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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 DEVELOPMENTS

FDA Issues Guidance Clarifying Communications Between Drug and Device Manufacturers and Insurers

On June 12, the Food and Drug Administration ("FDA") published two guidance documents regarding communications between drug and device manufacturers and insurers. The first guidance document – "Drug and Device Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers" – is meant to provide guidelines for drug and device manufacturers to follow in their communications with insurers in order "to enable truthful, non-misleading and appropriate company communications with insurers."

The second guidance document – "Medical Communications That Are Consistent With the FDA-Required Labeling" – provides clarification to manufacturers about how to ensure that their communications with insurers are consistent with FDA labeling requirements, again to make sure that such communications are truthful and non-misleading.

The first guidance document is available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537347.pdf.

The second guidance document is available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130.pdf.

CMS issues Guidance to States Explain How to Use Medicaid Coverage and Federal Funding to Combat Opioid Crisis

On June 11, the Centers for Medicare & Medicaid Services ("CMS") issued guidance that is intended to identify ways for states to take advantage of federal funding and regulatory flexibility to combat the opioid epidemic. One of the guidance documents included information about how Medicaid services can be utilized in the treatment of neonatal abstinence syndrome ("NAS") that occurs in newborns who are exposed to opioids in utero. The guidance also explains how Medicaid coverage may be available to provide substance use disorder treatment to fathers and mothers of infants receiving treatment for NAS.

The second guidance document is a letter to state Medicaid directors that includes information about federal grants that are available "to integrate innovative substance abuse treatment in areas facing provider shortages, particularly in rural areas, such as virtual treatment centers or remote counseling, into Medicaid care coordination technologies." The letter highlights a matching program for Medicaid Information Technology Architecture and a similar matching program through the Health Information Technology for Economic and Clinical Health (HITECH) Act. Both of these

matching programs are available regardless of whether the states are participating in a Section 1115 demonstration project.

The first guidance document is available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib060818.pdf.

The second guidance document is available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd18006.pdf.

OCR Issues Guidance for Streamlining HIPAA Authorizations for Research

In June 2018, the Department of Health and Human Services Office for Civil Rights ("OCR") issued guidance mandated by the 21st Century Cures Act to streamline authorizations for the use and disclosure of protected health information ("PHI") under the Health Insurance Portability and Accountability Act ("HIPAA") for future research. Specifically, the guidance, which OCR stated it was issuing on an interim basis, provides that authorizations for research "do not need to specify each specific future study if the particular studies to be conducted are not yet determined" and that the description will be compliant if it "sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for future research." With respect to expirations of authorizations for future research, the guidance states that the phrases "including for the creation and maintenance of a research database or research depository", "end of the research study" or "none" is sufficient, as well as a statement that it would remain valid unless revoked. The guidance also addresses the right to revoke, and states that despite a patient's revocation, a covered entity may continue to use PHI to the extent it has taken action relying on the authorization, such as, to maintain the integrity of the study to account for a subject's withdrawal, to conduct investigations of scientific misconduct, or to report an adverse event.

The interim guidance can be found here: https://www.hhs.gov/sites/default/files/hipaa-future-research-authorization-guidance-06122018%20v2.pdf

CMS Announces Strategy for Increasing Medicaid Program Integrity

On June 26, the Centers for Medicare & Medicaid Services ("CMS") announced a strategy to combat Medicaid fraud and increase Medicaid program integrity. CMS' "Robust Plan for New or Enhanced Medicaid Program Integrity Initiatives" includes the following measures: strengthen the program integrity focus of audits of states claiming federal match funds; conduct new audits of state beneficiary eligibility determinations; optimize state-provided claims and provider data; use data innovation to empower states and conduct innovative data analytics pilots; offer provider screening for states on an opt-in basis; enhanced data sharing and collaboration between CMS and the states; publicly report state performance on the Medicaid Scorecard; and provide Medicaid provider education to reduce improper payments. According to CMS Administrator Seema Verma, "With the historic growth in Medicaid comes an urgent federal responsibility to ensure sound fiscal stewardship and oversight of the program."

CMS' Medicaid Program Integrity Strategy is available at: https://www.medicaid.gov/state-resource-center/downloads/program-integrity-strategy-factsheet.pdf.

A Fact Sheet about the Medicaid Program Integrity Strategy is available at: https://www.cms.gov/newsroom/press-releases/cms-announces-initiatives-strengthen-medicaid-program-integrity.

OIG Declines to Impose Sanctions for Medical Center's Provision of Caregiver Support Services

On June 25, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published Advisory Opinion No. 18-05 regarding the Requestor's proposal to establish a medical center to offer free or reduced-cost support services to caregivers. Under the proposed arrangement, the medical center would provide certain support services – access to a resource library, educational sessions, support groups, an equipment lending program, stress-reduction workshops, low-cost ride-share programs – to caregivers in the community. While the medical center is aware that many of the caregivers who would be recipients of the free or reduced-fee services are likely Federal health care program participants, the medical center does not market, promote, or make referrals for any medical items or services that are reimbursable by a Federal health care program. It is likely that some of the caregivers who receive free or reduced-cost services from the medical center also receive health care from the Requestor that is reimbursable by a Federal health care program.

The OIG began its analysis of the proposed arrangement by finding that the provision of free or reduced-cost services to the caregivers could – because of the Requestor's relationship with the medical center – influence the caregivers to select the Requestor for federally reimbursable items or services in the future, thereby implicating the beneficiary inducement civil monetary penalties ("CMPs"). OIG then continued to conclude that the proposed arrangement did not meet the requirements for any exception to the CMPs, but that it would nonetheless not impose sanctions for the following reasons: 1) the services offered primarily benefit the caregivers, who are not necessarily in need of any particular health care provider, practitioner, or supplier; 2) the medical center's services are available to all caregivers; 3) the Requestor does not actively market its relationship with the medical center; and 4) the proposed arrangement is unlikely to increase costs to Federal health care programs. OIG concluded that it would not impose sanctions under the Antikickback Statute for the above reasons.

Advisory Opinion No. 18-05 is available at: https://www.justice.gov/usao-edtn/pr/caris-agrees-pay-85-million-court-settle-false-claims-act-lawsuit-alleging-it-billed.

CMS Launches "Data Element Library" to Improve Interoperability of CMS Assessments and Health IT

On June 21, the Centers for Medicare & Medicaid Services ("CMS") launched the Data Element Library ("DEL"), which CMS described as "the centralized resource for CMS assessment instrument data elements (e.g. questions and responses) and their associated health information (IT) standards." In addition to serving as the centralized resource for these data elements, the DEL is also intended to promote the sharing of electronic CMS assessment data sets and influence and support industry efforts to promote electronic health record and other health IT interoperability. According to a Fact Sheet on the DEL's launch, "CMS anticipates that the DEL will make it easier for IT vendors to incorporate data elements adopted by CMS into provider EHRs, thereby reducing burden, improving interoperable data exchange, and facilitating care coordination."

An overview of the DEL is available at: https://del.cms.gov/DELWeb/pubHome.

The Fact Sheet on the DEL is available at: https://www.cms.gov/newsroom/fact-sheets/cms-data-element-library-fact-sheet.

OIG Report Finds Part D Formularies Continue to Include Drugs Commonly Used by Dual Eligibles

On June 26, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published a report titled "Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2018." OIG's investigation was conducted and the report published in response to a mandate in the Affordable Care Act that requires OIG to study the extent to which formularies used by Medicare Part D plans include drugs commonly used by full-benefit dual-eligible individuals, who generally obtain coverage through Medicare Part D. OIG found that on average Part D formularies include 96% of the 197 commonly used drugs, with 68% of the commonly used drugs included in all the Part D plan formularies. These findings are consistent with OIG's findings in 2011 through 2017. OIG also found that the percentage of drugs that were subject to utilization management tools increased slightly since last year. OIG had no recommendations but stated that it will continue to monitor the Part D formularies as required by law.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-05-18-00240.pdf.

OIG Publishes Findings of Troubling Part D Beneficiary Opioid Use

On June 28, the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") issued a data brief titled "Opioid Use in Medicare Part D Remains Concerning." The data brief was produced as part of OIG's ongoing strategy to combat the opioid crisis and provides 2017 data on the extent to which Medicare Part D beneficiaries receive extreme amounts of opioids or appear to be "doctor shopping." OIG found that nearly one in three Part D beneficiaries received a prescription opioid in 2017, but that overall Part D spending for opioids had decreased. OIG found that almost 460,000 beneficiaries received high amounts of opioids in 2017 and about 71,000 beneficiaries are at serious risk of opioid misuse or overdose, however both figures are lower than in 2016. OIG found that almost 300 prescribers had questionable opioid prescribing for the 71,000 beneficiaries at serious risk. OIG concludes that "the high level of opioid use calls for the public and private sectors to work together to address this crisis."

The issue brief is available at: https://oig.hhs.gov/oei/reports/oei-02-18-00220.pdf.

CMS Issues Proposed Rule with Substantial Changes to Home Health Payments

On July 2, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule increasing payments to home health agencies ("HHAs") by 2.1%, or $400 million. The rule significantly updates the home health prospective payment system ("HH PPS") including the 60-day episode payment rates, the per-visit rates, and the non-routine medical supply conversion factor. Changes would be effective for episodes of care ending on or after January 1, 2019. Additionally, the rule proposes changes to the HH PPS case-mix weights for calendar year 2019 and proposes a rebasing of the HH market basket as required by the Bipartisan Budget Act of 2018. The rule also proposes changes to the Home Health Value-Based Purchasing Model by removing two OASIS-based measures, replacing others, and reweighting the measures in the applicable measures set, among other things.

Comments on the proposed rule were due August 31.

The proposed rule can be read in full here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14443.pdf

Court Strikes Kentucky Medicaid Work Requirements

On June 29, the U.S. District Court for the District of Columbia ruled that the Centers for Medicare & Medicaid ("CMS") improperly approved the State of Kentucky's section 1115 waiver application imposing work requirements on the State's Medicaid beneficiaries. In finding that the CMS Secretary's approval of the

waiver was arbitrary and capricious, the court stated that "the Secretary never adequately considered whether Kentucky HEALTH would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid."

The case, *Stewart v. Azar*, No. 18-152 (JEB) (D.D.C. June 29, 2018), can be read here: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv0152-74

Federal Circuit Upholds Government's Decision to Shortchange Insurers in Risk Corridor Payments

On July 14, the U.S. Court of Appeals for the Federal Circuit ruled against two insurers who were seeking millions from the government in unpaid risk corridor payments. The risk corridor payments were established in Section 1342 of the Affordable Care Act as a way to redistribute gains and losses among insurers that resulted from inaccurate rate-setting. In 2015 and 2016, Congress passed spending bills that blocked the government from using any outside funding to pay the risk corridor payments, limiting it instead to the amounts paid in by insurers that experienced gains. As a result, the government only paid out a small percentage of the risk corridor payments owed, leaving insurers with $12.3 billion in unpaid payments. In response to the unfulfilled payments, insurers filed lawsuits around the country. In *Moda Health Plan, Inc. v. United States*, the Federal Claims Court held that the government owed the balance of the risk corridor payments, despite the appropriations restrictions. In *Land of Lincoln Mutual Health Ins. Co. v. United States*, however, the Federal Claims Court held that the government was not obligated to make the payments in full.

In the latest decision on the issue – which addresses appeals of both the *Moda* and the *Land of Lincoln* decisions – the Federal Circuit, in a 2-1 opinion, held that the subsequent appropriations restrictions effectively repealed or suspended the governments obligation to pay in full. According to the majority of the court:

> Congress clearly indicated its intent here. It asked [the Government Accountability Office] what funding would be available to make risk corridors payments, and it cut off the sole source of funding identified beyond payments in [to the risk corridor program].

The Federal Circuit's decision in *Moda Health Plan Inc. v. United States*, No. 2017-1994 (Fed. Cir. June 14, 2018), is available at http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-1994.Opinion.6-14-2018.pdf.

The Federal Circuit Court's decision in *Land of Lincoln Mutual Health Ins. Co. v. United States*, No. 2017-1224 (Fed. Cir. June 14, 2018), which adopts its decision in *Moda*, is available at http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-1224.Opinion.6-14-2018.pdf.

CMS Final Rule Reverses Course on Risk Adjustment Payments; Payments to Continue

On July 24, the Centers for Medicare & Medicaid Services ("CMS") published a final rule that would continue the Risk Adjustment Payments under the Affordable Care Act, which is an abrupt reversal of its earlier announcement on July 7 that it planned to discontinue making the payments to insurers. CMS notes in the Final Rule that it "has determined that taking immediate action to allow for the continued operation of the risk adjustment program is imperative to maintain stability and predictability in the individual and small group health insurance markets." The Risk Adjustment Payments have been the recent target of insurers' ire, with multiple Consumer Operated and Oriented Plans having filed suit against CMS over the calculation of the payments in 2016.

The Final Rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-16190.pdf

CMS Publishes Proposed 2019 Physician Fee Schedule

On July 12, the Centers for Medicare & Medicaid Services unveiled the proposed Physician Fee Schedule and Quality Payment Program proposed rules for calendar year 2019. The Proposed Rule introduces a number of coding and payment changes aimed at reducing the administrative burden on physicians and to improve payment accuracy for E/M visits, including: allowing practitioners to choose to document office-outpatient E/M visits using medical decision-making or time instead of applying the 1995 or 1997 E/M documentation guidelines; allowing practitioners to use time as the governing factor in selecting visit level and documenting the E/M visit, regardless of whether counseling or care coordination dominate the visit; allowing practitioners to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting information; and allowing practitioners to simply review and verify certain information in the medical record that is entered by ancillary staff or the beneficiary, rather than re-entering it.

CMS also proposes new single blended payment rates for new and established patients for office/outpatient E/M level 2 through 5 visits and a series of add-on codes to reflect resources involved in furnishing primary care and non-procedural specialty generally recognized services. CMS also proposes to apply a minimum documentation standard where Medicare would require information to support a level 2 CPT visit code for history, exam and/or medical decision-making in cases where practitioners choose to use the current framework, or, as proposed, medical decision-making to document E/M level 2 through 5 visits.

CMS also proposes a multiple procedure payment adjustment that would apply when E/M visits are furnished in conjunction with other procedures and proposes to eliminate the requirement to justify the medical necessity of a home visit in lieu of an office visit.

CMS proposes including payment for two newly defined telehealth services: 1) "Brief Communication Technology-based Services, e.g. Virtual Check-in (HCPCS code GVCI1); and 2) "Remote Evaluation of Recorded Video and/or Images Submitted by the Patient (HCPCS code GRAS1). These two new payments are intended to increase efficiency for practitioners and convenience for beneficiaries.

The Proposed Rule contains a number of additional proposals, including: revising the supervision requirements for Radiological Assistants; discontinuing the functional status reporting requirements for outpatient therapy; establishing two new payment modifiers for services furnished by PT and OT assistants; and aligning the Medicare Shared Savings Program quality measures with the Meaningful Measures Initiative.

The Proposed Rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14985.pdf.

CMS' Fact Sheet on the Proposed Rule is available at: https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-3.

AMA and Medical Groups Speak Out Against CMS Proposal to Consolidate E/M Codes

On August 27, the American Medical Association ("AMA") and approximately 170 other medical groups sent a letter to Seema Verma, Administrator of the Centers for Medicare & Medicaid Services

(“CMS”) in opposition to CMS’s proposal in its 2019 Medicare Physician Fee Schedule to blend payment rates and reducing the number of billing codes for evaluation and management services. Although the letter offers strong support for the agency’s “Patients Over Paperwork” initiative, the groups opposed the proposal to “collapse payment rates for eight office visit services for new and established payments down to two each.” The organization cited concerns about unintended consequences of the rule, including that it would hurt providers in specialties treating the sickest patients or in comprehensive primary care, thereby jeopardizing access to care. They also argued that the multiple services payment reduction policy should not be adopted because valuations of affected codes already take into account multiple services on the same day of service. A separate letter from the American College of Rheumatology (“ACR”) and 120 physician and patient groups sent to CMS on August 28 also criticized the proposal to cut and consolidate the billing codes for evaluation and management services. Echoing some of the same concerns as the AMA letter regarding the proposal’s effects on those providers treating the sickest patients, the ACR letter also notes that the proposed add-on codes, meant to make up for the cuts for complex care, “would not be sufficient to ensure continued patient access, and moreover the application of new codes to some specialties and not others would effectively result in CMS picking winners and losers.”

The AMA letter is found here: https://www.ama-assn.org/170-groups-send-letter-proposed-changes-physician-payment-rule

The American College of Rheumatology letter is found here: https://www.rheumatology.org/Portals/0/Files/Stakeholder-Letter-Medicare-Fee-Schedule-EM-Proposals.pdf

CMS Announces Drastically Reduced ACA Navigator Funding for 2019 Open Enrollment

On July 10, the Centers for Medicare & Medicaid Services announced that it plans to award up to $10 million to Affordable Care Act (“ACA”) Navigators, down from $36 million last year and $63 million the year before. According to CMS, “Enrollment data from previous years show that Navigators failed to enroll a meaningful amount of people through the Federally-facilitated Exchange (FFE), and not nearly enough to justify the millions of federal dollars spent on the program.”

A minimum of $100,000 will be awarded in each of the 34 states on the Federally-facilitated exchange. CMS is adding a new requirement that the awards will be based partly on past years’ performance “to ensure accountability within the program and avoid rewarding grantees that have failed to meet performance measures.”

A press release on the Navigator funding is available at: https://www.cms.gov/newsroom/press-releases/cms-announces-new-funding-opportunity-announcement-federally-facilitated-exchange-navigator-program.

NH Medicare Beneficiaries to Receive New Medicare Cards

In July, the Centers for Medicare & Medicaid Services began to mail new Medicare cards to beneficiaries living in the “Wave 4” states: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont. CMS has completed mailing cards out to Waves 1 and 2 states and will continue to mail new cards out to beneficiaries in Wave 3 states and new beneficiaries nationwide. CMS expects to complete all the mailing by April 2019.

While beneficiaries wait to receive their new cards, suppliers and providers can use either the former Social Security number-based Health Insurance Claim Number or the new alpha-numeric Medicare Beneficiary Identifier (MBI) for all Medicare transactions through December 31, 2019.

Information about the new Medicare cards is available at: https://www.medicare.gov/NewCard/.

OIG Issues Favorable Advisory Opinion for Preferred Hospital Network for Medigap Policies

On July 11, the U.S. Department of Health & Human Services Office of Inspector General ("OIG") issued Advisory Opinion 18-06, in which it reviewed an arrangement regarding the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies (the "Proposed Arrangement"). Under the Proposed Arrangement, an insurance company would contract indirectly with hospitals for discounts (up to 100 percent) on Medicare Part A inpatient deductibles incurred by its policyholders that would otherwise be covered by the insurance company, and, in turn, would provide a premium credit of $100 off the next renewal premium to policyholders who use a network hospital for an inpatient stay.

The OIG found that the Proposed Arrangement did not qualify for protection under the safe harbor for waivers of beneficiary coinsurance and deductible amounts or the safe harbor for reduced premium amounts offered by health plans. Nevertheless, the OIG concluded it would not impose administrative sanctions under the anti-kickback statute because the Proposed Arrangement posed a sufficiently low risk of fraud or abuse. In reaching this conclusion, the OIG reasoned that: (1) neither the discounts nor the premium credits would increase or affect per-service Medicare payments because Part A payments for inpatient services are fixed and unaffected by beneficiary cost-sharing; (2) the Proposed Arrangement would be unlikely to increase utilization because the discounts would only apply to obligations that a policyholder's Medigap insurance would otherwise cover and that the OIG has long held that waiver of inpatient service fees are unlikely to result in significant increases in utilization; (3) the Proposed Arrangement should not unfairly affect competition among hospitals because membership in the preferred hospital network would be open to any accredited, Medicare-certified hospital meeting state law requirements; (4) the Proposed Arrangement would not likely affect professional medical judgment because physicians and surgeons would receive not remuneration and policyholders would be free to go to any hospital without incurring any additional out-of-pocket expense; and (5) the Proposed Arrangement would be transparent, as policyholders would be informed of their freedom to choose any hospital without incurring additional liability or penalty. Finally, the OIG concluded that it would also not impose administrative sanctions under the prohibition on inducements to beneficiaries because it reasoned that although the premium credit to policyholders would induce them to select a particular provider, that the credit would have substantially the same purpose and effect as differential for coinsurance and deductible amounts, which is an exception to the definition of remuneration for purposes of Section 1128A(a)(5) of the Social Security Act.

Advisory Opinion 18-06 can be found here:
https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-06.pdf

OIG Issues Advisory Opinion Approving of Preferred Hospital Network for Medigap Policies

On August 21, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") published Advisory Opinion No. 18-09 regarding the use of a "preferred hospital" network by Medigap policies. Under the proposed arrangement, an insurance company who offers Medigap policies would negotiate with hospitals to provide a discount on otherwise-applicable Medicare inpatient deductibles for the company's Medigap policyholders and would also provide a credit of $100 off the next renewal

premium to policyholders who use a preferred network hospital for an inpatient stay. The insurance company requested an advisory opinion as to whether the proposed arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalties for beneficiary inducements ("CMPs") or would violate the Anti-Kickback Statute ("AKS").

OIG first determined that neither the deductible discounts nor the premium credit would qualify for any AKS safe harbor. Nonetheless, OIG concluded that the proposed arrangement would pose a low risk of fraud or abuse under AKS because : 1) neither the discounts nor the premium credits would increase or affect per-service Medicare payments; 2) it would be unlikely to increase utilization; 3) it would not unfairly affect competition among hospitals because membership in the preferred hospital network would be open to any accredited, Medicare-certified hospital that meets state requirements; 4) it would be unlikely to affect professional medical judgment because the policyholders' physicians and surgeons would receive no remuneration, and the policyholders would remain free to go to any hospital without incurring any additional out-of-pocket expense for their inpatient hospital stay; and 5) the insurance company would inform policyholders of their right to go to any hospital without incurring any additional costs.

OIG concluded that it would not impose sanctions under the CMPs for the proposed arrangement, because the arrangement would present a sufficiently low risk of fraud and would have the potential to lower costs for policyholders.

The Advisory Opinion is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-09.pdf.

HHS Looking to Modernize Stark Law and Anti-Kickback Statute

On July 17 at a hearing before the House Ways and Means Committee, Deputy Secretary of the Department of Health and Human Services ("HHS"), Eric Hargan, testified that HHS is currently examining how fraud and abuse laws can be modernized in ways to enable physicians and healthcare providers to innovate ways to better coordinate patient care in a value-based system. The Centers for Medicare & Medicaid Services ("CMS") issued a Request for Information ("RFI") on June 25, 2018 for input on how the Stark Law may be impeding care coordination and whether exceptions should be revised or expanded and Hargan said HHS would also be issuing an RFI seeking input on similar Anti-Kickback Statute reforms. The Stark RFI seeks input in several specific areas, including those involving entities and referring physicians that participate in "alternative payment models or other novel financial arrangements" and on the utility of risk-sharing arrangements. Comments on the Stark RFI were due August 24. An RFI addressing Anti-Kickback Statute reforms was sent to the Office of Management and Budget on August 6. Hargan said that they will be consulting with the Office of Inspector General as well as with the Department of Justice throughout the process.

On August 24, the U.S. Department of Health and Human Services ("HHS") and the Office of the Inspector General ("OIG") issued a Request for Information ("RFI") seeking input from stakeholders on reforms to the Anti-Kickback Statute ("AKS"). Specifically, HHS and OIG are seeking "to identify ways in which it might modify or add new safe harbors to the anti-kickback statute and exceptions to the beneficiary inducements civil monetary penalty (CMP) definition of 'remuneration' in order to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse." In the RFI, the agencies recognize that the "broad reach of the anti-kickback statute and beneficiary inducements CMP [is] a potential impediment to beneficial arrangements that would advance coordinated care." The agencies are seeking comments on various general topics, including promoting care coordination and value-based care and beneficiary engagement.

Comments are due by October 26, 2018.

The RFI is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-18519.pdf

The recorded hearing, *Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program*, can be watched at the link below: https://waysandmeans.house.gov/event/hearing-on-modernizing-stark-law-to-ensure-the-successful-transition-from-volume-to-value-in-the-medicare-program/

The Stark RFI can be read here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-13529.pdf

Anthem Sued over Emergency Room Policy

On July 17, the American College of Emergency Physicians ("ACEP"), along with the Medical Association of Georgia ("MAG") filed a lawsuit in the U.S. District Court for the Northern District of Georgia against Anthem Inc.'s ("Anthem") Blue Cross Blue Shield of Georgia over Anthem's policy of denying coverage for emergency room services if it later determines that the condition was not an emergency. Anthem has notified policyholders in six states, Georgia, New Hampshire, Indiana, Kentucky, Missouri, and Ohio that claims for emergency room services would not be covered if Anthem determined on retrospective reviews that diagnoses were not truly emergencies. The lawsuit alleges that the policy violates the prudent layperson standard, a federal legal standard that requires insurance companies to cover the costs of emergency care based on a patient's symptoms and not the final diagnosis. It also alleges violations of the 1964 Civil Rights Act alleging that the denials disproportionally affect members of protected classes' access to emergency care. In a press release, Paul Kivela, MD, FACEP, president of ACEP, stated, "[w]e can't possibly expect people with no medical expertise to know the difference between something minor or something life-threatening, such as an ovarian cyst versus a burst appendix."

A press release from the ACEP can be accessed here: http://newsroom.acep.org/2018-07-17-Physician-Groups-Take-Legal-Action-Against-Anthems-Blue-Cross-Blue-Shield-of-Georgia

A copy of the complaint filed by the ACEP and MAG can be found here: https://acep.org/globalassets/sites/acep/media/advocacy/federal-advocacy-pdfs/acepvbcbsga071718.pdf

CMS Proposes 2019 Hospital Outpatient Prospective Payment System and ASC Payment System Rule

On July 25, the Centers for Medicare & Medicaid Services ("CMS") published the proposed rule for updating the Hospital Outpatient Prospective Payment System ("OPPS") and the Ambulatory Surgical Center ("ASC") Payment System. The Proposed Rule updates OPPS payment rates by 1.25 percent and ASC payment rates by 2.0 percent. The Proposed Rule contains several major provisions, including: applying a Physician Fee Schedule (PFS)-equivalent payment rate for the clinic visit service when provided at an off-campus provider-based department (PBD) that is paid under the OPPS; allowing certain CPT codes outside of the surgical code range that directly crosswalk or are clinically similar to procedures within the CPT surgical code range to be included on the ASC covered procedure list ("CPL") and also adding certain cardiovascular codes to the ASC CPL; adopt a policy to pay average sales price minus 22.5 percent for

340B-acquired drugs furnished by non-excepted off-campus provider-based departments; reducing the number of measures ASCs and hospital outpatient departments are required to report under the Ambulatory Surgical Center Quality Reporting and Hospital Outpatient Quality Reporting Programs; and paying for services in new clinical families of services furnished at excepted off-campus PBDs under the Physician Fee Schedule instead of the OPPS.

Comments on the Proposed Rule are due by September 24, 2018.

The Proposed Rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-15958.pdf.

CMS' Fact Sheet for the Proposed Rule is available at: https://www.cms.gov/newsroom/fact-sheets/cms-proposes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center.
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FDA Publishes Guidance on Use of EHR in Clinical Investigations

On July 18, the Food and Drug Administration ("FDA") published guidance titled "Use of Electronic Health Record Data in Clinical Investigations." According to FDA, the guidance "is intended to assist sponsors, clinical investigators, contract research organizations, institutional review boards (IRBs), and other interested parties on the use of electronic health record data in FDA-regulated clinical investigations." The guidance provides non-binding recommendations on "Interoperability and Integration of Systems," "Best Practices for Using EHRs in Clinical Investigations," and "Inspection, Recordkeeping, and Record Retention Requirements."

FDA's guidance is available at: https://www.fda.gov/ucm/groups/fdagov-public/%40fdagov-drugs-gen/documents/document/ucm501068.pdf.

CMS Publishes Final Rule on Changes to Hospital IPPS, LTCH PPS

On August 2, the Centers for Medicare & Medicaid Services ("CMS") published a final rule updating the Medicare Hospital Inpatient Prospective Payment System ("IPPS") and the Long-Term Acute Care Hospital ("LTCH") Prospective Payment System ("PPS"). The Final Rule includes a number of major provisions including: overhauls to the Medicare and Medicaid Promoting Interoperability Programs in order to better achieve program goals; requiring that hospitals make public a list of their standard charges via the Internet in a machine readable format; reducing the total number of measures acute care hospitals are require to report across the four quality and value-based purchasing programs, in accordance with the Meaningful Measures Initiative; and incorporating a variety of changes meant to reduce the burden on hospitals. The Final Rule also includes information about the Rural Community Hospital Demonstration and the Frontier Community Health Integration Project Demonstration.

CMS estimates that the changes to the IPPS in the Final Rule will result in an increase in Medicare spending on hospital services of approximately $4.8 billion in fiscal year 2019. CMS estimates that the changes to the LTCH PPS will result in a 0.9 percent increase in payments in fiscal year 2019, equal to approximately $39 million.

The Final Rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-16766.pdf.

CMS' Fact Sheet on the Final Rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2019-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0.

OIG Issues Report on Unimplemented Recommendations to HHS

On July 31, the U.S. Department of Health & Human Services ("HHS"), Office of the Inspector General published a report titled "Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented Recommendations," offering its annual look at its recommendations to HHS agencies that have not been implemented. The report contains the 25 unimplemented recommendations, broken down by specific program. The unimplemented recommendations for Medicare Parts A & B include: that CMS should seek legislative authority to change Medicare's method for paying for therapy in skilled nursing facilities; that CMS should implement the statutory mandate requiring surety bonds for home health agencies; and that CMS should analyze the potential impacts of counting time spent as an outpatient toward the 3-night requirement for skilled nursing facility services. The unimplemented recommendations for Medicare Parts C & D are that CMS should collect comprehensive data from Part D plan sponsors to improve oversight of its efforts to identify potential fraud and abuse, and that CMS should require Medicare Advantage plans to include ordering and referring provider identifiers in their encounter data. The top unimplemented recommendations for Medicaid include: that CMS should pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid drug rebate program; that CMS should ensure that national Medicaid data are complete, accurate and timely; and that CMS should require states to either enroll personal care services attendants as providers or require them to register with the state Medicaid agencies and assign them unique identifiers.

OIG's report is available at: https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2018.pdf.

Detroit Hospital Settles Anti-Kickback, Stark Law Claims for $85 Million

On August 2, the Department of Justice ("DOJ") announced a $84.5 million settlement with William Beaumont Hospital ("WBH") in Detroit, Michigan to settle allegations under the False Claim Act. The settlement resolved four qui tam actions that alleged WBH paid compensation in excess of fair market value and free or below-fair market value office space and employees to certain physicians in exchange for referrals from the physicians to WBH in violation of the Anti-Kickback Statute and the Stark Law. The settlement also included a five-year corporate integrity agreement with the U.S. Department of Health and Human Services Office of the Inspector General.

DOJ's announcement of the settlement is available at: https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising.

CMS Publishes Final Payment Rule for Skilled Nursing Facilities

On July 31, the Centers for Medicare & Medicaid Service ("CMS") published a final rule regarding payment for skilled nursing facilities ("SNFs"). The final rule includes a number of changes, including: modernizing the SNF prospective payment system case-mix classification system to improve the incentives to treat the needs of the whole patient, instead of focusing on the volume of services the patient receives; adding a factor for evaluating measures for removal that takes into account costs associated with a measure and weighs them against the benefit of its continued use; adjusting the SNF value-based purchasing scoring methodology. CMS estimates that the aggregate impact of the Final Rule will be an increase of $820 million in Medicare payments to SNFs.

The Final Rule is available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-16570.pdf.

CMS' Fact Sheet for the Final Rule is available at: https://www.cms.gov/newsroom/fact-sheets/medicare-issues-fiscal-year-2019-payment-policy-changes-skilled-nursing-facilities.

CMS Publishes Final Rule for FY 2019 IRF Payments

On July 31, the Centers for Medicare & Medicaid Services published a Final Rule for the inpatient rehabilitation facility ("IRF") payment system. The Final Rule follows an earlier Request for Information from CMS that solicited ideas to provide greater flexibilities and efficiencies in the IRF Prospective Payment System. One of the major provisions in the Final Rule are changes to the IRF coverage requirements, including: allowing the post-admission physician evaluation to count as one of the face-to-face physician visits; allowing the rehabilitation physician to lead the interdisciplinary team meeting remotely without any additional documentation requirements; and removing a duplicative admission order documentation requirement. The Final Rule also removes the Functional Independence Measure Instrument and associated Function Modifiers from the IRF-Patient Assessment Instrument ("PAI") because they collect data that overlaps with the data collected in the Quality Indicators section of the IRF-PAI. The Final Rule removes two measures from the IRF Quality Reporting Program in accordance with the Meaningful Measures Initiative: National Healthcare Safety Network Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure; and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay).

CMS estimates that the aggregated changes in the Final Rule will result in an overall payment increase of 1.3 percent, or $105 million.

The Final Rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-16517.pdf.

CMS' Fact Sheet on the Final Rule is available at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-2019-medicare-inpatient-rehabilitation-facility-prospective-payment-system-final-rule.

OIG Publishes Report Highlighting Vulnerabilities in Medicare Hospice Benefit

In July, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") published a report titled "Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio," in which it highlighted its history of identifying vulnerabilities in the hospice program. Notably, OIG has previously identified that hospices do not always provide needed services to beneficiaries and sometimes provide poor quality care. Additionally, OIG has found that beneficiaries and their families and caregivers often do not receive crucial information to make informed decisions about their care. OIG has also identified hundreds of millions of dollars in inappropriate hospice billing, including billing for an expensive level of care when the beneficiary does not need it.

OIG's report includes recommendations of 15 specific actions that relate to 7 areas of improvement, including analyzing claims data to inform the survey process; seeking statutory authority to establish additional, intermediate remedies for poor hospice performance; and ensuring that a physician is involved in the decision to start and continue general inpatient care.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf.

CMS Issues Proposed Rule for ACOs in Medicare Shared Savings Program

On August 9, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule referred to as the "Pathways to Success" for accountable care organizations ("ACOs") and deemed a "new direction" by CMS for the Medicare Shared Savings Program. Citing issues with the one-sided model, one in which ACOs do not take financial risk if costs exceed budgets but receive a share in any savings, a CMS press release stated that although the program was intended to decrease spending, an analysis has found increases in net spending for CMS and taxpayers. CMS explains in a fact sheet that the proposed rule is intended to encourage ACOs "to transition to two-sided models (in which they may share in savings and are accountable for repaying shared losses), increase savings for the Trust Funds and mitigate losses, reduce gaming opportunity and increase program integrity, and promote regulatory flexibility and free-market principles." CMS also stated that the proposals would improve beneficiary engagement and care, with a particular emphasis on combatting opioid addiction. Public comments are due on the proposed rule by October 16, 2018.

The CMS press release about the proposed rule is found here: https://www.cms.gov/newsroom/press-releases/cms-proposes-pathways-success-overhaul-medicares-aco-program

A CMS fact sheet about the proposed rule can be read here: https://www.cms.gov/newsroom/fact-sheets/proposed-pathways-success-medicare-shared-savings-program

The proposed rule in full is here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-17101.pdf

OIG Allows GPO to Provide Services to Affiliated Entities

On July 30, the U.S. Department of Health & Human Services Office of Inspector General ("OIG") issued Advisory Opinion 18-07, in which it reviewed an arrangement whereby a group purchasing organization ("GPO") would serve as the purchasing agent on behalf of GPO-affiliated entities on the same terms and conditions as those that apply to unaffiliated entities (the "Proposed Arrangement")

The OIG found that the Proposed Arrangement could generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, but the OIG concluded it would not impose administrative sanctions under the anti-kickback statute because the Proposed Arrangement would not materially increase the risk of fraud or abuse. In reaching this conclusion, the OIG reasoned that: (1) the GPO already exists as a GPO that complies with the GPO safe harbor (although the Proposed Arrangement would cause it to fall outside of the definition of "GPO" in the safe harbor); (2) the majority of the individuals and entities served by the GPO would be unaffiliated and the terms would be the same whether affiliated or not; and (3) the parent organization is an independent, public company that owns a number of legally distinct hospitals and other health-care related organizations, as distinguishable from wholly owned subsidiaries of a single corporate entity seeking referral fees.

Advisory Opinion 18-07 can be found here: https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-07.pdf

CMS Issues Proposed Rule for Risk Adjustment Payments

On August 8, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule extending risk adjustment payments using methodology previously established for the 2018 benefit year, which uses the statewide average premium in the transfer formula. In February, 2018, the U.S. District Court for the District of New Mexico vacated the use of the statewide premium for the 2014 through 2018 benefit years, reasoning that the government had not adequately explained the methodology to ensure it maintained the budget neutrality of the program. The rule proposes to use the same methodology and provides an additional explanation about the use of the statewide average premium and the budget neutral nature of the risk adjustment program. Comments on the proposed rule were due September 7.

A CMS press release about the proposed rule can be found here: https://www.cms.gov/newsroom/press-releases/cms-issues-proposed-additional-rule-address-risk-adjustment-program-2018-benefit-year

The proposed rule can be read in full here: https://www.gpo.gov/fdsys/pkg/FR-2018-08-10/pdf/2018-17142.pdf

OIG Finds CMS Open Payments Data Complete

On August 8, the U.S. Department of Health & Human Services Office of Inspector General ("OIG") issued a report titled *Open Payments Data: Accuracy, Precision, and Consistency in Reporting*, in which it found that less than 1 percent of the 11.9 million records published on the Open Payment website in 2015 were missing required data elements. Nonetheless, OIG did note that there were records where it identified inaccurate, imprecise, and inconsistent information, such as records that contain drug and device names that do not match database definitions; payment dates from a different reporting year; and national drug codes ("NDCs") not found in Food and Drug Administration databases or other resources. The OIG recommends that the Centers for Medicare & Medicaid Services ("CMS") take the following steps: "(1) ensure that records contain all required data; (2) strengthen validation rules and revise data-element definitions so that actual drug names and devices are reported; (3) revise the definition of the device-name data element so that the information reported is required to be more specific; and (4) ensure that manufacturers and group purchasing organizations report valid NDCs for drugs." CMS agreed with all the recommendations.

The report can be read at: https://oig.hhs.gov/oei/reports/oei-03-15-00220.pdf

OIG Allows Mutual Aid Agreement for Backup Emergency Ambulance Services

On August 7, the U.S. Department of Health & Human Services Office of Inspector General ("OIG") issued Advisory Opinion 18-08, in which it reviewed a proposed arrangement by six government-operated fire departments and fire protection districts (the "Fire Departments") to enter into a mutual aid agreement to provide backup ambulance services and to bill according to billing practices in the jurisdiction where the services are rendered (the "Proposed Arrangement"). Funding for the Fire Departments' respective budgets comes from a mix of user fees and local taxes, and the Fire Departments bill patients' insurers, including Medicare and Medicaid. Out of the six Fire Departments, four departments bill both residents and nonresidents for applicable cost-sharing amounts for emergency ambulance services provided in their respective jurisdictions, while two Fire Departments only bill nonresidents for cost-sharing amounts, treating local tax revenue from residents as payment in full. Under the Proposed Arrangement, the six Fire Departments propose to enter into a mutual aid agreement to provide backup emergency services, where the Fire Department providing the backup services would bill patients according to the billing practices of the Fire Department in the jurisdiction where services were provided.

The OIG found that the Proposed Arrangement implicates the anti-kickback statute because the Fire Departments would not bill certain patients (including Federal health care program beneficiaries) for cost-sharing amounts. However, the OIG concluded that the Proposed Arrangement presents a low risk of fraud and abuse under the anti-kickback statute because (1) the Fire Departments would provide backup emergency ambulance services only when a requesting Fire Department has exhausted their resources, and without regard to the number of Federal health care program beneficiaries receiving services or the Federal health care program reimbursement (therefore not taking into account the volume or value of Federal health care program referrals or other business generated among the parties); and (2) it would be unlikely to either increase utilization of emergency ambulance services or increase costs to the Federal health care programs because individuals within a jurisdiction would be treated the same for billing purposes no matter which Fire Department responded. The OIG also concluded that the Proposed Arrangement would not implicate the prohibition against beneficiary inducements because the waiver of cost-sharing amounts would not influence individual to receive ambulance services from a particular ambulance supplier.

Advisory Opinion 18-08 can be found here: https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-08.pdf

Court Approves $115 Million Anthem Data Breach Settlement

On August 15, a U.S. District Court judge in the Northern District of California gave final approval for the $115 million settlement in a class action against Anthem Inc. related to its 2015 data breach of the protected health information of 78.8 million insureds. The court had preliminarily approved the settlement on August 25, 2017. Since that date, the settlement has been amended to extend certain credit monitoring services. The effective date of the settlement, if there are no appeals, is September 18, 2018.

Please see the following link for further details about the settlement, including links to the final order: http://www.databreach-settlement.com/

OIG: CMS Double-Paid for Certain Radiation Therapy Planning

In August, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published a report titled: "Medicare Improperly Paid Hospitals Millions of Dollars for Intensity-Modulated Radiation Therapy Planning Services." In the report, OIG identified roughly $25 million paid by Medicare for certain therapy planning services that were also included in bundled payments to providers, effectively double paying for the services. While a claim processing edit exists to catch claims for the individual services and the bundled services that are submitted on the same day, there is no edit that would catch claims submitted for the separate therapy services days before the bundled claim is submitted. OIG recommended that the Centers for Medicare & Medicaid Services ("CMS") implement an edit to prevent improper payments for the therapy planning services that are billed before (e.g., up to 14 days before) the procedure code for the bundled payment is billed. OIG also recommended that CMS work with Medicare contractors to educate hospitals on properly billing for these services.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region9/91602033.pdf.

OIG: Medicare Paid Up to $1.9 Million in Improper Medicare Payments for Emergency Ambulance Transports

In August, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published a report titled: "Medicare Made Improper and Potentially Improper Payments for Emergency Transports to Destinations Other Than Hospitals or Skilled Nursing Facilities." The report states that Medicare made improper payments totaling $975,154 for transports to destinations that were not covered by Medicare for either emergency or nonemergency ambulance transports, including the identified ground mileage associated with the transports, and made potentially improper payments totaling $928,092 for transports that may not have met Medicare coverage requirements or might have been paid by Medicare as nonemergency ambulance transports.

OIG recommends that the Centers for Medicare and Medicaid Services ("CMS") direct Medicare contractors to recover the identified overpayments occurring within the 4-year claim-reopening period, and that CMS review claim lines that are within that period for emergency ambulance transports that might have been covered by Medicare for nonemergency ambulance transports and recover any improper payments identified.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region9/91703017.pdf.

GOP Senators Introduce Legislation to Protect Coverage of Pre-Existing Conditions

On August 23, several Republican Senators introduced legislation titled *Ensuring Coverage for Patients with Pre-Existing Conditions Act*. The purpose of the legislation, according to a press release from Senator Thom Tillis (R-NC), is to "guarantee Americans have equal health care coverage, regardless of their health status or pre-existing conditions." Motivation for the legislation comes as oral arguments in *Texas v. United States*, the most recent legal effort to undue the Affordable Care Act ("ACA"), began on September 5, 2018. The legislation prohibits discrimination by insurers against beneficiaries with pre-existing conditions, including increased premiums. However, critics of the legislation say that it does not do enough to provide the same protections to those with pre-existing conditions as those found under the ACA. A joint statement released from 25 patient and consumer advocate groups on September 4, 2018, said of the legislation: "We appreciate that this legislation would prohibit the denial of coverage and rating based on health status. However, it would not ban pre-existing condition exclusions and would remove rating restrictions based on age, gender, tobacco use, or occupation. This means that many individuals could still face higher premiums and out-of-pocket costs and, even if enrollees paid the increased premiums for many months, they could still be denied benefits because of a pre-existing condition.

Senator Tillis' press release and link to the legislation can be found here:
https://www.tillis.senate.gov/public/index.cfm/2018/8/senators-introduce-legislation-to-protect-americans-with-pre-existing-conditions

The patient and consumer advocate joint statement can be read here:
https://newsroom.heart.org/news/senate-health-care-bill-would-not-sufficiently-protect-patients-with-pre-existing-conditions

Drug Diversion Allegations Result in $4.3 Million Settlement for University of Michigan

On August 30, U.S. Attorney for the Eastern District of Michigan, Matthew Schneider, announced that the University of Michigan Health System ("UMHS") agreed to pay a record $4.3 million to settle allegations that it failed to comply with regulations under the Controlled Substances Act ("CSA"). The settlement is the largest in the United States resulting from allegations of drug diversion at a hospital and comes after years of investigation by the Drug Enforcement Agency ("DEA") into UMHS's handling of

controlled substances. The investigation was triggered in 2013 after two UMHS employees, a nurse and anesthesiology resident, overdosed on opioids, including fentanyl, at a UMHS facility. The nurse's overdose was fatal. The investigation found that UMHS failed to secure DEA registrations at 15 off-campus ambulatory care locations, which received narcotics from the main hospital and dispensed them to patients, resulting in all of the distributions from the hospital to the ambulatory care locations, and the subsequent dispensing by the ambulatory care locations to patients, being unlawful. The DEA also determined that there was deficient recordkeeping of controlled substances, as well as a failure by UMHS to notify the DEA of certain instances of theft or significant losses of controlled substances.

The press release from the U.S. Attorney's Office can be accessed here: https://www.justice.gov/usao-edmi/pr/eastern-district-michigan-announces-record-setting-hospital-drug-diversion-civil

Federal Court in South Carolina Enjoins Government from Recouping Alleged Overpayments While ALJ Appeal Pending

On August 21, the U.S. District Court for the District of South Carolina granted a chiropractic practice a temporary restraining order ("TRO") enjoining the recoupment of the practice's alleged overpayment while it is waiting for its appeal to be heard by an administrative law judge ("ALJ"). The alleged overpayments are for $5.6 million in Part B claims and another $1.02 million in durable medical equipment claims, found by a Zone Program Integrity Contractor ("ZPIC") investigation. Although the provider reduced the overpayment amount during the second-level of administrative appeal, the Centers for Medicare & Medicaid Services ("CMS") had withheld $1.8 million in payments while the appeal was pending. The court found that the backlog of cases at the ALJ far beyond the statutory deadline deprived the provider of due process and that its risk of harm from the erroneous deprivation of its property interest in the Medicare payments without an ALJ hearing was substantial. The court concluded the plaintiff was likely to prevail on the merits of its procedural due process claim, would likely go out of business if recoupment continued, and the balance of equities was in the provider's favor because while the government would suffer no harm, the provider served an underserved area, and therefore the public interest was served by granting the TRO.

The court's order in full can be read here: https://www.leagle.com/decision/infdco20180822e98

CMS Issues New Rules for Medicare Appeals Before the PRRB

On August 29, the Centers for Medicare & Medicaid Services ("CMS") issued "Version 2.0" of the "Provider Reimbursement Review Board Rules" for Medicare appeals. Major changes to the rules include the addition of a new electronic filing system for new and currently open cases that allows for submission of documents until 11:59 p.m. (EST) on the due date, and a new requirement that parties must file a preliminary position paper with the Provider Reimbursement Review Board in addition to the current requirement that they send them to the opposing party.

The new rules are available at: https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/IssuePrintVersion.aspx?Date=September%2007%202018&IsPrintIssue=True.

Following Dismissal, Hospitals Re-File 340B Lawsuit

On September 5, the American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals, along with three hospital plaintiffs, refiled their lawsuit

challenging cuts made by the U.S. Department of Health and Human Services ("HHS") to the 340B drug discount program. HHS issued a final rule in 2017 that drastically cut the reimbursement rate for drugs that hospitals receive at a discounted price, citing a concern that hospitals were not adequately passing on the discount savings. Hospitals have pushed back against the rule, arguing that the reimbursement cut denies them essential funding.

In July, the District Court dismissed the lawsuit because it concluded that the plaintiffs lacked standing to challenge the law, since none of the hospitals had yet presented a claim for reimbursement at the reduced rate. The refiled complaint alleges that the hospitals have now filed claims at the lower rate that have progressed through the appeals process.

Information on the refiled lawsuit is available from the American Hospital Association at: https://www.aha.org/legal-documents/2018-09-05-hospital-groups-refile-lawsuit-reverse-cuts-340b-hospitals?utm_source=newsletter&utm_medium=email&utm_content=09052018-at-pub&utm_campaign=aha-today.

STATE DEVELOPMENTS

New Commissioner of NH Department of Insurance Begins Term

Newly appointed Commissioner of the Department of Insurance, John Elias, began his five-year term on June 11, 2018 replacing Commissioner Roger Sevigny who had served in the role for 16 years. Commissioner Elias first joined the Department of Insurance in 2016 as the Director of Property and Casualty Insurance and was them promoted to Assistant Commissioner. According to a press release from the Department, his stated priorities include "regulatory modernization, operational efficiency and effectiveness in the pursuit of regulatory value, and the use of data to promote market transparency and to improve regulatory accountability and success in the reduction of public harms."

Three Insurers Offering Plans in the NH Health Care Marketplace in 2019

Anthem, Harvard Pilgrim and Ambetter (NH Healthy Families) have all applied to continue offering coverage in the 2019 health insurance marketplace that was formed under the Affordable Care Act. Most of the state's hospitals are offered in all three networks and all are offered in at least one.

New Rule Governing Network Adequacy Approved

On June 15, the Joint Legislative Committee on Administrative Rules approved the Department of Insurance's proposed network adequacy rule. The implementation of this rule will make New Hampshire the first state in the nation to use all-payer claims data to evaluate network adequacy. In its press release, the Department states that the rule uses a quantitative, service-based approach to evaluating network adequacy. It will allow the Department to compare various networks and allow it to distinguish network deficiencies from gaps in the overall coverage.

The rule may be found at: http://www.gencourt.state.nh.us/rules/state_agencies/ins2700.html

2018 LEGISLATIVE UPDATE

***HB 1102-FN** This bill authorizes the commissioner of the department of health and human services to contract with a physician certified by the Academy Society of Addiction Medicine to review medication assisted treatment in New Hampshire. Passed by the House with Amendment. The amendment allows

the HHS Commissioner to contract with multiple physicians, permits the physician(s) to be certified from one of multiple accrediting bodies, and describes the consultant's role in more general terms. The bill was introduced in the Senate which passed the bill with amendment on non-related new provisions. The House did not concur with the Senate amendments. A Committee of Conference was convened and voted to adopt the version of the bill passed by the House. Both the House and Senate voted to adopt the Committee of Conference report. **The bill was signed by the Governor on June 21, 2018 and became effective on August 20, 2018.**

HB 1418-FN This bill requires the commissioner of the department of health and human services, in consultation with the insurance commissioner, to develop a list of certain critical prescription drugs for purposes of cost control and transparency. Under this bill, the commissioner shall make an annual report on prescription drugs and their role in overall health care spending in New Hampshire. Passed with Amendment by the House. The amendment provides for the creation of a Commission to Study Greater Transparency in Pharmaceutical Costs and Drug Rebate Programs. Passed with Amendment by the Senate. House concurred with Senate Amendment. The amended bill reduces the representation of the Study Commission and adds a requirement that the Study Commission also study the role pharmacy benefit mangers play in the cost, administration, and distribution of prescription drugs.
Signed by the Governor. Section 2 effective November 1, 2018; remainder effective upon signing, July 2, 2018.

HB 1465: This bill requires Medicare supplemental insurance policies to provide coverage for hearing aids. Introduced and referred to House Commerce Committee. Referred for interim study by the House. **Interim Study Subcommittee Work Session scheduled for September 18, 2018.**

HB 1468: This bill establishes a commission to study legislative oversight activities related to the department of health and human services. Introduced and referred to House HHS Committee. Voted Ought to Pass by the House. The amendment extends the date for the study committee to report by one year to November 1, 2019 and repeals the study committee on the same date. Introduced and referred to Senate HHS Committee which voted Ought to Pass with Amendment. The Amendment requires an interim report by the study commission by November 1, 2019 and a final report by November 1, 2020 and repeal the study commission on November 1, 2020. The bill was referred to the Senate Finance Committee which voted Ought to Pass with Amendment. The Senate then voted Ought to Pass with Amendment. The House concurred with the Senate amendments and the bill was enrolled. The amendment was a non-germane amendment to establish a moratorium on licenses for new health care facilities and an increase in licensed capacity in existing facilities, except for rehabilitation facilities whose sole purpose is to treat individuals for substance use disorder or mental health issues. **Signed by the Governor on June 25, 2018. Effective upon signing except Section 2 which is effective November 1, 2020.**

HB 1471: This bill clarifies the law relating to telemedicine services. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the Committee and by the full House. Referred to House Commerce and Consumer Affairs Committee. The amendment clarified that the reimbursement rates will be the same as for services provided in the provider's office or facility, "provided that such rates do not exceed rate for in-person consultation at the originating site." The House passed the bill with another amendment. The amended bill eliminates the proposed provision regarding reimbursement rates. The bill instead establishes a committee to study health care reimbursement for telemedicine and telehealth. Introduced in the Senate and referred to the Senate HHS Committee. Voted

Ought to Pass by Senate. **Signed by the Governor on June 18, 2018. Sections 1-3 effective August 17, 2018. Remainder effective upon signing.**

HB 1506-FN This bill: I. Establishes the regulation and licensure of assistant physicians by the board of medicine. II. Regulates their practice through assistant physician collaborative practice arrangements. III. Establishes a grant program in the department of health and human services to provide matching funds for primary care clinics in medically underserved areas utilizing assistant physicians. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment replaces "assistant physicians" with "graduate physicians." Introduced and referred to the Senate HHS Committee which voted Ought to Pass with Amendment. The Amendment completely eliminates the text of the original bill and replaces it with language amending RSA 126-T, a statute related to the Commission on Primary Care Workforce Issues. It expands the membership of the commission, changes the scope of the review and extends the due dates for a report. Voted Ought to Pass with Amendment by the Senate. The House concurred with the Senate amendment and the bill was enrolled. **Signed by the Governor on June 12, 2018. Effective upon signing.**

HB 1530: This bill adds a requirement for submission of criminal history records prior to licensure or certification by an allied health professional governing board. Introduced, referred to House Executive Departments and Administration Committee and sent to subcommittee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment permits applicants for licensure to be employed in an allied health profession on a conditional basis for up to 90 days while awaiting the results of a criminal history record check, subject to certain requirements. Introduced and referred to the Senate Committee on Executive Departments and Administration. Voted Ought to Pass with Amendment by the Committee and Senate. The bill was enrolled. The amendment changes the criteria for conditional employment. **Signed by the Governor on June 12, 2018; Effective August 11, 2018.**

HB 1571: This bill authorizes the board of nursing to operate or contract for an alternative recovery monitoring program for nurses impaired by substance use disorders or mental or physical illness. Introduced and referred to House Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment reconfigures the proposed statutory language and adds a provision for the board of nursing to promulgate rules to implement the statute. Introduced and referred to Senate Committee, Executive Departments and Administration. Voted Ought to Pass by Committee and by the full Senate. **Signed by the Governor on June 18, 2018; Effective August 17, 2018.**

HB 1577: This bill provides for the regulation of the use of general anesthesia, deep sedation, or moderate anesthesia by dentists and the reporting of adverse events. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment adds a provision for dental insurance coverage for children under 13 years of age for dental procedures requiring anesthesia. Introduced and referred to Senate HHS Committee. The Senate voted Ought to Pass with Amendment. The House concurred with the amendment. The amendment allowed the board to exempt dentists with certain board certifications from the requirement to have a dedicated anesthesia provider to monitor anesthesia for children under the age of 13. **Signed by the Governor June 8, 2018; Effective August 7, 2018.**

HB 1606: This bill makes various changes to the regulation of doctors of naturopathic medicine including the scope of practice of naturopaths and the procedures of the naturopathic board of examiners.

Introduced and referred to House Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment provides for the election of a chairperson of the board of examiners, changes the quorum for the board from four members to three, and increases the frequency of submission by the licensee of proof of continuing education. Voted Ought to Pass by the Senate. **Signed by the Governor on May 25, 2018; Effective July 24, 2018.**

HB1654: This bill prohibits holding an injured driver or passenger responsible for medical costs determined to not be reasonable. Introduced and referred to House Commerce Committee. Voted Ought to Pass by the Committee and the full House**.** Introduced and referred to Senate Commerce Committee. Voted Ought to Pass by the Senate. **Signed by the Governor; Effective August 7, 2018.**

HB1664: This bill clarifies the eligibility to reappoint a member of a governing board of an allied health profession to an additional full term. Introduced and referred to House Executive Departments and Administration Committee. Voted Ought to Pass by the Committee and the full House. **Voted Ought to Pass by the Committee and Senate. Signed by the Governor; Effective July 24, 2018.**

HB1665: This bill clarifies the authority of the governing boards of allied health professionals concerning individuals who are certified by such boards. Introduced and referred to House Executive Departments and Administration Committee. Voted Ought to Pass by the Committee and the full House. **Introduced and referred to Senate Executive Departments and Administration. Voted Ought to Pass by Committee and the full Senate. Signed by the Governor; Effective July 24, 2018.**

HB 1707-FN: This bill requires the physician who performs an abortion, or the referring physician, to provide a pregnant woman with certain information at least 24 hours prior to the abortion, and to obtain her consent that she has received such information. **Introduced and referred to House HHS Committee. House voted to refer the bill for interim study.**

HB 1740: This bill repeals the provision relating to the costs of blood testing orders when certain individuals have been exposed to another person's bodily fluids. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment does not repeal the current statute but rather eliminates the requirement that private health or automobile insurance be responsible for payment when there is no workers' compensation coverage. Introduced and referred to Senate Commerce Committee. **Senate Voted Ought to Pass. Signed by the Governor June 8, 2018; Effective upon signing.**

HB 1741: This bill allows an insured to pay the least amount for covered prescription medication under the managed care law. Introduced and referred to House Commerce Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment deletes the entire bill and provides only for a new definition for "contracted copayment." **Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee. Bill subsequently Laid on Table.**

HB 1746: This bill prohibits certain practices of pharmacy benefit managers. Introduced, referred to House Commerce Committee and sent to subcommittee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment adds a repeal of the prohibition to take effect on June 30, 2020. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee and Senate. Signed by the Governor on May 25, 2018; Section 2 effective June 30, 2020; Remainder effective upon signing.**

HB 1751: This bill requires insurance coverage for treatment for pediatric autoimmune neuropsychiatric disorders. **Introduced, referred to House Commerce Committee and sent to subcommittee. Referred for interim study by the House.**

HB 1769-FN: This bill prohibits discrimination against physicians based on maintenance of certification. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment makes a small change to those entities that are prohibited from differentiating between physicians based on a physician's maintenance of certification. **Introduced and referred to Senate HHS. Senate referred the bill for interim study.**

HB 1782-FN This bill establishes a committee to study insurance payments to ambulance providers and balance billing by ambulance providers. The committee must report its findings and recommendations on or before November 1, 2018. Passed by the House and Senate. **Signed by the Governor on May 25, 2018; Effective upon signing.**

HB 1791-FN: This bill declares that a contract between an insurance carrier or pharmacy benefit manager and a contracted pharmacy shall not contain a provision prohibiting the pharmacist from providing certain information to an insured. Introduced and referred to House Commerce Committee. Voted Ought to Pass by Committee. Voted Ought to Pass by the Committee and the full House. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by the Senate. The House concurred with the Senate amendment and the bill was enrolled. The amendment establishes requirements for the dispensing and substitution of biological products by pharmacists. **Signed by the Governor on June 7, 2018; Section 5 effective upon signing; Remainder effective January 1, 2019.**

HB 1809-FN: This bill prohibits balance billing under the managed care law. This bill is the result of the committee established in 2017. It prohibits hospital-based providers from billing patients for fees other than copayments, deductibles, or coinsurance if the service is performed in a hospital or ambulatory surgery center that is in-network under the patient's insurance plan. Introduced, referred to House Commerce Committee and sent to subcommittee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment moves the new statutory language to a different chapter and updates internal references. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by the Senate. The House concurred with the Senate amendment and the bill was enrolled. The amendment requires the commissioner of HHS to provide an annual report on network adequacy to the House and Senate. It also adds new language regarding the definition of emergency services to add a prudent layperson standard. **Signed by the Governor; Effective July 1, 2018.**

HB 1816-FN: This bill requires the commissioner of the department of health and human services to adjust the Medicaid managed care program by requesting a certain waiver from the Centers for Medicare and Medicaid Services, implementing enhanced eligibility screening, and requiring managed care organizations to meet the federal medical loss ratio provision with any surplus to be deposited into the general fund. This bill also eliminates certain provisions under step 2 of the program. Introduced, referred to House HHS Committee and sent to subcommittee. Voted Ought to Pass with Amendment by the Committee. The bill as amended declares that the remaining unimplemented phases of step 2 of the program shall not be implemented and requires the commissioner to implement enhanced eligibility screening and require managed care organizations to meet the Federal medical loss ratio provision with any nonfederal surplus to be deposited into the general fund. Introduced and referred to Senate HHS

Committee. The Senate voted Ought to Pass with Amendment. The House concurred with the amendment and the bill was enrolled. The amended bill as passed removes the requirement that managed care organizations meet the federal medical loss ratio. It also permits HHS to develop a plan to offer on a voluntary basis PACE and/or ACO models to provide non-fee-for-service basis nursing facility and home care services. **Signed by the Governor on June 25, 2018; Section 1 effective June 25, 2018; Remainder effective August 24, 2018.**

HB 1822-FN: This bill allows pharmacists to dispense hormonal contraceptives pursuant to a standing order entered into by health care providers. This bill is the result of the commission established pursuant to 2017, 23. Introduced and referred to House HHS Committee where it was Voted Inexpedient to Legislate. The full House rejected the Committee's vote and instead voted Ought to Pass. It was then sent to the House Commerce Committee to assess its economic impact. Committee and House voted Ought to Pass with Amendment. The amendment changes the language related to contraceptive coverage to reference payment for an initial screening performed by the pharmacist rather than medication therapy management services. Senate voted Ought to Pass. **Signed by the Governor; Sections 4-7 effective January 1, 2019; Remainder effective August 7, 2018.**

SB 189: This bill requires insurance policies to cover 3-D mammography. The bill was voted Ought to Pass by the Senate. It was introduced in the House and referred to the Commerce Committee. The committee voted to refer the bill for interim study but the full House voted Ought to Pass. **Signed by the Governor; Effective August 7, 2018.**

SB 313-FN: This bill establishes the New Hampshire Granite Advantage Health Care Program which shall replace the current New Hampshire health protection program. Under this program, those individuals eligible to receive benefits under the Medicaid program and newly eligible adults shall choose coverage offered by one of the managed care organizations contracted as vendors under the Medicaid program. Introduced and referred to Senate Finance Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The bill as amended provides for the establishment of the Granite Workforce Pilot Program and increases the amount of liquor revenues to be deposited into the Alcohol Abuse Prevention and Treatment fund and provides that moneys deposited into the fund shall be transferred to the Granite Advantage Health Care Trust Fund for substance use disorder prevention, treatment, and recovery. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by House. Senate concurred with House amendment. **Signed by the Governor on June 28, 2018 with different sections becoming effective between December 31, 2018 through December 31, 2023.**

SB 327: This bill removes the requirement that a member of the medical review subcommittee be from the Board of Medicine and reduces the time limitation for allegations of professional misconduct enforced by the Board of Medicine from six years to five years. This bill is a request of the Board of Medicine. Introduced and referred to Senate Executive Departments and Administration. Voted Ought to Pass by the Committee and the full Senate. Introduced and referred to House Executive Departments and Administration. Voted Ought to Pass by the House. **Signed by the Governor to be effective January 1, 2019.**

SB 332: This bill requires insurers offering health insurance policies with prescription drug coverage to allow covered persons to synchronize the dispensing dates of their prescription drugs**.** Introduced and

referred to Senate HHS Committee. Voted Ought to Pass with Amendment by the Committee and the full Senate. The amendment revises the bill by adding specificity to the circumstances under which the synchronization is available. Introduced and referred to House Commerce Committee. Voted Ought to Pass by House. **Signed by Governor to be effective January 1, 2019.**

SB 333: This bill allows a pharmacy intern under the supervision of a pharmacist to administer hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines. Passed by the House and Senate. **Signed by the Governor on May 25, 2018; Effective July 24, 2018.**

SB 334: This bill allows persons licensed for certain allied health professions in Connecticut, Rhode Island, Massachusetts, Maine, New York, or Vermont to be granted a temporary license to practice in this state while applying for regular licensure. The bill also requires boards and commissions of regulated occupations and professions to allow for reciprocal and temporary licensure for an applicant for full licensure for 120 days while awaiting a determination for such licensure. **Signed by the Governor; section 3 effective on January 1, 2019; Remainder effective August 20, 2018.**

SB 374: This bill exempts the adoption of emergency medical and trauma services protocols from the rulemaking process under RSA 541-A. Introduced and referred to Senate Executive Departments and Administration. Voted Ought to Pass by the Committee and the full Senate. Introduced and referred to House Executive Departments and Administration. **Voted Ought to** Pass with Amendment by the House. The Senate concurred with the House amendment and the bill was enrolled. The amendment required notice and hearing prior to a final vote regarding minimum standards and protocols. **Signed by the Governor on June 8, 2018; Effective August 7, 2018.**

SB 377: This bill makes various changes to the regulation of dentists and dental hygienists, including requiring criminal history records checks for new applicants and establishing a professionals' health program for impaired dentists. This bill is a request of the board of dental examiners. Introduced and referred to Senate HHS Committee. Voted Ought to Pass by the Committee and the full Senate. Introduced and referred to House Executive Departments and Administration. Voted Ought to Pass with Amendment by House. The Senate concurred with the House amendment and the bill was enrolled. The amendment deleted the provision regarding dentists advertising as a specialist. **Signed by the Governor on June 25, 2018; Section 5 and 16 take effect as provided in Section 17 of the bill; Remainder effective August 24, 2018.**

SB 378-FN: This bill exempts certain health care facilities from the requirements of employing registered medical technicians. Introduced and referred to Senate HHS Committee. Voted Ought to Pass by the Committee and the full Senate. **Introduced and referred to House Executive Departments and Administration. Laid on Table by House.**

SB 379: This bill changes the time frame for insurance companies and managed care organizations to recover payments from a health care provider for services completed. As introduced, the bill would have reduced the time period for retroactive denials from 18 months to 6 months. The amended bill changes the time frame to 12 months. Voted Ought to Pass by the Senate. Introduced and referred to House Commerce Committee. House voted Ought to Pass with Amendment. The amendment related to second medical opinions for prisoners. The Senate did not concur with the amendment and the bill went to a Committee of Conference. The Committee of Conference recommended the Senate version of the bill be

passed. Both the House and Senate adopted the Committee of Conference report and the bill was enrolled. **Signed by the Governor on June 25, 2018; Effective January 1, 2019.**

SB 421: This bill clarifies insurance coverage for prescription contraceptive drugs and prescription contraceptive devices and for contraceptive services. Introduced and referred to Senate Commerce Committee. Voted Ought to Pass by the Senate; Introduced and referred to House Commerce Committee. The House voted Ought to Pass with Amendment. The Senate concurred with the House amendment and the bill was enrolled. The amendment relates primarily to the provision of generic contraceptive drugs. **Signed by the Governor; Sections 1-3 take effect as provided in Section 11; Sections 5 & 7 effective January 1, 2021; Remainder effective January 1, 2019.**

SB 473: This bill prohibits contract provisions for practice by nurses and podiatrists that limit the ability of such professionals to practice their profession in any geographic area after leaving a partnership, employment, or professional relationship. The bill was passed by the Senate and House and enrolled. **Signed by the Governor June 25, 2018; Effective upon signing.**

SB 475: This bill requires health care providers to provide certain information to persons being tested for Lyme disease**.** Voted Ought to Pass with Amendment by the Senate. The amendment changes the notice to be provided to patient who are screened for Lyme disease and adds a repeal of the newly-added chapter effective July 1, 2023. Introduced and referred to the House HHS Committee. **The House referred the bill for interim study.**

SB 477: This bill establishes the therapeutic cannabis medical oversight board which shall monitor and contribute to the oversight of the clinical, quality, and public health related matters of the use of cannabis for therapeutic purposes law under RSA 126-X**. Passed by the House and Senate. Signed by the Governor June 8, 2018; Effective August 7, 2018.**

SB 502-FN: This bill clarifies the standards for acquisition transactions involving health care charitable trusts and the review required by the director of charitable trusts. Voted Ought to Pass by the Senate. Introduced and referred to House Commerce Committee. **The House referred the bill for interim study.**

SB 531-FN: This bill provides for the office of professional licensure and certification to establish by rule and collect the fees for boards and commissions administered by the office, and to deposit the fees collected in the office of professional licensure and certification fund for payment of the costs and salaries of the office. This bill is a request of the office of professional licensure and certification. Senate voted Ought to Pass. Introduced to House Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by the House. The Amendment requires the establishment of fees by the office of professional licensure to be done on a biennial basis in conjunction with the preparation of the biennial budget. It also makes clear that current board, commission and council rules addressing fees shall remain in effect until they expire or new rules are adopted. The Senate did not concur with the House amendment and the bill went to a Committee of Conference. The Committee of Conference recommended the adoption of the House version of the bill. Both the House and the Senate adopted the Committee of Conference report and the bill as amended by the House was enrolled. **Signed by the Governor on June 25, 2018; Effective July 1, 2018.**

SB 573-FN-A: This bill allows the chief medical examiner and designees to register and access the controlled drug prescription health and safety program. This bill also makes an appropriation to the

controlled drug prescription health and safety program. This bill is a request of the controlled drug prescription health and safety program, established in RSA 318-B:32. Introduced and referred to Senate HHS Committee which voted Ought to Pass with Amendment. Senate voted Ought to Pass with Amendment. The amendment clarifies the access by the Chief Medical Examiner and delegates**. House voted Ought to Pass. The Bill was enrolled and signed by the Governor to be effective July 29, 2018.**

SB 578-FN: This bill clarifies the terms of appointment and salary for the following positions in the department of health and human services: deputy commissioner, associate commissioner of human services and behavioral health, associate commissioner of operations, and associate commissioner for population health. The bill is a request of the department of health and human services. Senate voted Ought to Pass. Introduced and referred to House Executive Departments and Administration. House voted Ought to Pass with Amendment. As amended the bill revises the titles and salaries of various unclassified positions in the department of health and human services. The bill also provides for the nomination and appointment of the deputy commissioner and 3 associate commissioners in the department of health and human services and repeals procedures regarding the nomination of a state physician epidemiologist, state senior dentist and state senior physician. The Senate concurred with the amendment and the bill was enrolled. **Signed by the Governor on June 25, 2018; Effective upon signing.**

SB 589-FN: This bill establishes a procedure for individuals to petition a state board or commission for occupational or professional licensure for a determination of whether the individual's criminal record will disqualify the individual from obtaining state recognition for the occupation or profession.
Signed by the Governor on July 2, 2018; Effective August 31, 2018.

These are the bills we have been watching. This is not a comprehensive list of legislative changes.

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

BIOS

CINDE WARMINGTON, ESQ.
Cinde, a partner at Shaheen & Gordon, leads the Health Care Practice Group and focuses her practice entirely on representing health care clients. Her prior clinical and administrative experience makes her uniquely qualified to assist providers in facing a rapidly changing regulatory environment.

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Kara Dowal practices health care law and corporate business law at Shaheen & Gordon, P.A. Kara works with health care providers on a variety of legal issues, including corporate governance, contracting, employment, regulatory compliance, and provider transition matters.

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