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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

### *Lawsuit against CMS for Implementing Clinical Lab Payment System*

On December 11, 2017, the American Clinical Laboratory Association ("ACLA") filed a lawsuit against the Acting Secretary of the Department of Health and Human Services ("HHS") arguing that a final rule issued by the Centers for Medicare and Medicaid Services ("CMS") should be struck down because it exempts a large swath of laboratories from Medicare reporting requirements, contrary to the requirements of the Protecting Access to Medicare Act of 2014 ("PAMA"). PAMA requires that labs report private payer rates and test volumes if they receive at least $12,500 in Medicare revenues from laboratory services paid under the Clinical Laboratory Fee Schedule ("CLFS") and more than 50% of their Medicare revenues from laboratory and/or physician services. The CMS final rule excludes 99.3% of the laboratory market from being required to report market information to the Secretary. The complaint argues that CMS' interpretation of PAMA is unreasonable, that the exclusion is contrary to Congress' intent in implementing PAMA, and that the laboratories that did report information are not representative of the market as a whole.

A copy of the complaint filed by ALCA can be viewed here: http://www.acla.com/wp-content/uploads/2017/12/ACLA-PAMA-Complaint.pdf

A copy of the CMS final rule can be viewed here: https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Documents/062416/clia_rule.pdf

### *OIG Says CMS Lacks Program Integrity Plan for QPP, Risking Fraud and Improper Payments*

On December 14, 2017, the Department of Health and Human Services Office of Inspector General ("OIG") issued a report stating that the Centers for Medicare and Medicaid Services ("CMS") continues to make progress implementing the Quality Payment Program ("QPP"), but hasn't yet developed a comprehensive program integrity plan, which heightens the risk of fraud and improper payments. The OIG provided this review because the Medicare Access and CHIP Reauthorization Act ("MACRA") enacted clinician payment reforms designed to promote quality and value of care. These reforms, known as QPP, are a significant shift in how Medicare calculates compensation for clinicians and require CMS to develop a system for measuring, reporting and scoring the value and quality of care. The first performance year began on January 1, 2017. Last year, OIG reviewed QPP implementation and stated that CMS needed to focus on two areas: 1) Developing information technology systems to support data reporting, scoring, and payment adjustments; and 2) Provide guidance and technical help to physicians. In this year's report, the OIG has stated that CMS now "appears on track to deploy the IT systems" which will be used for data submissions starting January 1, 2018. However, CMS stated that while

general outreach has been extensive in terms of preparing clinicians, specialized technical assistance for practice-specific needs requires further work in 2018. The OIG also indicated that the QPP is lacking a comprehensive program integrity plan which is of concern because clinicians are currently submitting their own performance data and self-attestations, which could lead to inaccurate and possibly fraudulent data submissions under the QPP.

The report can be viewed at: https://oig.hhs.gov/oei/reports/oei-12-17-00350.pdf

***OIG Issues Advisory Opinion Approving of Discounts to Insurers and Policyholders***

On December 15, 2017, the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") posted Advisory Opinion No. 17-08, addressing the Requestor's proposal to develop a state-wide network of nursing facilities that would provide discounts on the daily rates they charge to private long-term care insurers and the insurers' policyholders. Under the Proposed Arrangement, nursing facilities in the proposed network would contract with participating insurers and would provide a discount to those insurers and their policyholders for stays covered by the insurers. The discount would not apply to any stays covered by Medicare or Medicaid.

OIG concluded that the Proposed Arrangement implicates both the anti-kickback statute and the beneficiary inducement civil monetary penalties, because it has the potential to induce Medicare/Medicaid beneficiaries to choose a network nursing facility because of the discount applied to any part of their stay covered by their private insurer. However, OIG concluded that it would not impose sanctions on the Requestor arising out of the Proposed Arrangement, in part for the following reasons: 1) whether a beneficiary's circumstances may change to require a federally reimbursable stay at some point in the future is outside a network nursing facility's control; 2) although some beneficiaries may need certain federally reimbursable items or services that a network nursing facility could furnish while the beneficiaries are in a participating payor-covered stay, the beneficiaries would not be required to receive those items or services from the network nursing facility to receive the discount; 3) any nursing facility that is willing to offer the discount and that meets Requestor's quality standards may participate in the network; and 4) although the discount would be offered to induce beneficiaries to select a particular type of nursing facility (i.e., a network nursing facility) from a broader group of eligible nursing facilities, access to Requestor's network is sufficiently open to avoid the type of highly problematic steering arrangements that are structured to "leapfrog" or bypass providers equipped to provide quality medical care.

Advisory Opinion No. 17-08 is available at:
https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-08.pdf.

***U.S. Court in Pennsylvania Blocks Trump Administration Rules Expanding Exemption to Contraceptive Mandate***

On December 15, 2017, the U.S. District Court for the Eastern District of Pennsylvania granted a preliminary injunction in *Commonwealth of Pa. v. Trump,* No. 17-4540 (E.D. Pa. Dec. 15, 2017) against two interim final rules issued by the Departments of Health and Human Services, the Department of Treasury, and the Department of Labor on October 6, 2017. The rules would allow employers to opt out of providing coverage for contraceptives for employees at no cost, based on the employers' sincerely held religious beliefs or moral convictions. The Court held that the Commonwealth of Pennsylvania had standing to challenge the rules, because they were likely to impose "substantial financial burdens on State coffers" that could be directly traced to a decrease in employer-covered contraceptives. The Court concluded that the

Commonwealth had made a sufficient showing to obtain a preliminary injunction, including that it was likely to succeed on its claim that the promulgation of the two rules violated the Administrative Procedure Act.

The Court's decision is available at: https://www.attorneygeneral.gov/uploadedFiles/MainSite/Content/Related_Content/PressReleases/Inunction%20%28003%29.pdf.

***White House, House of Representatives Settle Lawsuit Challenging ACA Insurer Payments***

On December 15, 2017, the Trump administration, the House of Representatives, and state intervenors announced a settlement of the House of Representatives' challenge to payments to insurers under the Affordable Care Act's ("ACA") cost-sharing reduction ("CSR") program. The challenge was based on the Obama administration's interpretation of Section 1402 of the ACA, which authorizes the federal government to provide payments to insurers to offset CSR payments for certain beneficiaries. The House of Representatives argued that such payments can only be made in accordance with a Congressional appropriation of funds, which never occurred. Through the joint status report, the parties announce their entering into a Settlement Agreement and their intention to seek an indicative ruling from the District Court that it would vacate its earlier injunction that blocked CSR payments absent any congressional appropriation. If the District Court grants the motion, the parties would then request that the Court of Appeals remand the case back to the District Court so that the District Court can vacate its earlier injunction. Because of their negotiated resolution of the issue, the parties do not want the District Court's injunction to be used as a precedent in any future litigation of the same or similar issues.

The December 15 joint status report in *House of Representatives v. Hargan*, No. 16-5202 (D.C. Cir.) is available at: http://images.law.com/contrib/content/uploads/documents/398/6808/16-5202_Documents.pdf.

***CMS Discontinues Federal Matching Funds for State Expenditures for Designated State Health Programs***

On December 15, 2017, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") announced that it would no longer accept state proposals for new or renewing demonstration projects under Section 1115 of the Social Security Act that rely on federal matching funds for state expenditures for designated state health programs ("DSHPs"). While the intended purpose of federal DSHP funding was to allow states to continue the DSHPs in the face of additional costs for other health service delivery reforms, CMS states that "the result has been that many states are not contributing state funds toward these delivery system reform efforts" and are instead "relying on dollars freed up by the federal Medicaid contribution to DSHP to draw down additional federal Medicaid matching expenditures to support delivery system reforms." CMS states that "[a]uthority for DSHP in current demonstrations will continue until the end of the state's current demonstration period but will not be extended or renewed."

CMS' announcement to state Medicaid directors is available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd17005.pdf.

***OIG Report: Potential Drug Misclassification by Manufacturers May Have Cost $1 Billion in Medicaid Rebates***

On December 20, 2017, the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") published a report titled: "Potential Misclassifications Reported by Drug Manufacturers May Have Led to $1 Billion in Lost Medicaid Rebates." The report details the potential loss of approximately $1.3 billion to Medicaid from manufacturers misclassifying drugs as a single-source or an innovator multiple-

source product. Drugs with such classifications are entitled to a rebate from the manufacturer equal to the greater of 32.1% of the average manufacturer price ("AMP") or the difference between AMP and best price. Rebates for all other drugs are equal to 13% of AMP. By misclassifying drugs as non-innovator drugs, manufacturers benefit from a smaller rebate.

The report states that the Centers for Medicare & Medicaid Services does have a procedure in place to request that manufacturers change drug classification data when it determined that such information may be incorrect. However, OIG notes that CMS lacks legal authority to require any change in the information. OIG provided three recommendations in its report: (1) that CMS follow up with manufacturers associated with potentially-misclassified drugs identified in the report to determine whether current classifications are correct; (2) that CMS improve its Drug Data Reporting for Medicaid System to minimize inconsistent data submissions and track potential classification errors for follow-up; and (3) that CMS pursue a means to compel manufacturers to correct inaccurate classification data reported to the Medicaid rebate program.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-03-17-00100.pdf.

***OCR Provides Reorganized and Updated Guidance on Permissible Sharing of Mental Health, Substance Use Records***

On December 18, 2017, the U.S. Department of Health & Human Services, Office of Civil Rights ("OCR") launched two new webpages containing information on permissible disclosures under HIPAA for sharing information related to mental health and substance use with patients' families. The webpages – one for consumers, one for professionals – collect and reorganize previous guidance from OCR in these issues, as well as new guidance, including a number of fact sheets, an infographic, and decision charts. OCR also announced updated guidance on HIPAA and research required by the 21st Century Cures Act.

OCR's announcement of the webpages and guidance is available at: https://www.hhs.gov/about/news/2017/12/18/hhs-highlights-office-civil-rights-ongoing-response-opioid-crisis-implementing-21st-century.html.

***DOJ Recovers More Than $3.7 Billion in FY 2017 for False Claim Act Cases***

On December 21, 2017, the U.S. Department of Justice ("DOJ") announced it obtained more than $3.7 billion in both settlements and judgments from civil cases fraud and false claims civil cases in the fiscal year ending September 30, 2017. The DOJ's announcement stated that out of the $3.7 billion, $2.4 billion involved the health care industry. It also explained that the $2.4 billion only accounts for federal recoveries and that in many cases, millions of additional dollars were recovered for state Medicaid programs. In the health care industry, the DOJ cited that the largest recoveries involved the drug and medical device industry (totaling over $900 million), giving the examples of a $350 million settlement with Shire Pharmaceuticals, LLC to resolve allegations that it induced clinics and physicians to use or overuse its bioengineered human skin substitute by providing lavish dinners, drinks, entertainment and travel; medical equipment and supplies; unwarranted payments for purported speaking engagements and bogus cases studies, and cash credit and rebates, as well as the well-publicized $465 million settlement with Mylan Inc. to resolve allegations that it underpaid rebates owed under the Medicaid Drug Rebate Program by erroneously classifying its patented, brand name drug EpiPen as a generic drug to avoid its obligation to pay higher rebates. The vast majority of the amount recovered ($3.4 out of the $3.7 billion) related to lawsuits filed under the qui tam provisions of the False Claims Act, with the government paying out $392 million to individuals who filed qui tam complaints in fiscal year 2017.

The full announcement may be read here: https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.

***IRS Extends Deadline for Employers to Report Health Coverage Information***

On December 22, 2017, the Internal Revenue Service ("IRS") announced it is extending the deadline for employers to report health care coverage information as required by the Affordable Care Act ("ACA") by 30 days. The due date for employers to give individuals the Form 1095-B, Health Coverage, and the Form 1095-C, Employer-Provided Health Insurance Offer and Coverage has moved from January 31, 2018 to March 2, 2018. The ACA requires that insurers, self-insuring employers, applicable large employers, and other providers of minimum essential coverage report certain information about health care coverage to employees and to the IRS.

The IRS announcement can be found here: https://www.irs.gov/newsroom/irs-extends-due-date-for-employers-and-providers-to-issue-health-coverage-forms-to-individuals-in-2018.

***OIG Solicits Suggestions for New Safe Harbors under Anti-Kickback Statute***

On December 27, 2017, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") published its annual request for recommendations to develop new safe harbors or modify existing safe harbors under the federal Anti-Kickback Statute. The OIG explained that to develop safe harbors, it "thoroughly reviews the range of factual circumstances that may fall within the proposed safe harbor subject area so as to uncover potential opportunities for fraud and abuse." The notice explained that in accordance with section 205 of HIPAA, the factors it will consider when reviewing proposals for new or modified safe harbor provisions include whether the proposal would affect an increase or decrease in access to health care services; the quality of health care services; patient freedom of choice among health care providers; competition among health care providers; the cost to Federal health care programs; the potential overutilization of health care services; and the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations. The OIG also stated it would consider other factors, including the existence or nonexistence of any potential financial benefit to health care professional or provider that may take into account the provider's decision whether to order a health care item or services or arrange for the referral of health care items or services to a particular practitioner or provider.

In addition to soliciting proposals for safe harbors, the OIG also requested suggestions for special fraud alerts to give providers guidance for practices the OIG considers to be concerning.

Comments are due February 26, 2018.

The OIG's request may be accessed here: https://www.gpo.gov/fdsys/pkg/FR-2017-12-27/pdf/2017-27117.pdf.

***CMS Releases Advance Notice of Proposed Changes to 2019 MA Risk Adjustment Model***

On December 27, 2017, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") released Part I of the 2019 Advance Notice of Methodological Changes for Medicare Advantage ("MA") Capitation Rates and Part D Payment Policies ("Advance Notice"), with information about proposed updates to the Part C Risk Adjustment Model and the use of encounter data. CMS explained in the announcement that the 21st Century Cures Act requires CMS to make improvements to risk adjustment for 2019 and subsequent years and that it is therefore proposing changes to the CMS-HCC Risk Adjustment model used to pay for aged and disabled beneficiaries enrolled in Medicare

Advantage plans. Proposed changes include adding mental health, substance use disorder, and chronic kidney disease conditions to the risk adjustment model as well as taking into account the number of conditions a beneficiary may have.

The Advance Notice puts forth two proposed alternative models, a "Payment Condition Count model" that takes into account the number of conditions that a beneficiary has only among the conditions including in the payment model and a "All Condition Count model", that, as the name suggests, takes into account all conditions that a beneficiary has, whether included in the payment model or not. CMS projects that the Payment Condition Count model would increase MA risk scores by 1.1% while the All Condition Count model would decrease MA risk scores by -0.28%.

Because the 21st Century Cures Act requires that CMS fully phase in the required changes to the risk adjustment model by 2022, CMS is proposing to begin the phase in of the new model in 2019, starting with a blend of 75% of the risk adjustment model used for payment in 2017 and 2018 and 25% of the new risk adjustment model proposed.

Comments on the proposals set forth in Part I of the proposed Advance Notice must be submitted by Friday, March 2, 2018, and the final 2019 Rate Announcement will be published by Monday, April 2, 2019.

The Advance Notice may be accessed here: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part1.pdf.

***CMS States that Texting Physician Orders Does Not Comply with CoPs***

On December 28, 2017 the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") issued a Memorandum to State Survey Agency Directors stating that the texting of orders by physicians and other health care providers does not comply with Medicare Conditions of Participation ("CoPs") or Conditions for Coverage ("CfCs"). Instead, CMS states that providers should be using the preferred method of Computerized Provider Order Entry ("CPOE") for orders, or alternatively through a hand written order into the medical record. Although CMS acknowledged that texting among health care providers is an "essential and valuable method of communication among the team members" it emphasized that to be in compliance with CoPs or CfCs, "all providers must utilize and maintain systems/platforms that are secure, encrypted, and minimize the risks to patient privacy and confidentiality as per HIPAA regulations and the CoPs or CfCs."

The CMS memo to State Survey Agency Directors is available here: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-10.pdf.

***SAMSHA Issues Final Rule for Disclosures of Substance Use Disorder Records***

On January 3, 2018, the Substance Abuse and Mental Health Services Administration ("SAMHSA") published a final rule (83 Fed. Reg. 239) allowing certain additional disclosures of patient identifying information under the Confidentiality of Alcohol and Drug Abuse Patient Records regulations at 42 C.F.R. Part 2 ("Part 2"). The goal of the rule is to promote integrated and coordinated care for those with substance use disorders and also attempts to better align the Part 2 regulations with the Health Insurance Portability and Accountability Act ("HIPAA") and the Health Information Technology for Economic and Clinical Health ("HITECH") Act. The final rule permits disclosures of patient identifying information for payment and health care operations with patient consent and allows disclosures to certain contractors, subcontractors, and legal

representatives for Medicare, Medicaid, or Children's Health Insurance Program audits or evaluations. The final rule also permits the use of an abbreviated notice on prohibiting re-disclosures, intended to accommodate electronic health record text fields.

The full text of the final rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2018-01-03/pdf/2017-28400.pdf.

***DOL Issues Proposed Rule for Association Health Plans***

On January 5, 2018, the U.S. Department of Labor ("DOL") issued a proposed rule expanding opportunities for Small Business Health Plans, also known as Association Health Plans ("AHPs"). The proposed rule is intended to make it easier for small businesses, including sole proprietors in the same geographic area or industry to come together and offer more affordable, quality health insurance. The proposed rule provides that employers in a state, city, county, or multi-state metropolitan area could join a single plan, or a plan could serve a particular industry nationwide. In a press release, the DOL stated that "[b]y joining together, employers may reduce administrative costs through economies of scale, strengthen their bargaining position to obtain more favorable deals, enhance their ability to self-insurance, and offer a wider array of insurance options." The DOL's press release also cited the statistic that up to 11 million Americans who are working for small businesses/sole proprietors and their families lack employer-sponsored insurance. The rule broadens the criteria under Section 3(5) of the Employee Retirement Income Security Act ("ERISA") for determining when employers can join together to collectively be treated as the employer sponsor of a multiple-employer "employee welfare benefit plan" and "group health plan." The definition of "employer" under ERISA would be expanded because of a more flexible "commonality of interest" test. The proposed rule comes in response to President Trump's October 12, 2017 executive order requiring agencies, including the Department of Labor to issue regulations expanding access to AHPs and permitting the purchase of insurance across state lines.

Comments on the proposed rule are due March 6, 2018.

The proposed rule can be read in its entirety at: https://www.gpo.gov/fdsys/pkg/FR-2018-01-05/pdf/2017-28103.pdf.

***OIG Changes Enforcement of Certain Free Drug Programs***

In a January 4, 2018 letter to the Pharmaceutical Research and Manufacturers of America, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") announced it would be scaling back its enforcement of drug companies that provide free drugs to Federal health care beneficiaries and who are impacted by the Caring Voice Coalition, Inc. ("CVC") decision to not provide patient financial assistance in 2018. The OIG stated in the letter that it would not seek administrative sanctions from any drug company that provides free drugs during 2018 to beneficiaries who were receiving cost sharing support for those drugs from CVC as of November 28, 2017, as long as the drug companies comply with certain safeguards, including, among other things, that the drugs are provided without regard to the beneficiary's choice of provider, practitioner, supplier, or health plan, or that the provision of free drugs is not conditioned on the future purchase of drugs or any other item or service.

CVC's decision to stop providing financing assistance comes in the wake of the OIG's November 28, 2017 Final Notice of Recision of its favorable Advisory Opinion 06-04 to CVC because, as OIG explained in the letter, "CVC failed to fully, completely, and accurately disclose all relevant and material facts to OIG.

CVC's failure to comply with the certifications it made to OIG materially increased the risk that it served as a conduit for improper financial assistance from a Drug Company donor to a patient."

The OIG's January 4 letter can be read here: https://oig.hhs.gov/compliance/alerts/guidance/stansel-letter.pdf.

***CMS Implements New Data Submission System for QPP Reporting***

On January 2, 2018, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") announced the launch of a new system on the Quality Payment Program ("QPP") website (qpp.cms.gov) where physicians and other eligible clinicians participating in the QPP can submit their 2017 performance data. The system is meant to be an improvement on former programs which required physicians to submit data on multiple websites. The 2017 submission period runs from January 2, 2018 to March 31, 2018, except for groups using the CMS Web Interface, who have a shorter reporting period of January 22, 2018 to March 16, 2018.

The announcement and other details about the system may be read here: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-01-02.html.

***CMS Reveals New Bundled Payment Model***

On January 9, 2018, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") announced a new voluntary bundled payment model called Bundled Payments for Care Improvement Advanced (BPCI Advanced). CMS explained that under BPCI Advanced, participants can earn additional payment if all expenditures for a beneficiary's episode of care are under a spending target that factors in quality. CMS stated that the BPCI Advanced model provided participants with payments for performance on 32 difference clinical episodes, such as major joint replacement of the lower extremity (inpatient). CMS notes that BPCI Advanced will qualify as an Advanced Alternative Payment Model ("Advanced APM") under the Quality Payment Program. The announcement quoted CMS Administrator Seema Verma as stating "BPCI Advanced builds on the earlier success of bundled payment models and is an important step in the move away from fee-for-service and towards paying for value. Under this model, providers will have an incentive to deliver efficient, high-quality care." The Model Performance Period for BPCI Advanced starts on October 1, 2018 and continues through December 31, 2023.

The announcement for BPCI Advanced may be found here: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-01-09.html.

***Trump Administration Permits Medicaid to Impose Work Requirements***

On January 11, 2018, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") released guidance on a new policy to "support state efforts to test incentives that make participation in work or other community engagements a requirement for continued Medicaid eligibility or coverage for certain adult Medicaid beneficiaries in demonstration projects authorized by section 1115 of the Social Security Act (the Act)." CMS stated that the guidance is in response to state requests to test incentives under section 1115 of the Act and cited its March 14, 2017 letter to state governors promising that it would empower states to develop innovative proposals to improve Medicaid. The guidance provides that exempted from any work or community engagement requirements would be individuals eligible for Medicaid because of a disability, the elderly, children, and pregnant women. As of February 8, 2018, the Henry J.

Kaiser Foundation reported that there exist 2 approved (Kentucky and Indiana) and 8 pending (Arkansas, Arizona, Kansas, Maine, Mississippi, New Hampshire, Utah, and Wisconsin) section 1115 demonstration applications from states that include a work requirement as a condition of eligibility.

The CMS guidance is located here: https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf.

For a link to the Henry J. Kaiser Foundation section 1115 demonstration statistics, see the following https://www.kff.org/medicaid/issue-brief/which-states-have-approved-and-pending-section-1115-medicaid-waivers/ and click on the links to download that approved and pending waiver spreadsheets.

***OIG Issues Favorable Advisory Opinion for Hospital Gainsharing Arrangement***

On January 5, 2018 the U.S. Department of Health and Human Services Office of Inspector General ("OIG") posted favorable advisory opinion No. 17-09 (issued December 29, 2017) related to an arrangement where neurosurgeons agree to implement cost-reduction measures in designated surgical procedures performed at a medical center and the medical center will share with the neurosurgeons a percentage of the cost-savings resulting from those measures (the "Arrangement"). After noting that the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent was present, the OIG would not impose sanctions because the Arrangement was structured to mitigate fraud and abuse, including that:

- A program administer would monitor and track changes in cost, resource utilization, or quality of patient care and provide quarterly reports on its findings to an oversight committee.
- To prevent cherry-picking or steering away from more costly patients, the oversight committee would periodically monitor the neurosurgeons' patient populations undergoing spinal fusions against historical benchmarks, with the option to terminate those physicians who fail to admit a historically consistent set of patients or don't follow the Arrangement's clinical or administrative guidelines.
- Concerns that the incentive payments could induce referrals to the medical center in violation of the anti-kickback statute were mitigated because the payments would be distributed to the neurosurgeons on a per capita basis and would be subject to certain caps.
- The neurosurgeon's group practice retaining a portion of the savings would retain savings only to cover administrative and recruitment expenses and pursuant to a preexisting compensation structure and those savings would not be passed on to individual physicians.
- The multi-year gainsharing arrangement included an annual rebasing method to remove savings from prior years, ensuring that "the performance year savings are calculated only as compared to the most recent base year, which prevents improper duplicate payments to the neurosurgeons."
- The Arrangement tied the neurosurgeons' incentives to actual, verifiable cost savings attributable to each cost-sharing measure implemented during the surgeries, which reduces the risk of improperly generating savings.
- Under the Arrangement, the neurosurgeons share in savings when they choose to use a preferred product but also continue to decide what devices or supplies are clinically appropriate for a particular patient.

Advisory Opinion 17-19 may be read in full at:
https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-09.pdf.

***Congress Passes, Trump Signs, Bill Funding CHIP for Six Years***

On January 22, 2018, following several short-term continuing resolutions and a three-day government shutdown, Congress passed a new continuing resolution funding the government through February 8 and providing funding for the Children's Health Insurance Program ("CHIP") for the next six-years. CHIP funding – along with providing a solution for beneficiaries of the Deferred Action for Childhood Arrivals program – had become a contentious issue for Democrats and Republicans in the debate over a bill to fund the government, with both parties claiming that the other was holding CHIP funding hostage as a bargaining chip. President Trump signed the funding bill into law on the same day of its passage.

The text of H.R. 195 is available at https://www.congress.gov/bill/115th-congress/house-bill/195/text.

***GAO Report Notes Only Few Problematic Enrollments in Federal ACA Marketplace for Plan Year 2015***

On January 23, 2018, the Government Accountability Office ("GAO") released a report titled "Federal Health-Insurance Marketplace: Analysis of Plan Year 2015 Application, Enrollment, and Eligibility-Verification Process." The report details the GAO investigation into enrollments in the Affordable Care Act ("ACA") federally-facilitated marketplace ("FFM") for plan year 2015 to determine whether any enrollments were improper or fraudulent. In its report, GAO notes that the FFM had systems in place to verify enrollees' citizenship or other lawful status, and Social Security number, and that such systems only resulted in about 1% of the enrollments for 2015 being improper or fraudulent. GAO noted that the FFM has, since 2015, implemented or upgraded its systems for verifying this information for enrollees. GAO also found that one of the issues with FFM's verification process was that it did not always identify deceased enrollees in a timely manner, and that this vulnerability still exists within FFM's verification process. GAO recommended, and the U.S. Department of Health and Human Services concurred, that the Centers for Medicare & Medicaid Services should assess and document the feasibility of approached to identify the deaths of individuals prior to automatic reenrollment.

GAO's report is available at: https://www.gao.gov/assets/690/689141.pdf.

***GAO Calls for More State Oversight of Potential Conflicts of Interest in Medicaid Home- and Community-Based Services Needs Assessments***

In a recent report titled "Medicaid: CMS Should Take Additional Steps to Improve Assessments of Individuals' Needs for Home- and Community-Based Services," the Government Accountability Office ("GAO") detailed its findings from a review of home- and community-based services ("HCBS") needs assessments in six states. GAO found that while the six states it reviewed had all taken steps to address the efficiency and effectiveness of needs assessments within their Medicaid programs, conflict-of-interest concerns remained regarding providers and managed care plans who conduct the needs assessments. GAO stated:

> HCBS providers may have a financial interest in the outcome of needs assessments, which could lead to overstating needs and overprovision of services. . . . Similarly, managed care plans may have a financial interest in the outcome of HCBS assessments used for both determining eligibility and service amounts. Managed care plans could have an incentive to enroll beneficiaries with few needs, as plans typically receive a fixed payment per enrollee.

GAO recommended that requirements be imposed on states to address both service providers' and managed care plans' potential conflicts of interest in conducting needs assessments.

GAO's report is available at: https://www.gao.gov/assets/690/689053.pdf.

***Amazon, Berkshire Hathaway, JPMorgan Announce Independent Company to Lower Their Employees' Health Care Costs***

On January 30, 2018, three large U.S. companies – Amazon, Berkshire Hathaway, and JPMorgan Chase & Co. – announced plans to establish a joint venture to lower their employees' health care costs. The announcement contained few details on how the new independent company would address health care costs but did state that it would be "free from profit-making incentives and constraints."

"The ballooning costs of healthcare act as a hungry tapeworm on the American economy. Our group does not come to this problem with answers. But we also do not accept it as inevitable. Rather, we share the belief that putting our collective resources behind the country's best talent can, in time, check the rise in health costs while concurrently enhancing patient satisfaction and outcomes," said Berkshire Hathaway Chairman and CEO, Warren Buffett.

"The healthcare system is complex, and we enter into this challenge open-eyed about the degree of difficulty," said Jeff Bezos, Amazon founder and CEO. "Hard as it might be, reducing healthcare's burden on the economy while improving outcomes for employees and their families would be worth the effort. Success is going to require talented experts, a beginner's mind, and a long-term orientation."

"Our people want transparency, knowledge and control when it comes to managing their healthcare," said Jamie Dimon, Chairman and CEO of JPMorgan Chase. "The three of our companies have extraordinary resources, and our goal is to create solutions that benefit our U.S. employees, their families and, potentially, all Americans," he added.

The announcement, published by BusinessWire, a Berkshire Hathaway Company, is available at: https://www.businesswire.com/news/home/20180130005676/en/Amazon-Berkshire-Hathaway-JPMorgan-Chase-partner-U.S.

***CMS Proposes 1.84% Increase to Medicare Advantage Rates for 2019, Other Changes***

On February 1, 2018, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") published Part II of the 2019 Advance Notice of Methodological Changes for Medicare Advantage ("MA") Capitation Rates and Part D Payment Policies (the "Advance Notice"), and Draft Call Letter. Part I of the Advance Notice was previously released on December 27, 2017. The Advance Notice proposed updates to the methodologies used to pay MA plans and Medicare Part D sponsors. Based on the proposed changes, CMS estimated that MA payment rates will increase by 1.84% on average in 2019. This increase does not include any adjustment for differences in coding between MA plans and fee-for-service providers, which CMS expects will increase risk scores by 3.1% on average. The Advance Notice and Draft Call Letter also include other proposed changes, including reconfiguring the health-related supplemental benefit standard to allow payment for supplemental benefits whose primary purposes is daily maintenance.

CMS is accepting comments on the Advance Notice and Draft Call Letter through March 5, 2018 and expects to publish a final 2019 Rate Announcement and final Call Letter on April 2, 2018.

CMS' Fact Sheet on the Advance Notice and Draft Call Letter is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-02-01.html.

***DOJ Announces New Policy Prohibiting Use of Federal Agency Guidance Documents as Basis for Civil Enforcement***

On January 25, 2018, U.S. Department of Justice ("DOJ") announced a new internal policy prohibiting DOJ litigators from using a party's noncompliance with any federal agency's guidance documents as a basis for proving violations of applicable laws in affirmative civil enforcement cases. This new policy follows an earlier policy announcement from November 16, 2017 that prohibits DOJ employees from issuing guidance documents that effectively bind the public without undergoing notice-and-comment rulemaking. The new policy confirms that it is applicable not just to guidance documents published by the DOJ but also to documents published by other agencies. DOJ also stated that it is prohibited from "using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation."

The new policy announcement is available at: https://www.justice.gov/file/1028756/download.

***DOJ Memo: US Attorneys Should Give More Consideration to Dismissing Qui Tam Actions Brought Under the False Claims Act***

On January 10, 2018, Michael D. Granston, Director of the U.S. Department of Justice's ("DOJ") Commercial Litigation Branch, Fraud Section, issued a memo to U.S. Attorneys in the Fraud Section ("Granston Memo"), advising them to consider seeking dismissal of qui tam actions brought under the False Claims Act ("FCA"). The Granston Memo's directive is contrary to the DOJ's historical reluctance to dismiss qui tam actions brought by private parties seeking to enforce the FCA on the government's behalf. The Granston Memo states that when U.S. Attorneys decide not to intervene in such actions, they should also consider whether the government's interests – in, for example, preserving limited resources and avoiding adverse precedence – would be best served by seeking dismissal of the action under 31 U.S.C. § 3730(c)(2)(A), which provides authority to the government to dismiss qui tam actions.

The Granston Memo provides a non-exhaustive list of seven considerations for U.S. Attorneys when deciding whether to intervene or dismiss an action: 1) curbing meritless qui tams; 2) preventing parasitic or opportunistic qui tam actions; 3) preventing interference with agency policies and programs; 4) controlling litigation brought on behalf of the United States; 5) safeguarding classified information and National Security Interests; 6) preserving government resources; and 7) addressing egregious procedural errors. The Granston Memo also lays out additional points for U.S. Attorneys: attorneys should be mindful of the dismissal standard adopted by the relevant court ("unfettered discretion" vs. "rational basis"); the seven consideration above are not mutually-exclusive; independent grounds for dismissal may exist, including the first to file bar and public disclosure bar; the FCA allows the government to seek only partial dismissal of qui tam claims; attorneys should consult with affected agencies on any dismissal decision; attorneys should be wary of waiting too long to seek dismissal; and attorneys planning to seek dismissal should consider advising relators of perceived deficiencies in their cases.

The Granston Memo will likely provide fodder for defense counsel seeking to encourage U.S. Attorneys to dismiss qui tam actions, but may also result in plaintiffs bringing stronger qui tam actions crafted to withstand the dismissal factors laid out in the memo.

The Granston Memo is available at:
https://drive.google.com/file/d/1PjNaQyopCs_KDWy8RL0QPAEIPTnv31ph/view.

***Fresenius Agrees to Pay $3.5 Million to Settle Five Potential HIPAA Breaches***

On February 1, 2018, the U.S. Department of Health & Human Services, Office of Civil Rights ("OCR") announced that Fresenius Medical Care North America had agreed to pay $3.5 million to settle potential HIPAA violations stemming from five breaches of ePHI at five of its dialysis sites. After Fresenius reported the five breaches, OCR conducted an investigation, which revealed that Fresenius facilities provided access to patients' ePHI for a purpose not permitted by the Privacy Rule, and "failed to conduct an accurate and thorough risk analysis of potential risks and vulnerabilities to the confidentiality, integrity, and availability of all of its ePHI."

"The number of breaches, involving a variety of locations and vulnerabilities, highlights why there is no substitute for an enterprise-wide risk analysis for a covered entity," said OCR Director Roger Severino. "Covered entities must take a thorough look at their internal policies and procedures to ensure they are protecting their patients' health information in accordance with the law."

OCR's announcement of the settlement is available at: https://www.hhs.gov/about/news/2018/02/01/five-breaches-add-millions-settlement-costs-entity-failed-heed-hipaa-s-risk-analysis-and-risk.html.

***CMS Announces 20-day Rolling Hold of Certain Therapy Claims***

In January 2018, the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS") announced a 20-day "rolling hold" of all therapy claims containing the KX modifier indicating that the exception to the outpatient therapy cap had been met. CMS has taken steps to limit the impact on beneficiaries of the recent expiration of several Medicare legislative provisions affecting health care providers and beneficiaries, including the exceptions to the outpatient therapy cap. Starting on January 1, 2018, CMS began holding therapy claims with the KX modifier that were affected by the expiration of the therapy cap exceptions. CMS announced that, beginning on January 25, it would begin releasing therapy claims with the KX modifier on a rolling basis, starting with claims received January 1-10, and then, starting on January 31, it would proceed to release claim one day at a time while at the same time implementing a 20-day hold on all new claims with the KX modifier.

CMS announcement of this process is available at: https://www.cms.gov/Center/Provider-Type/All-Fee-For-Service-Providers-Center.html.

***Enrollment Opens for Suppliers Seeking to Participate in Medicare Diabetes Prevention Program***

On January 1, 2018, enrollment opened for suppliers wishing to participate in the Medicare Diabetes Prevention Program ("MDPP"). The MDPP was established on November 15, 2017 by final rule published by the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services ("CMS"). According to CMS' website, the MDPP is "a structured intervention with the goal of preventing type 2 diabetes in individuals with an indication of prediabetes," and includes a CDC-approved curriculum of 16 sessions "furnished over six months in a group-based, classroom-style setting that provides practice training in long-term dietary change, increased physical activity, and behavior change strategies for weight control." Delivery of and billing for MDPP services will begin April 1.

CMS' Fact Sheet for supplier enrollment is available at: https://innovation.cms.gov/Files/x/mdpp-enrollmentfs.pdf.

***GAO Report Recommends Improved Oversight of Assisted Living Facilities***

On February 2, 2015, the Government Accountability Office ("GAO") released the report *Medicaid Assisted Living Services: Improved Federal Oversight of Beneficiary Health and Welfare is Needed* (GAO-18-179). According to the report, the 48 state agencies that cover assisted living services reported state and federal spending of more than $10 billion on assisted living services in 2014. However, the report found that twenty-six Medicaid state agencies were unable to report on the number of "critical incidents", such as physical abuse or neglect that occurred at assisted living facilities in their states. Part of the problem, says the GAO, is that the Centers for Medicare & Medicaid Services ("CMS") does not have clear guidance on what constitutes a critical incident and therefore some states are not monitoring for critical deficiencies that could serve as red flags for problems, such as medication errors or unexplained deaths. States also cited an inability to track such incidents by provider type or the lack of a system to collect the data on critical incidents. States also varied as to whether and how they made information about critical incidents at assisted living facilities available to the public, with 14 states not making such information public at all.

The full report may be accessed here: https://www.gao.gov/assets/690/689302.pdf.

***ACA Enrollment Stable in 2018***

On February 7, 2018, a nonprofit, nonpartisan, and independent academy of state health policymakers, the National Academy for State Health Policy ("NASHP), released new data revealing that enrollment through the Affordable Cara Act ("ACA") marketplace remained generally stable in 2018, despite the shortened enrollment period and reduction in enrollment outreach and assistance. The data indicates that enrollment via both federal and state-based marketplaces fell by 3.7% from 2017. The total number of consumers enrolling in 2018 was 11.8 million, while in 2017 the number totaled 12.2 million.

The press release that includes tables with the data by state can be found here: https://nashp.org/individual-marketplace-enrollment-remains-stable-in-the-face-of-national-uncertainty/.

## STATE DEVELOPMENTS

**REMINDERS:**

- **Annual Reports for New Hampshire business entities are due to the Secretary of State by April 1, 2018.**
- **Annual Breach Notification Reports must be made to the Office of Civil Rights by March 1, 2018 at:** https://ocrportal.hhs.gov/ocr/breach/wizard_breach.jsf?faces-redirect=true.

***Federal Court Rules State of New Hampshire Can Sue Purdue Pharma in Federal Court***

On January 9th, U.S. District Judge Paul Barbadoro ruled that the State of New Hampshire could pursue in State court, a lawsuit claiming deceptive marketing against Purdue Pharma LP, the maker of OxyContin. Purdue had argued that the federal court should exercise jurisdiction under the Class Action Fairness Act because the State sought restitution on behalf of consumers. The Court rejected the argument stating that a lawsuit by a state does not become a class action merely by seeking relief that benefits

particular individuals. In reaching his decision, Judge Barbadoro cited the impact of the opioid epidemic and its alarming death rate in holding that Purdue's argument did not overcome the state's power to sue on behalf of its citizens and its duty to protect their health and welfare. Purdue sought to appeal the issue to the First Circuit, but the petition for permission to appeal was denied on January 31st and, therefore, the case will now proceed in State Court. Attorney General Gordon McDonald has recused himself from these proceedings because prior to becoming Attorney General, he represented Purdue in this case.

***Future of NH Medicaid Expansion is Uncertain***

After weeks of discussion, the House voted to send a bill (HB 1811) that would extend the NH Health Protection Program for further study making its future uncertain. The program, which provides insurance for over 50,000 New Hampshire residents, is set to end on December 31st if not reauthorized. Efforts to reach agreement on reauthorization have included discussion around how to pay for the State's share of the cost, the imposition of work requirements on those enrolled in the Program and a shift to a managed care delivery model.

## 2018 LEGISLATIVE UPDATES

### House Bills

**HB572:** This bill extends the suspension of prior authorization requirement for a community mental health program on drugs used to treat mental illness. **This 2017 bill was voted Ought to Pass by the House during the 2017 session. It was then referred to the Finance Committee where it was retained and taken up again in the 2018 session. Voted Inexpedient to Legislate by the Finance Committee and the House.**

**HB 610:** This bill requires the commissioner of the department of health and human services to establish guidelines for the operation of needle exchange programs in New Hampshire. The bill grants rulemaking authority to the commissioner of the department of health and human services for the purposes of the bill. **This is a 2017 bill that was retained in the HHS Committee. Voted Inexpedient to Legislate by Committee and full House.**

**HB 628-FN:** This bill establishes a system of paid family and medical leave insurance. **Voted Ought to Pass with Amendment by the House. Referred to Finance Committee.**

**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. **Introduced and referred to House HHS Committee.**

**HB 1241:** This bill establishes a commission to study the benefits and cost of a "health care for all" program for New Hampshire. **Introduced and referred to House Commerce Committee.**

**HB 1362:** This bill authorizes individuals and certain businesses to purchase health insurance from out-of-state companies. The bill grants rulemaking authority to the insurance commissioner for the purposes of the bill. **Introduced and referred to House Commerce Committee.**

**HB 1367:** This bill declares that children do not have to be immunized against tetanus. **Introduced and referred to House HHS Committee which Voted Inexpedient to Legislate.**

**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 the New Hampshire. **Introduced and referred to House Commerce Committee and sent to subcommittee.**

**HB 1462-FN:** This bill requires employers who offer health or dental benefits, or both, to its employees to maintain that coverage for an employee who has filed a compensable claim under the workers' compensation law for 24 months or until the employee has returned to work, whichever is shorter. **Introduced and referred to House Labor Committee.**

**HB 1465:** This bill requires Medicare supplemental insurance policies to provide coverage for hearing aids. **Introduced and referred to House Commerce Committee.**

**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 with Amendment by Committee. The amendment extends the date for the study committee to report by one year to November 1, 2019.**

**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. The amendment clarifies 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."**

**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.**

**HB 1516:** This bill establishes a commission to examine the feasibility of the New England states entering into a compact for a single payer health care program. **Introduced, referred to House Commerce Committee and sent to subcommittee.**

**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.**

**HB 1560:** This bill provides that sex reassignment drug or hormone therapy or surgery shall not be covered under the state Medicaid plan. **Introduced and referred to House HHS Committee.**

**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.**

**HB 1574:** This bill requires a health care provider and a patient to sign a form upon dispensing controlled drugs explaining the addictive nature of such drugs. **Introduced and referred to House HHS Committee. Voted Inexpedient to Legislate by Committee and full House.**

**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.**

**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.**

**HB1617:** This bill inserts definitions in the RSA chapter relating to communicable disease for clarification purposes. **Introduced and referred to House HHS Committee. Voted Inexpedient to Legislate by Committee.**

**HB 1625:** This bill requires facilities licensed under RSA 151 which perform digital foot scanning of patients and newborns to provide patients and the parents of the newborn an opportunity to "opt out" of such procedure. **Introduced and referred to House HHS Committee. Voted Inexpedient to Legislate by Committee.**

**HB 1643:** This bill prohibits balance billing under the managed care law. **Introduced, referred to House Commerce Committee and sent to subcommittee.**

**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.**

**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.**

**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.**

**HB 1672-FN:** This bill requires a search warrant issued by a judge based upon probable cause for any federal request for information relative to users of therapeutic cannabis created by the registry. **Introduced and referred to House Judiciary Committee.**

**HB 1707-FN:** This bill requires the physician who performs an abortion, or the referring physician, to provide the 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.**

**HB 1732-FN:** This bill establishes a nursing professionals' health program for aiding nurses impaired or potentially impaired by mental or physical illness including substance abuse or disruptive behavior. **Introduced and referred to House Executive Departments and Administration Committee.**
**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 by Committee with Amendment. 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.**

**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.**

**HB 1743:** This bill increases the percentage of money distributed to the alcohol abuse prevention and treatment fund. This bill also repeals the ability of the commissioner to get fiscal committee approval to use certain funds to pay for the operational costs of the Sununu Youth Services Center. **Introduced and referred to House Finance Committee.**

**HB 1746:** This bill prohibits certain practices of pharmacy benefit managers. **Introduced, referred to House Commerce Committee and sent to subcommittee.**

**HB 1747-FN:** This bill requires manufacturers to pre-package class II controlled drugs which are going to be dispensed in New Hampshire in blister packs with serial numbers on each pill. **Introduced and referred to House HHS Committee. Voted Inexpedient to Legislate by Committee and full House.**

**HB1751:** This bill requires insurance coverage for treatment for pediatric autoimmune neuropsychiatric disorders. **Introduced, referred to House Commerce Committee and sent to subcommittee.**

**HB 1755-FN:** This bill establishes an office of the inspector general to independently advocate for the people and provide assistance in the exercise of their Article 14 rights. **Introduced and referred to House Executive Departments and Administration Committee.**

**HB 1769-FN:** This bill prohibits discrimination against physicians based on maintenance of certification. **Introduced and referred to House HHS Committee.**

**HB 1783-FN:** This bill requires newborns to be screened for Krabbe Leukodystrophy. **Introduced and referred to House HHS Committee. Voted Inexpedient to Legislate by Committee and full House.**

**HB 1787-FN:** This bill prohibits discrimination against health care providers who conscientiously object to participating in certain medical procedures. **Introduced and referred to House HHS Committee where it was vacated and referred to House Judiciary Committee.**

**HB 1790-FN-A:** This bill establishes a New Hampshire health access corporation and health access fund. **Introduced and referred to House Commerce Committee. Voted Inexpedient to Legislate by Committee.**

**HB1791-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.**

**HB 1793-FN-A** This bill establishes a single payer health care system to provide health care for the citizens of New Hampshire. **Introduced and referred to House Commerce Committee. Voted Inexpedient to Legislate by Committee and full House.**

**HB 1806:** This bill clarifies the notification procedure if the federal match falls below a certain percentage for the New Hampshire health protection program. **Introduced and referred to House HHS Committee.**

**HB 1809-FN:** This bill prohibits balance billing under the managed care law. This bill is the result of the committee established in 2017, 20. **Introduced, referred to House Commerce Committee and sent to subcommittee.**

**HB 1811-FN-A:** This bill: I. Extends the New Hampshire Health Protection Program. II. Requires the commissioner of the department of health and human services to apply to the Centers for Medicare and Medicaid Services for a waiver to develop a screening process for medically complex persons who are enrolled in the New Hampshire health protection program. III. Allows the use of general funds to fund the New Hampshire health protection program. **Introduced and referred to House HHS Committee. Voted by Committee and House to refer to Interim Study.**

**HB 1813-FN:** This bill requires the commissioner of the department of health and human services to seek a waiver from the Centers for Medicare and Medicaid Services to reduce eligibility for benefits under the New Hampshire health protection program from 138 percent of the poverty level to 100 percent. This bill also requires the commissioner to develop and implement enhanced eligibility screening procedures. **Introduced, referred to House HHS Committee and sent to subcommittee.**

**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.**

**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.**

**<u>Senate Bills</u>**

**SB 154:** This bill allows pharmacies to dispense oral contraceptives to persons 18 years of age or older without a prescription. **This 2017 bill was sent to interim study by the HHS Committee in 2017 and again during this 2018 Session.**

**SB 189-FN:** This bill requires insurance policies to cover 3-D tomosynthesis mammography. **Voted Ought to Pass by the Senate.**

**SB 325:** This bill establishes a committee to study the consolidation of the Board of Mental Health Practice and the Board of Licensing for Alcohol and Other Drug Use Professionals. **Introduced, referred to Senate Executive Departments and Administration. Voted Inexpedient to Legislate by Committee and full Senate.**

**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. **This bill is a request of the Board of Medicine. Introduced and referred to Senate Executive Departments and Administration. Voted Ought to Pass by Committee.**

**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 which voted Ought to Pass with Amendment. The amendment revises the bill by adding specificity to the circumstances under which the synchronization is available.**

**SB 354:** This bill prohibits a pharmacy benefits manager or insurer from charging or holding a pharmacy responsible for a fee related to a claim under certain circumstances. This bill also prohibits a pharmacy benefits manager or insurer from charging higher copayments and or inserting gag clauses in contracts. **Introduced and referred to the Senate Commerce Committee.**

**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 Committee.**

**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 Committee and Senate.**

**SB 378-FN:** This bill exempts certain health care facilities from the requirement of employing registered medical technicians. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee and Senate.**

**SB 381:** This bill declares that a parent or legal guardian shall not be required to have their child immunized against Hepatitis B or other sexually transmitted diseases. **Introduced and referred to Senate HHS Committee. Voted Inexpedient to Legislate by Committee.**

**SB 383:** This bill establishes a commission to study the benefits and costs of a "health care for all" program for New Hampshire. **Introduced and referred to Senate HHS Committee.**

**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.**

**SB 475:** This bill requires health care providers to provide certain information to persons being tested for Lyme disease. **Introduced and referred to Senate HHS Committee.**
**SB 480:** This bill prohibits the use of electroconvulsive therapy on persons under 16 years of age and individuals who are involuntary patients but who have not yet had a competency hearing. The bill requires adults and guardians to sign a detailed written consent form before electroconvulsive therapy is administered. **Introduced and referred to Senate HHS Committee.**

**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. **Introduced and referred to Senate Judiciary Committee.**

**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. **Introduced and referred to Senate Executive Departments and Administration which voted Ought to Pass. Senate voted Ought to Pass. Referred to Senate Finance Committee.**

**SB 551:** This bill requires insurers offering health insurance policies with coverage for prescription drugs to credit against any deductible out-of-pocket expenses for medication. **Introduced and referred to House HHS Committee which referred the bill for interim study.**

**SB 573:** 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. The amendment clarifies the access by the Chief Medical Examiner and delegates.**

**SB 576-FN:** This bill repeals the provision suspending home health services rate setting established in 2017, 156. **Introduced and referred to Senate Finance Committee.**

**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. **Introduced and referred to Senate Executive Departments and Administration which voted Ought to Pass.**

**LSR**

**2018-2956 SB**: Title: reforming New Hampshire's Medicaid and Premium Assistance Program.

## 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.

**KARA J. DOWAL, ESQ.**
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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Alex practices health care law and civil litigation at Shaheen & Gordon, P.A. Alex focuses his health care practice on assisting providers in regulatory compliance, contracting, provider transition, and litigation.