1, 2020-January 1, 2021. Referred to Finance Committee which voted Ought to Pass with Amendment by Finance Committee and Senate. The Amendment appropriates the amount of $1,250,000 for the program. **Bill Laid on Table by Senator D'Allesandro.**

SB 272-FN: AN ACT relative to mental health parity under the insurance laws. This bill authorizes the insurance commissioner to enforce the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 and requires the commissioner to examine and evaluate health insurers, health service corporations, and health maintenance organizations for compliance. Introduced and referred to Senate Commerce Committee. Voted Ought to Pass with Amendment by Committee and Senate. The amendment requires the Insurance Commissioner to periodically examine and evaluate provider reimbursement practices rather than provider reimbursement rates. Introduced in the House and referred to Commerce Committee. **Voted Ought to Pass with Amendment by Committee (14-5). Amendment failed on House floor. Voted Ought to Pass by House (same version passed by Senate.)**

SB 273-FN: AN ACT relative to the regulation of nursing assistants by the board of nursing. This bill changes the regulation of licensed nursing assistants to certified nursing assistants and makes administrative changes for the board of nursing. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by Committee and Senate. The amendment completely deletes the original language and instead establishes a study committee to study the regulation of nursing assistants. Introduced in the House and referred to Executive Departments and Administration Committee. **Voted Ought to Pass with Amendment by Committee (19-0) and House. The amendment adds changes to the regulation of nurses concerning fees for specialty certificates.**

SB 279-FN: AN ACT relative to access to fertility care. This bill requires insurers to cover fertility treatment. Introduced and referred to Senate Commerce Committee. Voted Ought to Pass with Amendment by Committee and Senate. The Amendment makes numerous changes to the specific requirements for the provision of fertility treatment and excludes certain plans/policies (SHOP and extended transition to ACA Compliant policies) plans from the requirements. **Introduced in the House and referred to Commerce Committee. Voted Ought to Pass with Amendment by Committee (12-8) and House. Amendment provides additional detail on coverage requirements.**

SB 289: AN ACT relative to health and human services. This bill: I. Requires collection stations, not just those operated by laboratories, to be licensed under RSA 151 and revises the responsibilities of an individual home care service provider to include health support services. II. Authorizes reimbursement for a legally responsible relative who provides personal care services under RSA 161-I. III. Requires services provided to individuals with disabilities by area agencies and authorized agencies to comply with RSA 171-A and the federal requirements for the home and community-based care waiver. IV. Requires that home-based long-term care services provided under RSA 151-E comply with the federal requirements

for the home and community-based care waiver. V. Provides that the committee for the protection of human subjects shall defer to the institutional review board designated by the federal agency responsible for funding in certain cases. VI. Clarifies the authority of pharmacies to dispense prescription drugs and removes the requirement that the protocol and criteria for dispensing drugs be approved by the department of health and human services. VII. Revises the medical support obligation for purposes of determining parental rights and responsibilities and child support to mean the obligation to provide health care coverage for a dependent child whether in the form of private health insurance or public health care. The bill is a request of the department of health and human services. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment. The amendment adds physician assistants to the list of providers who may dispense certain noncontrolled prescription drugs and vaccines in certain settings and makes other technical changes**. Voted Ought to Pass with Amendment by HHS Committee, Finance Committee and House. Amendments provide clarification regarding dispensing of controlled substances and to the definition of "Area agency."**

SB 290-FN: AN ACT relative to the New Hampshire granite advantage health care program. This bill makes various changes to the New Hampshire granite advantage health care program, some of which include: I. Allowing general funds to be used for the program. II. Clarifies which beneficiaries may be subject to the work and community engagement requirement. III. Reducing the number of hours for the work and community engagement requirement. IV. Adding exemptions for certain persons from the community engagement requirement. V. Adding circumstances for the elimination of the community engagement requirement. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. The Amendment reverses the effort to lower the number of hours needed to meet the work and community engagement program, eliminates the proposed exemption for individuals over age 50, modifies the childcare exemption to apply to those caring for a child under the age of 13 old, allows for the use of general funds for the program under certain specific circumstances, and imposes certain standards for the review and evaluation of the program. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee and House. Amendment provides individuals with an opportunity to cure the failure to comply with the work or community engagement requirements.**

SB 292-FN: AN ACT relative to implementation of the new mental health 10-year plan. This bill requires the commissioner to submit a report containing the procedures for implementation of New Hampshire's 10-year mental health plan of 2018 within 6 months of finalization of the plan to the president of the senate, the speaker of the house of representatives, and the governor. Under this bill, the commissioner of the department of health and human services shall fully implement the plan within 2 years of the date when it was finalized. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by the Committee and Senate. The amended bill requires the commissioner to submit a report containing the priorities for implementing the 10-year mental health plan and thereafter submit an annual report on the status of implementation. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass with Amendment by Committee and House. Amendment requires the commissioner to report on the 10-year mental health plan to be made by September 1, 2020.**

SB 293-FN: AN ACT relative to federally qualified health care centers and rural health centers reimbursement. This bill requires the department of health and human services to reimburse federally qualified health care centers and rural health centers for services provided to persons whose Medicaid eligibility has been suspended for failure to comply with the work and community engagement requirement established under the New Hampshire granite advantage health care program. Introduced and referred to

Senate HHS Committee. Voted Ought to Pass by Committee and Senate. Introduced in the House and referred to HHS Committee. **Voted Ought to Pass by Committee (16-4). Referred to Finance. Bill was retained in Committee.**

SB 308-FN-A: AN ACT relative to the health care workforce and making appropriations therefor. This bill: I. Increases the Medicaid provider rates. II. Requires certain health care professionals to complete a survey collecting data on the primary care workforce. III. Requires the department of health and human services to amend the income standard used for eligibility for the "in and out" medical assistance policy. IV. Permits the department of safety to contract with a private agency to process background check applications and requires the department to accept and process background check applications online. V. Amends the definitions and services covered through telemedicine. VI. Makes appropriations to the department of health and human services, rural health and primary care section to establish new positions and programs to develop and enhance the state's healthcare workforce. VII. Makes an appropriation to the governor's scholarship program for scholarships to students majoring in a health care field and to postsecondary educational institutions to develop and enhance programs of study offered in health care. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by Committee and Senate. The amendment delays the 5% increase in Medicaid provider rates for an additional year to June 30, 2020 and the additional 7% increase to June 30, 2021. It also eliminates some of the proposed changes to the telemedicine requirements. The amount of the appropriate for the Governor's Scholarship Program was reduced from $5M to $1.25M. **Bill was Laid on Table by Senator D'Allesandro.**

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Cinde Warmington and Alexander W. Campbell contributed to this month's Legal Update.

BIOS

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