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# Health Care Practice Group

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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**

## Colorado Hospital Agrees to Pay \$111,400 to Settle Allegations of HIPAA Violation

On December 11, 2018, the U.S. Department of Health and Human Services Office of Civil Rights ("OCR") announced a \$111,400 settlement of allegations that a Colorado critical access hospital violated the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") by failing to terminate a former employee's access to its web-based scheduling calendar. According to OCR, the hospital's failure resulted in the disclosure of 557 individuals' PHI to the former employee. In addition to the payment, the settlement also includes the hospital's agreement to a two-year corrective action plan to update its security management and business associate agreements, policies and procedures, and train its workforce members regarding the same.

OCR's announcement of the settlement is available at: <a href="https://www.hhs.gov/about/news/2018/12/11/colorado-hospital-failed-to-terminate-former-employees-access-to-electronic-protected-health-information.html">https://www.hhs.gov/about/news/2018/12/11/colorado-hospital-failed-to-terminate-former-employees-access-to-electronic-protected-health-information.html</a>.

# OIG Reports that CMS Has Failed to Recover Over \$1 Billion in Identified Medicaid Overpayments

On December 11, 2018, the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG") published a report titled "The Centers for Medicare & Medicaid Services Had Not Recovered More Than a Billion Dollars in Medicaid Overpayments Identified by OIG Audits." OIG performed an audit of the Centers for Medicare & Medicaid Services ("CMS") efforts to collect overpayments identified in audits in fiscal years 2010 through 2015. OIG's audit was a follow-up to a prior audit they had conducted for fiscal years 2000 through 2009. OIG's review found that CMS had failed to collect almost \$1.8 billion in overpayments identified in 84 audits, in part because CMS' policies and procedures did not include timelines for resolving overpayments when states disagreed with the recommendations. In addition to recommending that CMS recover the \$1.8 billion, OIG recommended that CMS set guidelines regarding the timing of its work with states to resolve the overpayment issues and that CMS verify that states are reporting overpayments correctly.

OIG's report is available at: <a href="https://oig.hhs.gov/oas/reports/region5/51700013.pdf">https://oig.hhs.gov/oas/reports/region5/51700013.pdf</a>.

## HHS Seeks Public Input on Reforming HIPAA to Improve Care Coordination

On December 14, 2018, the U.S. Department of Health and Human Services Office of Civil Rights ("OCR") published a Request for Information ("RFI") seeking public input on ways to modify the Health Insurance



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Portability and Accountability Act of 1996 ("HIPAA") to remove regulatory obstacles and decrease regulatory burdens to care coordination. The RFI also seeks comment on certain proposed modifications to the HIPAA Privacy Rule, including:

- Promoting information sharing for treatment and care coordination and/or case management by amending the Privacy Rule to encourage, incentivize, or require covered entities to disclose PHI to other covered entities;
- Encouraging covered entities, particularly providers, to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies, with a particular focus on the opioid crisis:
- Implementing the HITECH Act requirement to include, in an accounting of disclosures, disclosures for treatment, payment, and health care operations from an electronic health record (EHR) in a manner that provides helpful information to individuals, while minimizing regulatory burdens and disincentives to the adoption and use of interoperable EHRs; and
- Eliminating or modifying the requirement for covered health care providers to make a good faith effort to obtain individuals' written acknowledgment of receipt of providers' Notice of Privacy Practices.

The comment period for the RFI closed on February 11.

The RFI is available at: <a href="https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf">https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf</a>.

### ACA Ruled Invalid by Texas Court

On December 14, 2018, the U.S. District Court for the Northern District of Texas ruled that the entire Affordable Care Act ("ACA") was invalid, although it did not issue an injunction barring the ACA's enforcement, resulting in no immediate effect. The lawsuit, filed by 20 Republican-led states, sought to declare the ACA unconstitutional after-tax reform legislation removed the tax penalty for failing to maintain coverage, effective January 1, 2019. Texas Judge Reed O'Connor held that once the penalty was eliminated, the entire statute could not stand. Sixteen states and the District of Columbia intervened in the action to defend the ACA and subsequently filed a motion seeking to Judge O'Connor to either stay the order or certify it for review by the Fifth Circuit. On December 30, 2018, Judge O'Connor issued an order staying its judgment pending resolution of appeals of the decision.

The decision, *Texas v. United States*, No. 4:18-cv-00167-O (N.D. Tex. Dec. 14, 2018), may be found here: <a href="https://oag.ca.gov/system/files/attachments/press-docs/211-texas-order-granting-plaintiffs-partial-gummary-judgment.pdf">https://oag.ca.gov/system/files/attachments/press-docs/211-texas-order-granting-plaintiffs-partial-gummary-judgment.pdf</a>

The order staying the judgment may be found here: <a href="https://www.calt.iastate.edu/files/document%2812%29.pdf">https://www.calt.iastate.edu/files/document%2812%29.pdf</a>

### Virginia Court Finds Hospital Has Duty to Protect Patient from Assault

On December 18, 2019, a trial court in Virginia held that a hospital has a duty to protect a patient from foreseeable harm. (*Denisenko v. Sentara Hosps.,* No. CL177986 (Va. Cir. Ct. Dec. 18, 2018)). The plaintiff in the action checked in to the emergency room at Sentara Norfolk General Hospital and was in the waiting room. Another patient, who was checked by the triage nurse and then returned to the waiting room, attacked the plaintiff without warning or provocation. The plaintiff alleged that the other patient had a known



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history of violence and that the hospital owed a duty to protect him from assault. The hospital argued it did not owe him a duty to the plaintiff because the Emergency Medical Treatment and Labor Act ("EMTALA") requires that hospitals not exclude anyone who enters their emergency departments seeking treatment. Although the court acknowledged the hospital's duty under EMTALA, it still found that the hospital had a duty to protect its patients from foreseeable harm.

#### Court Order Causes EEOC to Drop Rules on Workplace Wellness Incentives

On December 20, 2018, the Equal Employment Opportunity Commission ("EEOC") published a final rule to remove a workplace wellness regulatory section originally published on May 17, 2016 and promulgated under the Genetic Information Nondiscrimination Act ("GINA"). The section of the EEOC regulations to be removed was an incentive section intended to be effective January 1, 2019 but was vacated by the U.S. District Court for the District of Columbia. The original rule allowed employers to offer financial incentives to employees who participate in workplace wellness programs, up to 30% of employee-only coverage, and offered the same financial incentive for an employee's spouse. The court determined that the incentives under the EEOC rule failed to meet the "voluntary" standard under both GINA and the Americans with Disabilities Act ("ADA"), which allow employers to ask health-related questions and conduct medical examinations only if it is voluntary for employees. The AARP challenged the rule, saying that the 30% cost of coverage incentive was more coercive than voluntary.

The final rule is found here: <a href="https://www.federalregister.gov/documents/2018/12/20/2018-27538/removal-of-final-gina-wellness-rule-vacated-by-court">https://www.federalregister.gov/documents/2018/12/20/2018-27538/removal-of-final-gina-wellness-rule-vacated-by-court</a>

#### CMS Issues Final Rule for ACOs

On December 21, 2018, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule (published December 31, 2018 in the *Federal Register*), redesigning the Medicare Shared Savings Program, including making Accountable Care Organizations ("ACOs") take on more financial risk. Citing the fact that most Medicare ACOs do not face financial consequences when costs increase, CMS explained in a press release that the final rule, "Pathways to Success," is designed to ensure that ACOs deliver the most value. Pathways to Success is designed to encourage ACOs to transition to two-sided risk models where they share in savings and are also accountable for repaying shared losses. The final rule summarizes that its "policies are designed to increase savings for the Trust Funds and mitigate losses, reduce gaming opportunities, and promote regulatory flexibility and free-market principles" and also provide "new tools to support coordination of care across settings and strengthen beneficiary engagement; and ensure rigorous benchmarking." CMS projects savings to Medicare from the changes to amount to \$2.9 billion over 10 years.

The final rule is effective February 14, 2019.

The CMS press release on the final rule is here: <a href="https://www.cms.gov/newsroom/press-releases/cms-finalizes-pathways-success-overhaul-medicares-national-aco-program">https://www.cms.gov/newsroom/press-releases/cms-finalizes-pathways-success-overhaul-medicares-national-aco-program</a>

The final rule may be found here: <a href="https://www.federalregister.gov/documents/2018/12/31/2018-27981/medicare-program-medicare-shared-savings-program-accountable-care-organizations-pathways-to-success">https://www.federalregister.gov/documents/2018/12/31/2018-27981/medicare-program-medicare-shared-savings-program-accountable-care-organizations-pathways-to-success</a>



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### U.S. District Court Enjoins Implementation of 340B Drug Payment Cuts

On December 27, 2018, the U.S. District Court for the District of Columbia granted a permanent injunction against the implementation of a planned cut to the 340B reimbursement rate from the average sales price ("ASP") plus 6% to ASP minus 22.5%. In granting the injunction, the Court held that the Department of Health and Human Services Secretary exceeded his statutory authority when he implemented the rate cut because the almost 30% reduction in reimbursement was too severe to be considered an "adjustment" within his authority. Rather than vacate the cuts entirely, which the Court recognized could wreak havoc on the complex Medicare reimbursement system, the Court ordered the parties to submit briefing on an appropriate remedy in 30 days.

The Court's order in *American Hosp. Ass'n v. Azar*, No. 18-2084 (RC) (D.D.C. Dec. 27, 2018) is available at https://ecf.dcd.uscourts.gov/cgi-bin/show\_public\_doc?2018cv2084-25.

#### Task Force Issues Report of Pain Management Recommendations

On December 28, 2018, the U.S. Department of Health and Human Services ("HHS") announced a draft report issued by the Pain Management Best Practices Inter-Agency Task Force. The 29-member Task Force was established by the Comprehensive Addiction and Recovery Act of 2016 to propose updates to best practices and issue recommendations that address gaps or inconsistencies for managing chronic and acute pain. The draft report encourages a patient-centered approach to treating chronic pain, and includes recommendations in several areas, including: clinical best practices; approaches to acute and chronic pain management; pain treatments; access to pain care; education, training, and evaluation; and specific approaches to treating pain in special populations.

The public has 90 days to submit comments on the draft report.

The draft report is available at: <a href="https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html">https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html</a>.

HHS' announcement of the draft report is available at:

https://www.hhs.gov/about/news/2018/12/28/pain-management-task-force-calls-patient-centered-approachimprove-treatment-pain.html.

Information about submitting a comment to the draft report is available at: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html.

#### HHS Issues Publication Identifying Cybersecurity Threats and Best Practices

On December 28, 2018, the U.S. Department of Health and Human Services ("HHS") issued a publication titled "Health Industry Cybersecurity Practices (HICP): Managing Threats and Protecting Patients." According to an HHS press release, the publication was created "in response to a mandate set forth by the Cybersecurity Act of 2015 Section 405(d), to develop practical cybersecurity guidelines to cost-effectively reduce cybersecurity risks for the healthcare industry." The publication examines current cybersecurity threats facing the health care sector, identifies specific weaknesses that make organizations more vulnerable to the threats; and provides practices that cybersecurity experts rank as the most effective to mitigate the threats. The threats identified in the publication include email phishing attacks; ransomware attacks; loss or theft of equipment or data; and insider, accidental or intentional data loss.



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The publication is available at: <a href="https://www.phe.gov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf">https://www.phe.gov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf</a>.

HHS' press release is available at: <a href="https://www.hhs.gov/about/news/2018/12/28/hhs-in-partnership-with-industry-releases-voluntary-cybersecurity-practices-for-the-health-industry.html">https://www.hhs.gov/about/news/2018/12/28/hhs-in-partnership-with-industry-releases-voluntary-cybersecurity-practices-for-the-health-industry.html</a>.

#### CMS Increases Fees Charged to Clinical Labs

On December 31, 2018, the Centers for Medicare & Medicaid Services ("CMS") published a notice in the Federal Register announcing that fees charged to clinical laboratories will increase by 20% in 2019. According to CMS, the increase in certification and other fees assessed to clinical laboratories is needed to provide continued funding to CMS' laboratory oversight under the Continued Laboratory Improvement Amendments ("CLIA") program, and that without the increase the CLIA program will no longer be solvent as of 2020. The fee increase – the first since 1992 – is effective immediately.

CMS seeks public comment on the fee increase through March 1.

The notice is available at: https://www.govinfo.gov/content/pkg/FR-2018-12-31/pdf/2018-28359.pdf.

### Guidance from IRS on Nonprofit Executive Compensation

On December 31, 2018, the Internal Revenue Service ("IRS") issued guidance concerning the 21% excise tax imposed on certain tax-exempt employers for executive compensation paid to covered employees over \$1 million and on any excess parachute payments. The excise tax is part of the Tax Cuts and Jobs Act, enacted on December 22, 2017, and amends Section 4960 of the Internal Revenue Code ("IRC"). The tax takes effect for tax years effective after December 31, 2017. Both components of Section 4960 (compensation over \$1 million and excess parachute payments) are triggered by compensation paid to "covered employees," defined as one of the organization's five highest compensated employees in any tax year after December 31, 2016. The IRS' interim guidance, Notice 2019-09 (the "Notice") states that it intends is issue proposed regulations regarding Section 4960, however, until that time, the Notice reflects the IRS' and the Treasury Department's good faith, reasonable interpretation of the statute. Topics covered by the Notice include how to determine when an employee is a "covered employee", when covered employee status ends, when compensation is counted for purposes of the excise tax, and how to deal with old vested compensation that has not been paid (an exception to the scope of the tax).

The IRS requested comments on the Notice by April 2, 2019.

The IRS Notice 2019-09 can be read in full here: https://www.irs.gov/pub/irs-drop/n-19-09.pdf

#### Supreme Court Declines Review of FCA Case on Materiality

On January 7, 2019, the Supreme Court of the United States denied a petition to hear a case coming out of the Ninth Circuit involving the question of whether a False Claims Act ("FCA") claim fails if the government continues to approve and pay for claims after it knows of regulatory violations. (*Gilead Sci. Inc. v. United States ex rel. Campie*, No. 17-936, *rev. denied* (U.S. Jan. 7, 2019)). A *qui tam* action was brought against Gilead Sciences, Inc., alleging that in its manufacturing of HIV drugs it made false statements about its compliance with Food and Drug Administration ("FDA") regulations, resulting in false claims. Gilead argued that since the government continued to pay on the claims even after it knew of the violations, this meant that the violations were in fact not material. However, the Ninth Circuit held that seeking payment for



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drugs that did not comply with FDA regulations could result in FCA liability and that relators in the case adequately pled "materiality." The petition to the Supreme Court cited the fact that six other circuit courts had determined that the government's continued payment after knowing of regulatory violations was strong evidence of immateriality.

The Ninth Circuit decision, *United States ex rel. Campie v. Gilead Sciences, Inc.*, No. 15-16380 (9th Cir. July 7, 2017), can be read here: <a href="http://cdn.ca9.uscourts.gov/datastore/opinions/2017/07/07/15-16380.pdf">http://cdn.ca9.uscourts.gov/datastore/opinions/2017/07/07/15-16380.pdf</a>

### OIG Approves Charitable Clinic's Cost-Sharing Waivers

On January 9, 2019, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued Advisory Opinion No. 19-01, in which it approved a charitable pediatric clinic's waiver of cost-sharing amounts for Federal health care program beneficiaries. The clinic provides medical, psychiatric and dental care to at-risk children in a Health Professional Shortage Area. While the OIG determined that the arrangement implicates both the Anti-Kickback Statute ("AKS") and the prohibition against beneficiary inducements, it ultimately concluded that the arrangement posed a minimal risk of fraud and abuse because of several characteristics, including: that it does not advertise the cost-sharing waivers; it does not offer any financial incentives to its providers based on the volume or value of services or referrals; and it does not consider a patient's medical condition or insurance status when determining eligibility for services.

The advisory opinion is available at: <a href="https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-01.pdf">https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-01.pdf</a>.

## Federal Courts Issue Injunctions Against Rules Expanding Exceptions to ACA Contraceptive Mandate

On January 13 and 14, 2019, two Federal courts issued preliminary injunctions against two final rules that were set to go into effect on January 14 that would have expanded the exemption to the Affordable Care Act's ("ACA") mandate that employers-based health insurance cover contraceptives. The injunctions are based, in part, on the courts' determinations that the parties challenging the rules are likely to succeed on their claims that the rules conflict with Federal law. One of the rules expands the exception to the mandate to apply to entities that object to contraceptives because of sincerely-held religious beliefs, and the other provides protections for entities that object on moral grounds.

The decision in *California v. Health and Human Servs.*, No. 17-cv-05783-HSG (N.D. Cal. Jan. 13, 2019) is available at: https://oag.ca.gov/system/files/attachments/press-docs/pi-order.pdf.

The decision in *Pennsylvania v. Trump*, No. 17-450 (E.D. Pa. Jan. 14, 2019) is available at: <a href="https://www.attorneygeneral.gov/wp-content/uploads/2019/01/2019-01-14-Opinion.pdf">https://www.attorneygeneral.gov/wp-content/uploads/2019/01/2019-01-14-Opinion.pdf</a>.

#### California Abortion Notice Requirement Violates Federal Conscience Protection Laws

On January 18, 2019, the U.S. Department of Health and Human Services Office for Civil Rights ("OCR") announced its first finding of a violation of newly-enacted Federal "conscience protection" laws that prohibit state and local governments that receive certain Federal funds from subjecting health care entities to discrimination based on the fact that health care entity does not perform abortions. The newly-created Conscience and Religious Freedom Division of OCR found that California's Reproductive Freedom, Accountability, Comprehensive Care, and Transparency Act violated Federal law by fining health care



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entities that fail or refuse to post notices stating that California provides free or low-cost family planning services and abortion.

OCR's announcement is available at: <a href="https://www.hhs.gov/about/news/2019/01/18/ocr-finds-state-california-violated-federal-law-discriminating-against-pregnancy-resource-centers.html">https://www.hhs.gov/about/news/2019/01/18/ocr-finds-state-california-violated-federal-law-discriminating-against-pregnancy-resource-centers.html</a>.

#### CMS Rolls out New Risk Model for Medicare Part D and Updated Medicare Advantage Model

On January 18, 2019, the Centers for Medicare & Medicaid Services announced the "Part D Payment Modernization" model for Medicare Part D. The model is intended to "test the impact of a revised Part D program design and incentive alignment on overall Part D prescription drug spending and beneficiary out-of-pocket costs." The voluntary, five-year model will attempt to decrease total Part D spending in two ways:

- 1. Creating new incentives for plans, patients, and providers to choose drugs with lower list prices to better manage catastrophic phase federal reinsurance subsidy spending by introducing two-sided risk to align payment incentives for plan sponsors with their enrollees and CMS; and
- 2. Providing programmatic flexibilities, including Part D Rewards and Incentives programs, to ensure Medicare beneficiaries can maintain affordable access to the prescription drugs that they need.

CMS also announced updates to the existing Value-Based Insurance Design ("VBID") for Medicare Advantages plans. The changes to the VBID model are intended to "contribute to the modernization of Medicare Advantage through increasing choice, lowering cost, and improving the quality of care for Medicare beneficiaries."

CMS' announcement and fact sheets for the two new model updates are available at: <a href="https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-lower-drug-prices-medicare-part-d-and-transformative-updates-existing-model">https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-lower-drug-prices-medicare-part-d-and-transformative-updates-existing-model</a>.

### Site-Neutral Payments Result in Hospital Suits

On January 18, 2019, thirty-eight (38) hospitals filed suit in the U.S. District Court for the District of Columbia challenging a final rule by the Centers for Medicare & Medicaid Services ("CMS") that expanded the site-neutral payment policy to grandfathered, off-campus hospital departments. A similar suit was filed in December 2018 by the American Hospital Association, the Association of American Medical Colleges, and other hospitals. The rule was issued in November 2018 as part of the 2019 Outpatient Prospective Payment Rule. The policy reimburses clinical visits at excepted provider-based departments ("PBDs") at the Physician Fee Schedule rate beginning January 1, 2019, as opposed to the higher payment for clinical visits in the hospital outpatient setting. The policy will phase-in over a period of two years. The complaint argues that the site-neutral policy is irrational, exceeded its authority under the Medicare Act and directly contravened congressional intent to except grandfathered PBD's under Section 603 of the Bipartisan Budget Act of 2015.

The 2019 Outpatient Prospective Payment Rule can be found here: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24243.pdf

# OIG Issues Advisory Opinion Approving of Drug Maker's Proposal to Loan Smartphones to Patients for Digital Medicine Use

On January 29, 2019, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") issued Advisory Opinion No. 19-02, in which it approved a pharmaceutical manufacturer's



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proposal to loan, on a temporary basis, a limited-functionality smartphone to financially needy patients who do not have the technology necessary to receive adherence data from a sensor embedded in prescribed antipsychotic medication. The medication works via a drug embedded with an ingestible sensor which gives off a signal that is detected by a wearable sensor patch on the patient's abdomen. To use the drug effectively, the patient must possess a smartphone capable of running an application that displays the information recorded by the patch and through which the patient can record their mood, sleep activity, and other information.

Under the Proposed Arrangement, the manufacturer would loan a device with highly limited functionality to patients who: (1) have a prescription for the drug for on-label use; (2) meet any applicable prior-authorization or therapeutic-step-edit requirements required by the patient's insurer; (3) have an annual income below a specific percentage of the Federal poverty level; (4) do not already possess a device capable of running the application; and (5) are United States citizens or legal permanent residents.

In approving the manufacturer's proposal, OIG found that it fell under the "Promotes Access to Care" exception to the prohibition against beneficiary inducements and would, therefore, not implicate the related civil monetary penalties. OIG's conclusion was based on its findings that the free smart device would improve a patient's ability to access the full scope of the benefits of the drug, would be unlikely to interfere with clinical decision making, would be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization, and would not raise patient safety or quality of care concerns. OIG concluded that the arrangement would not violate the Anti-Kickback Statute for similar reasons.

The Advisory Opinion is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-02.pdf.

## Court Sentences Physician Who Prescribed Pain Meds Without Physical Exams Six Months in Prison for Health Care Fraud

On January 30, 2019, the U.S. District Court for the Middle District of Florida sentenced a Florida doctor to six months in Federal prison for committing health care fraud for billing Medicare for face-to-face office visits at her pain management clinic when in fact she had been meeting with patients' family members and writing prescriptions for Schedule II drugs in the patients' names. The scheme violated a Florida law requiring doctors to perform in office visits and examinations of patients before issuing prescriptions for Schedule II drugs. The scheme resulted in at least \$52,000 in claims falsely submitted to Medicare and Medicaid, which the doctor was ordered to pay back as part of her sentence. Additionally, her Florida medical license, Medicare enrollment, and DEA registration were all revoked.

The U.S. Attorney's announcement of the sentence is available at: <a href="https://www.justice.gov/usao-mdfl/pr/clearwater-doctor-sentenced-prison-health-care-fraud">https://www.justice.gov/usao-mdfl/pr/clearwater-doctor-sentenced-prison-health-care-fraud</a>.

#### Proposed Rule Revises Safe Harbor for Drug Rebates to Bring Down Drug Costs

On January 31, 2019, the U.S. Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") published a proposed rule that would remove the safe harbor to the Anti-Kickback Statute that protects the payment of rebates from drug manufacturers to pharmacy benefit managers, Medicare Part D plans, and Medicaid managed care organizations. According to HHS Secretary Azar, the proposed rule is intended to result in lower drug prices for seniors, by removing the most significant incentive for drug manufacturers to raise list prices and by the addition of a new safe harbor for drug discounts offered



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directly to patients. The proposed rule also adds a second new safe harbor for fixed-fee service agreements between drug manufactures and pharmacy benefit managers.

Comments on the proposed rule must be submitted by April 8, 2019.

The proposed rule is available at: <a href="https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals">https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals</a>.

HHS' press release on the proposed rule is available at:

https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html.

### STATE DEVELOPMENTS

#### **REMINDERS:**

- Annual Reports for New Hampshire business entities are due to the Secretary of State by April 1, 2019.
- Annual Breach Notification Reports must be made to the Office of Civil Rights by March 1,
   2019 at: https://ocrportal.hhs.gov/ocr/breach/wizard\_breach.jsf?faces-redirect=true

#### Governor Establishes Council to Address Opioid Prescribing

On January 10, Governor Sununu signed an Executive Order establishing the NH Opioid Overprescribing and Misuse Project Advisory Council. The Order recognizes the continued opioid epidemic with resulting high levels of overdose deaths and cites opioid overprescribing as a primary factor in the rise of such deaths. CMS is committed to working with states to address this issue and has selected NH to begin its State Engagement to Address Opioid Overprescribing and Misuse. As part of this new initiative MITRE Corporation, a federally funded non-profit, will develop a quantitative framework for measuring patterns of opioid prescribing practice and will create and apply advanced analytic methods to identify abnormal and suspect patterns of provider behavior. The Advisory Council will help facilitate the State's efforts to coordinate with CMS and the MITRE Corporation in this initiative.

The full text of the Governor's Executive Order may be found at: https://www.governor.nh.gov/news-media/orders-2019/documents/2019-01.pdf

#### State Launches Doorway-NH for Assistance to Individuals with Substance Use Disorders

On January 1, the State launched its new program to help individuals suffering from substance use disorders. Doorway-NH is a hub and spoke model which provides a state-wide 24 hour/day call-in number (2-1-1) to connect callers with one of the nine hubs which are located in Berlin, Littleton, Lebanon, Laconia, Dover, Keene, Manchester, Nashua and Concord. The hubs then work with individuals to obtain the assessment and treatment needed through contracts with local providers. The program is funded with a federal grant of \$45.8 million. DHHS held education sessions about the program throughout the state in January.



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### NH Hospital Association Intervenes in ACLU Lawsuit Against State

On January 7, the New Hampshire Hospital Association issued a statement explaining its decision to intervene in a lawsuit previously filed by the ACLU against the State alleging mental health patients being held in hospital emergency rooms are being denied their due process rights. Steven Ahnen, President of the NH Hospital Association, noted that patients are not only being deprived of their due process rights but also of their right to timely treatment. Ahnen stated that the State has not been in compliance with its obligation to provide treatment for years and instead relied on hospitals to hold these patients in their emergency departments until a bed becomes available. Ahnen further noted that hospital emergency departments are "ill-equipped to meet the specialized needs to these patients." However, due to the shortage of designated receiving facility beds, patients are forced to wait days, sometime weeks, in hospital emergency departments before they are transferred to appropriate sites of care. The NHHA agrees with a number of the allegations in the ACLU lawsuit but believes the narrow focus on due process does not adequate address the patients' needs. In addition, the NHHA disagrees with the ACLU that holding probable cause hearings in hospital emergency departments is a viable option. "The solution is not to build courtrooms in hospital EDs; the solution is to move these patients to appropriate DRFs where they can get the care and due process to which they are entitled by state law" said Ahnen.

The full text of the statement released by NHHA may be found at: <a href="https://nhha.org/index.php/whats-new/1507-nhha-releases-statement-on-aclu-nh-lawsuit-intervention">https://nhha.org/index.php/whats-new/1507-nhha-releases-statement-on-aclu-nh-lawsuit-intervention</a>

#### DHHS proposes Administrative Rules Governing the NH Granite Advantage Program

The proposed new rule describes the new community engagement requirements for the Granite Advantage program, exemption from the work and community engagement program, qualifying activities, the impact of noncompliance and the means for curing deficits in community engagement hours. The proposed rules will affect beneficiaries in the Granite Advantage Program who, if not exempted, will be required to engage in 100 hours per month of qualifying community engagement activities as a condition of eligibility for the Program. A public hearing on the proposed rule is scheduled for Tuesday, February 19.

The full text of the proposed rule and details of the public hearing may be found at: https://www.dhhs.nh.gov/oos/aru/documents/hew837ip.pdf

### **LEGISATIVE UPDATES**

#### **House Bills**

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

**HB 118:** AN ACT requiring a child's primary health care provider to be notified of a report of suspected abuse or neglect and relative to access to the department of health and human services case record. This bill requires the department of health and human services to notify a child's primary health care provider of a



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report of suspected abuse or neglect regarding the child. The bill also permits a child's primary health care provider to access the child's case record if such access is necessary to provide treatment or services or to determine the status of a report under investigation by the department. **Introduced and referred to House Children and Family Law Committee.** 

**HB 124:** AN ACT repealing the law relative to the buffer zones to reproductive health care facilities. This bill repeals the law relative to the buffer zones to reproductive health care facilities. **Voted inexpedient to legislate by House.** 

HB 127: AN ACT relative to the board of medicine and the medical review subcommittee. This bill clarifies the service of the medical director on the board of medicine and the employment of the medical review subcommittee investigator. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee. Amendment provides that physician to serve as medical review subcommittee investigator shall be contracted.

**HB 179-FN-A:** AN ACT establishing a New Hampshire health access corporation. This bill establishes a New Hampshire health access corporation and health access fund. **Introduced and referred to House Commerce Committee.** 

**HB 180:** AN ACT establishing a commission to examine the feasibility of the New England states entering into a compact for a single payer health care program. 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 and referred to House Commerce Committee.** 

**HB 200:** AN ACT relative to serologic testing including Lyme disease. This bill requires the commissioner of the department of health and human services to adopt rules clarifying serologic testing for communicable diseases and for Lyme disease. **Introduced and referred to House HHS Committee.** 

**HB 227:** AN ACT relative to the length of time an employer may lease an employee through an employee leasing company. This bill limits the length of time that a person may work for an employee leasing company. **Introduced and referred to House Labor Committee.** 

**HB 233:** AN ACT relative to the group and individual health insurance market. This bill establishes the provisions of the Patient Protection and Affordable Care Act of 2009, Public Law 111-148, as amended in statute. **Introduced and referred to House Commerce Committee.** 

**HB 239:** AN ACT relative to license requirements for certain mental health and drug counselors. This bill reduces the number of hours or work experience required for licensure as a master licensed alcohol and drug counselor, a licensed alcohol and drug counselor, a licensed clinical supervisor, a clinical social worker, and a clinical mental health counselor. **Introduced and referred to House HHS Committee.** 

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



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**HB 277:** AN ACT establishing a commission to study a public option for health insurance. This bill establishes a commission to study a public option program for health insurance in New Hampshire. **Introduced and referred to House Commerce Committee.** 

**HB 278:** AN ACT relative to the New Hampshire insurance department's annual hearing requirement. This bill updates the insurance commissioner's annual public hearing requirement relative to premium rates. This bill is a request of the insurance department. **Introduced and referred to House Commerce Committee.** 

HB 284: AN ACT relative to biennial controlled substance inventories conducted under the Controlled Drug Act. This bill requires persons required by federal law to conduct biennial controlled substance inventories to conduct them every odd-numbered year. Current law provides specific dates for such inventories. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee. Amendment permits the pharmacy board to enact rules to ensure compliance.

**HB 335**: AN ACT relative to therapeutic cannabis dispensary locations. This bill clarifies where a second dispensary may be geographically located for the purposes of the use of cannabis for therapeutic purposes law. **Introduced and referred to House HHS Committee.** 

**HB 350:** AN ACT relative to licensed prescribers of medical marijuana. This bill adds physician assistants as prescribing providers for purposes of the use of cannabis for therapeutic purposes law. **Introduced and referred to House HHS Committee.** 

**HB 359:** AN ACT relative to warning labels on prescription drugs containing opiates. This bill requires any drug which contains an opiate dispensed by a health care provider or pharmacy to have a red cap and a warning label regarding the risks of the drug. **Introduced and referred to House Commerce Committee.** 

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

**HB 369-FN:** AN ACT relative to the controlled drug prescription health and safety program. This bill clarifies the rule regarding querying the controlled drug prescription health and safety program when writing an initial opioid prescription for a patient's pain or substance use disorder. **Introduced and referred to House HHS Committee.** 

**HB 422:** AN ACT relative to certain procedures performed in teaching hospitals. This bill prohibits a physician or surgeon or a student undertaking a course of professional instruction from performing a pelvic examination on an anesthetized or unconscious female patient unless such examination is within the scope of care for the surgical procedure. **Introduced and referred to House HHS Committee.** 

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

**HB 463-FN:** AN ACT relative to voluntary licensure of pharmacist assistants. This bill establishes voluntary licensure of pharmacist assistants to allow persons working as pharmacist assistants for supervising



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pharmacists to be licensed to perform certain pharmacist tasks. **Introduced and referred to House Executive Departments and Administration Committee.** 

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

**HB 490:** AN ACT relative to testing for Lyme disease. This bill requires health care providers to provide certain information to persons being tested for Lyme disease. **Introduced and referred to House HHS Committee.** 

**HB 508:** AN ACT relative to direct primary care. This bill declares that primary care providers providing direct primary care pursuant to a primary care agreement are not subject to the insurance laws, provided that certain conditions are met. **Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by Committee. Amendment makes minor to conditions.** 

**HB 509:** AN ACT relative to a graduate physician pilot program. This bill establishes a pilot program for the regulation and licensure of graduate physicians each year by the board of medicine. Practice of a graduate physician is limited to medically underserved areas and rural health clinics. **Introduced and referred to House HHS Committee. Voted Inexpedient to Legislate by Committee.** 

**HB 528-FN:** AN ACT relative to insurance reimbursement for emergency medical services. This bill requires insurers to consider the presenting symptoms rather than the final diagnosis when determining whether to cover and pay for emergency services. **Introduced and referred to House Commerce Committee.** 

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

**HB 547-FN:** AN ACT relative to licensure of polysomnographers. This bill requires persons practicing polysomnography to be licensed and establishes the governing board of polysomnographers under allied health professionals. **Introduced and referred to House Executive Departments and Administration Committee.** 

**HB 552-FN:** AN ACT relative to transparency and standards for acquisition transactions in health care. This bill clarifies the standards for acquisition transactions involving health care charitable trusts and the review required by the director of charitable trusts. **Introduced and referred to House Judiciary Committee.** 

**HB 604:** AN ACT establishing a commission to assess benefits and costs of a "health care for all" program for New Hampshire. This bill establishes a commission to study the benefits and cost of a "health care for all" program for New Hampshire. **Introduced and referred to House Commerce Committee.** 

**HB 610-FN:** AN ACT relative to treatment alternatives to opioids. This bill requires the department of health and human services to create a voluntary non-opioid directive form which may be used for nonopioid



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treatment options for pain. This bill also establishes insurance coverage for such treatment options. **Introduced and referred to House HHS Committee.** 

**HB 615:** AN ACT relative to the regulation of pharmacies and pharmacists. This bill makes various changes to the regulation of pharmacies and pharmacists by the board of pharmacy, including procedures of the board, exceptions to possessing prescription drugs, license expirations and renewals, and establishing the licensure of drug distribution agents. **Introduced and referred to House Executive Departments and Administration Committee.** 

**HB 638:** AN ACT requiring health care providers to provide an opioid disclosure form to patients for whom an opioid is prescribed. This bill requires health care providers to require patients to sign a form upon dispensing controlled drugs explaining the addictive nature of such drugs. **Introduced and referred to House HHS Committee.** 

**HB 656:** AN ACT establishing a commission to study the impact of financial initiatives for commercially insured members by drug manufacturers on prescription drug prices and health insurance premiums. This bill establishes a commission to study the impact of financial initiatives for commercially insured members by drug manufacturers on prescription drug prices and health insurance premiums. **Introduced and referred to House Commerce Committee.** 

**HB 658-FN:** AN ACT relative to price increases of drugs under the managed care law. This bill clarifies the content of provider contract standards under the managed care law. This bill is a result of the commission to study greater transparency in pharmaceutical costs and rebate programs established in 2018, 350. **Introduced and referred to House Commerce Committee.** 

**HB 659:** AN ACT relative to reporting of internal pharmaceutical costs. This bill requires the insurance commissioner to request data from health carriers regarding prescription drug benefits which are outsourced to a pharmacy benefit manager or similar entity as part of the preparation for the department's annual hearing requirement. This bill is a result of the commission to study greater transparency in pharmaceutical costs and rebate programs established in 2018, 350. **Introduced and referred to House Commerce Committee.** 

**HB 670-FN:** AN ACT relative to the cost of prescription drugs. This bill requires health insurance carriers to maintain certain information relative to prescription drug costs within their data systems for purposes of the managed care law. **Introduced and referred to House Commerce Committee.** 

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

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



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

**HB 693-FN:** AN ACT relative to aid to persons funded by Medicaid and for persons who are uninsured and establishing a special fund. This bill requires health care practitioners and health care facilities to accept persons who are funded by Medicaid and who are uninsured. A health care practitioner or facility may opt out of this requirement by paying an annual fee to the department of health and human services which shall be deposited into a fund to aid such persons. **Introduced and referred to House HHS Committee.** 

**HB 697-FN-A:** AN ACT relative to Medicare for all. 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.** 

**HB 703-FN:** AN ACT relative to providing notice of the introduction of new high-cost prescription drugs. This bill requires prescription drug manufacturers to provide certain notice to the office of the attorney general if they are introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. **Introduced and referred to House Commerce Committee.** 

**HB 717-FN:** AN ACT prohibiting prescription drug manufacturers from offering coupons or discounts to cover insurance copayments or deductibles. This bill prohibits with limited exceptions, prescription drug manufacturers from offering coupons or discounts to cover insurance copayments, or deductibles. **Introduced and referred to House Commerce Committee.** 

**HB 725-FN:** AN ACT including Medicaid care organizations under the managed contractor requirements for provider care law. This bill includes Medicaid managed care organizations for the purposes of the managed care law pursuant to RSA 420-J. **Introduced and referred to House Commerce Committee.** 

#### **Senate Bills**

**SB 4:** AN ACT relative to the group and individual health insurance market. This bill establishes the provisions of the Patient Protection and Affordable Care Act of 2009, Public Law 111-148, as amended in statute. **Introduced and referred to Senate HHS Committee.** 

SB 11-FN-A: AN ACT relative to mental health services and making appropriations therefor. This bill: I. Authorizes the department of health and human services to use general surplus funds for designated receiving facilities and for voluntary inpatient psychiatric admissions. II. Makes an appropriation to the department of health and human services for the purpose of renovating certain existing facilities. III. Provides for rulemaking for involuntary admission hearing requirements. IV. Makes an appropriation to the affordable housing fund, established in RSA 204-C:5, for transitional housing for persons leaving mental health treatment facilities. V. Requires insurers to reimburse certain facilities for emergency room boarding. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by Committee and Senate. Amendment makes changes to the provision related to appropriations to the affordable housing fund.



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SB 26: AN ACT relative to the New Hampshire health care quality assurance commission. This bill changes the name of the New Hampshire health care quality assurance commission to the New Hampshire health care quality and safety commission. This bill also removes the prospective repeal of the commission. Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by Committee. Amendment changes composition of Commission to include one representative of each licensed hospital rather than each acute care and specialty care hospital and adds the CEO of NH Hospital or his designee to the Commission.

- **SB 32:** AN ACT reestablishing the commission to study greater transparency in pharmaceutical costs and drug rebate programs. This bill reestablishes the commission to study greater transparency in pharmaceutical costs and drug rebate programs. **Introduced and referred to Senate HHS Committee.**
- **SB 33:** AN ACT relative to the therapeutic use of cannabis. This bill authorizes the department of health and human services to collect certain data regarding the therapeutic use of cannabis. This bill also requires the commissioner of the department of health and human services to adopt rules regarding disclosure of information resulting from inspections and investigations under RSA 126-X. **Introduced and referred to Senate HHS Committee.**
- **SB** 58: AN ACT relative to reimbursement rates for low-dose mammography coverage. This bill clarifies the reimbursement rates for low-dose mammography. Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee.
- **SB 88-FN:** AN ACT relative to registry identification cards under the use of cannabis for therapeutic purposes law. This bill makes certain changes in the use of cannabis for therapeutic purposes law, including: I. Eliminating the time frame for a provider-patient relationship. II. Repealing the requirement for a photograph of an applicant's face for purposes of the registry identification card. **Introduced and referred to Senate HHS Committee.**
- **SB 90-FN:** AN ACT relative to certain disclosures by health care provider facilities. This bill extends immunity to staff licensed by the division of health professions, office of professional licensure and certification, to disclose certain employment information. **Introduced and referred to Senate Judiciary Committee.**
- **SB 97:** AN ACT relative to licensure of health facilities near a critical access hospital. This bill requires an applicant seeking to construct certain health care facilities for licensure under RSA 151 to submit a report showing how the proposed project will affect certain health care services. This bill is a request of the department of health and human services. **Introduced and referred to Senate Executive Departments and Administration Committee.**
- **SB 111:** AN ACT relative to the collection of health care data. This bill clarifies the collection of health care data. This bill is a request of the department of health and human services. **Introduced and referred to Executive Departments and Administration Committee.**



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**SB 119:** AN ACT directing hospitals to develop an operational plan for the care of patients with dementia. This bill requires hospitals licensed under RSA 151 to complete and implement an operational plan for the recognition and management of patients with dementia or delirium in acute-care settings. Under this bill, each hospital shall keep the plan on file and make it available to the bureau of health facilities administration, department of health and human services, upon request. **Introduced and referred to Senate HHS Committee.** 

- **SB 145:** AN ACT relative to the organization of alternative treatment centers. This bill permits alternative treatment centers to organize as business corporations and limited liability companies, and provides the procedure for alternative treatment centers organized as voluntary corporations to convert to business corporations or limited liability companies. **Introduced and referred to Senate Commerce Committee.**
- **SB 175:** AN ACT relative to qualifying medical conditions for therapeutic cannabis. This bill changes the definition of qualifying medical condition for the purposes of the law governing the use of cannabis for therapeutic purposes. **Introduced and referred to Senate HHS Committee.**
- **SB 177:** AN ACT relative to the use of physical restraints on persons who are involuntarily committed. This bill clarifies when physical restraints may be used to transport a person being admitted to New Hampshire hospital or a designated receiving facility. **Introduced and referred to Senate HHS Committee.**
- **SB 178:** AN ACT relative to telemedicine for spectacle and contact lenses. This bill clarifies the procedure for health care providers who prescribe spectacle lenses and contact lenses by telemedicine. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass by Committee.**
- **SB 179:** AN ACT relative to pharmacist administration of vaccines. This bill modifies the authority for pharmacists and pharmacy interns to administer vaccinations by including vaccines listed in the recommended adult immunization schedule by the Centers for Disease Control and Prevention. **Introduced and referred to Senate HHS Committee.**
- **SB 182:** AN ACT relative to a duty to report when another person has suffered grave physical harm. This bill establishes a duty to report when another person has suffered grave physical harm. **Introduced and referred to Senate Judiciary Committee.**
- **SB 184:** AN ACT relative to limitation of liability for prescribing an approved drug or device. This bill establishes limited immunity from civil liability for health care professionals who prescribe an approved drug or device to a patient resulting in injury or death. **Introduced and referred to Senate Judiciary Committee.**
- **SB 210:** AN ACT relative to emergency medical and trauma services. This bill makes certain reference changes and adds a definition of "telecommunicators" to the law governing emergency medical and trauma services. **Introduced and referred to Senate Executive Departments and Administration Committee.**



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

**SB 226-FN:** AN ACT relative to registration of pharmacy benefit managers and reestablishing the commission to study greater transparency in pharmaceutical costs and drug rebate programs. This bill establishes the registration and regulation of pharmacy benefits managers by the insurance commissioner. This bill also reestablishes the commission to study greater transparency in pharmaceutical costs and drug rebate programs. **Introduced and referred to Senate Executive Departments and Administration Committee.** 

**SB 232:** AN ACT adopting the model psychology interjurisdictional compact. This bill enacts the adoption of the psychology interjurisdictional compact (PSYPACT). **Introduced and referred to Senate Executive Departments and Administration Committee.** 

**SB 233-FN:** AN ACT relative to the regulation of nursing assistants by the board of nursing. This bill changes the regulation of licensed nursing assistants to certified nursing assistants, and makes administrative changes for the board of nursing. **Introduced and referred to Senate Executive Departments and Administration Committee. Voted Ought to Pass by Committee.** 

**SB 255-FN:** AN ACT relative to dementia training for direct care staff in residential facilities and community-based settings. This bill requires dementia training for direct care staff in residential facilities and community-based settings. The bill grants rulemaking authority to the commissioner for the purposes of the bill. **Introduced and referred to Senate Executive Departments and Administration Committee.** 

**SB 258:** AN ACT relative to telemedicine and telehealth services. This bill adds definitions to and clarifies the statute governing telemedicine and Medicaid coverage for telehealth services. **Introduced and referred to Senate HHS Committee.** 

**SB 259-FN:** AN ACT expanding eligibility for the Medicaid for employed adults with disabilities (MEAD) program. This bill directs the department of health and human services to submit an amendment to the state Medicaid plan to expand coverage under the MEAD program, which provides Medicaid for employed adults, to individuals 65 years of age and older. **Introduced and referred to Senate HHS Committee.** 

**SB 260-FN:** AN ACT relative to a program for prescription drug costs for certain seniors and making an appropriation therefor. This bill directs the department of health and human services to develop a prescription drug assistance program to pay out-of-pocket prescription drug costs for seniors who have reached the gap in standard Medicare Part D coverage. The bill also makes an appropriation to the department of health and human services to fund the program. **Introduced and referred to Senate HHS Committee.** 

**SB 272-FN:** AN ACT relative to mental health parity under the insurance laws. This bill authorizes the insurance commissioner to enforce the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 and requires the commissioner to examine and evaluate health insurers,



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health service corporations, and health maintenance organizations for compliance. **Introduced and referred to Senate Commerce Committee.** 

**SB 279-FN:** AN ACT relative to access to fertility care. This bill requires insurers to cover fertility treatment. **Introduced and referred to Senate Commerce Committee.** 

SB 289: AN ACT relative to health and human services. This bill: I. Requires collection stations, not just those operated by laboratories, to be licensed under RSA 151 and revises the responsibilities of an individual home care service provider to include health support services. II. Authorizes reimbursement for a legally responsible relative who provides personal care services under RSA 161-I. III. Requires services provided to individuals with disabilities by area agencies and authorized agencies to comply with RSA 171-A and the federal requirements for the home and community-based care waiver. IV. Requires that home-based long-term care services provided under RSA 151-E comply with the federal requirements for the home and community-based care waiver. V. Provides that the committee for the protection of human subjects shall defer to the institutional review board designated by the federal agency responsible for funding in certain cases. VI. Clarifies the authority of pharmacies to dispense prescription drugs and removes the requirement that the protocol and criteria for dispensing drugs be approved by the department of health and human services. VII. Revises the medical support obligation for purposes of determining parental rights and responsibilities and child support to mean the obligation to provide health care coverage for a dependent child whether in the form of private health insurance or public health care. The bill is a request of the department of health and human services. Introduced and referred to Senate **HHS Committee.** 

**SB 290-FN:** AN ACT relative to the New Hampshire granite advantage health care program. This bill makes various changes to the New Hampshire granite advantage health care program, some of which include: I. Allowing general funds to be used for the program. II. Clarifies which beneficiaries may be subject to the work and community engagement requirement. III. Reducing the number of hours for the work and community engagement requirement. IV. Adding exemptions for certain persons from the community engagement requirement. V. Adding circumstances for the elimination of the community engagement requirement. **Introduced and referred to Senate HHS Committee.** 

**SB 292-FN:** AN ACT relative to implementation of the new mental health 10-year plan. This bill requires the commissioner to submit a report containing the procedures for implementation of New Hampshire's 10-year mental health plan of 2018 within 6 months of finalization of the plan to the president of the senate, the speaker of the house of representatives, and the governor. Under this bill, the commissioner of the department of health and human services shall fully implement the plan within 2 years of the date when it was finalized. **Introduced and referred to Senate HHS Committee.** 

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



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SB 308-FN-A: AN ACT relative to the health care workforce and making appropriations therefor. This bill:

I. Increases the Medicaid provider rates. II. Requires certain health care professionals to complete a survey collecting data on the primary care workforce. III. Requires the department of health and human services to amend the income standard used for eligibility for the "in and out" medical assistance policy.

IV. Permits the department of safety to contract with a private agency to process background check applications and requires the department to accept and process background check applications online.

V. Amends the definitions and services covered through telemedicine. VI. Makes appropriations to the department of health and human services, rural health and primary care section to establish new positions and programs to develop and enhance the state's healthcare workforce. VII. Makes an appropriation to the governor's scholarship program for scholarships to students majoring in a health care field and to postsecondary educational institutions to develop and enhance programs of study offered in health care.

Introduced and referred to Senate Executive Departments and Administration Committee.

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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.

#### 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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