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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 UPDATES

CMS Establishes New Patient Rights Standard for Dialysis Patients with Third-Party Premium Payments

On December 14, 2016, the Centers for Medicare & Medicaid Services (CMS) published an interim final rule (81 Fed. Reg. 90211) affecting Medicare-certified dialysis facilities that make premium payments for individual market health plans. The rule establishes a new patient rights standard under the Conditions for Coverage for dialysis facilities and requires the facilities to provide information to patients regarding health and financial risks and benefits of enrolling in available individual market plans. The requirements are intended to protect patient health and safety, improve patient disclosure and transparency, ensure that health insurance coverage decisions are not inappropriately influenced by the financial interests of dialysis facilities, and protect patients from mid-year interruptions in coverage.

The rule follows a request for information (RFI) issued by CMS in August that addressed conflict of interest concerns regarding dialysis facilities "steering" Medicare or Medicaid eligible patients into individual market plans that provide greater reimbursement. During the RFI period, CMS received a number of comments expressing concern over dialysis facilities' arrangement and payment for individual market health care premiums for patients with end-stage renal disease (ESRD). The agency is considering whether to prohibit third-party premium payments for private coverage for individuals eligible for public coverage.

The interim final rule went into effect January 13, 2017 and can be found at:

https://www.gpo.gov/fdsys/pkg/FR-2016-12-14/pdf/2016-30016.pdf#sthash.li3K6Oqk.dpuf

GAO Identifies Participation Challenges and Available Assistance for Small and Rural Providers

On December 9, 2016, the Government Accountability Office (GAO) published a report titled *Medicare-Value-based Payment Models: Participation Challenges and Available Assistance for Small and Rural Practices* (GAO-17-55). The report identifies a number of challenges faced by small and rural providers under new value-based models contained in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). GAO classified the challenges into five key topic areas:

1. Financial resources and risk management;
2. Health IT and data;
3. Population health and management care delivery;
4. Quality and efficiency performance measurement and reporting; and

5. Effects of model participation and managing compliance with requirements.

The report also suggests that organizations (i.e., group practices, private companies, nonprofit groups, and universities) may offer a number of services that can assist small and rural providers with these challenges. The GAO categorizes these organizations into partner organizations and non-partner organizations. Partner organizations share in the financial risk associated with the value-based models and provide comprehensive services to small and rural providers, while non-partner organizations do not share the financial risk but provide specific services to address certain challenges. The GAO recognizes that not all small and rural practices have access to organizations and their services.

The full report may be found at: http://www.gao.gov/assets/690/681541.pdf.

CMS Finalizes Cardiac and Orthopedic Bundle Payment & Announces New ACO Track 1+ Models

On December 20, 2016, the Centers for Medicare & Medicaid Services (CMS) finalized new models for mandatory cardiac and orthopedic bundled payments. The final rule, (amending 42 CFR Parts 510 and 512) implements three new Medicare Parts A and B payment models, a Cardiac Rehabilitation (CR) Incentive Payment model, and modifications to the current Comprehensive Care for Joint Replacement (CJR) model. Acute care hospitals in selected geographic regions will participate in retrospective episode payment models targeting care for Medicare fee-for-service beneficiaries receiving services during acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes. All related care within 90 days of hospital discharge will be included in the episode of care.

On December 20, CMS also announced the new Medicare Accountable Care Organization (ACO) Track 1+ Model, which gives clinicians the opportunity to qualify for a five-percent (5%) incentive payment through the Advanced Alternative Payment Model (APM) path under the Quality Payment Program.

CMS states: "We believe these models will further our goals of improving the efficiency and quality of care for Medicare beneficiaries receiving care for these common clinical conditions and procedures." In a fact sheet, CMS stated it intends that the models will:

- **Improve cardiac care:** Three new payment models will support clinicians in providing care to patients who receive treatment for heart attacks, heart surgery to bypass blocked coronary arteries, or cardiac rehabilitation following a heart attack or heart surgery.
- **Improve orthopedic care:** One new payment model will support clinicians in providing care to patients who receive surgery after a hip fracture, other than hip replacement. In addition, CMS is finalizing updates to the Comprehensive Care for Joint Replacement Model, which began in April 2016.
- **Provides an Accountable Care Organization opportunity for small practices:** The new Medicare ACO Track 1+ Model will have more limited downside risk than Tracks 2 or 3 of the Medicare Shared Savings Program in order to encourage more practices, especially small practices, to advance to performance-based risk.

For more details on the final rule, view the CMS Fact Sheet at:

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-12-20.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending

The final rule was published in the January 3, 2017 *Federal Register* and is effective February 18, 2017. It may be viewed at: https://www.gpo.gov/fdsys/pkg/FR-2015-11-24/pdf/2015-29438.pdf.

First Circuit Affirms Dismissal of FCA Claims

On December 16, 2016, the First Circuit Court of Appeals affirmed the dismissal of a False Claims Act complaint against a medical device company, finding the claim was not pled with the particularity required to satisfy Fed. R. Civ. P. 9(b). The First Circuit also affirmed the district court's denial of leave to amend on the basis of undue delay.

Relator Andrew Hagerty filed the original *qui tam* action against Cyberonics on February 4, 2013. The complaint alleged that Cyberonics engaged in a fraudulent scheme to encourage doctors and patients to prematurely and unnecessarily replace batteries in Vagus Nerve Stimulator (VNS) systems, a medical device implanted in patients with refractory epilepsy. The complaint further alleged that the scheme caused significant monetary damages to government healthcare programs by encouraging patients and providers to file false reimbursement claims. Cyberonics moved to dismiss the complaint under Fed. R. Civ. P. 12(b)(6) for failure to state a claim and under Fed. R. Civ. P. 9(b) for failure to allege instances of fraud with particularity. Hagerty filed the First Amended Complaint and supported his argument with statistical allegations (i.e., "over 10,000 medically unnecessary and unreasonable VNS device replacements since 2007" and "government healthcare reimbursement programs account for at least 50-60% of these"). The district court granted Cyberonics' second motion to dismiss on March 31, 2015 and denied Hagerty's request for leave to file a Second Amended Complaint. Hagerty then appealed to the First Circuit Court of Appeals.

The First Circuit affirmed the lower court's decision, finding that the claims were not pled with sufficient particularity, that the statistical evidence is "too broad to be given much weight," and that the factual and statistical evidence "struggles to connect these allegations with the submission of any false claims to government programs." The appeals court also upheld the district court's denial of leave citing that over a year passed between Cyberonics' first motion to dismiss and the First Amended Complaint, and Hagerty's motion for leave to file the Second Amended Complaint came four months after the district court's dismissal of the First Amended Complaint.

The First Circuit's full opinion in *Hagerty ex rel. United States v. Cyberonics, Inc.,* No. 16-1304 (1st Cir. Dec. 16, 2016) can be read at: http://media.ca1.uscourts.gov/pdf.opinions/16-1304P-01A.pdf.

CMS Focuses on Stabilization in Final 2018 Marketplace Rule

On December 22, 2016, the Centers for Medicare and Medicaid Services (CMS) published the final Notice of Benefit and Payment Parameters for 2018. The final rule stabilizes premiums in the individual and small group markets by setting maximum payment parameters and provisions related to the risk adjustment program, cost-sharing parameters, and cost-sharing reductions. Other parameters and provisions include user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. In addition, the rule finalizes a number of amendments that promote consumer choice in health plans. The final rule also provides additional guidance on the following topics: standardized options; qualified health plans; consumer assistance tools; network adequacy; the Small Business Health Options Programs; stand-alone dental plans; fair health insurance premiums; guaranteed availability and guaranteed renewability; the medical loss ratio program; eligibility and enrollment; appeals; consumer-operated and oriented plans; and special enrollment periods.

The regulations went into effect on January 17, 2017 and may be found at:

https://www.gpo.gov/fdsys/pkg/FR-2016-12-22/pdf/2016-30433.pdf.

CMS's fact sheet on the final rule may be found at:

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-12-16.html#sthash.NqjmnodK.dpuf.

Every State Sees Drop in Percentage of Uninsured Since 2014

In a report posted on December 21, 2016, the Commonwealth Fund found that the percentage of uninsured adults ages 19 to 64 declined in every state and the District of Columbia since the implementation of the Affordable Care Act (ACA) in 2014. In 2013, prior to the ACA, 38% of adults with incomes below 200% of the federal poverty level lacked health insurance. By 2015, this rate dropped below 25%, with more than a third of states seeing rates below 10%. The report identified that the greatest cumulative gains came in states that had expanded Medicaid programs once federal resources became available. The report also identified an increase in access to care for at-risk adults but noted no gains in access to dental care for adults. (The ACA does not require plans to provide dental coverage for adults.) Finally, the report recognized that despite the progress on lowering the number of uninsured, many people still spend as much as 10% of their income on health care, with the highest share of people with high out-of-pocket costs in southern and western states.

To view the report, *A Long Way in a Short Time: States' Progress on Health Care Coverage and Access, 2013-2015*, visit:

http://www.commonwealthfund.org/publications/issue-briefs/2016/dec/state-progress-coverage-and-access

Marketplace Enrollments Reach 8.8 Million

In its December 14, 2016 Biweekly Enrollment Snapshot, the Center for Medicare and Medicaid Services (CMS) reported that over 4 million people have selected healthcare plans for 2017 through HealthCare.gov, including over 1.1 million new consumers and 2.9 million renewing their coverage. December 12 and 13 saw the greatest number of enrollments in the platform's history with over 700,000 sign-ups. After the December 14 Snapshot was released, the agency extended the December 15 deadline to enroll for January 1 coverage to December 19.

By the January 4, 2017 Biweekly Enrollment Snapshot, CMS noted the number of people who have selected healthcare plans for 2017 through HealthCare.gov reached 8.8 including over 2.2 million new consumers and 6.6 million renewing their coverage. Americans who are still uninsured may sign up by January 15 for coverage beginning February 1.

CMS also released its most recent Medicaid and CHIP enrollment numbers. As of October 2016, 69 million individuals were enrolled in Medicaid and 5 million were enrolled in CHIP. Nearly 17 million of these are new enrollments—representing a 30% increase over the baseline period.

To view the Medicaid and CHIP Enrollment Data Highlights, visit:

https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html

To view the Biweekly Enrollment Snapshot, visit:

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-12-14-3.html#sthash.xHLsLPmD.dpuf.

Senate Initiates Repeal of ACA

On January 3, 2017, Chairman of the Senate Budget Committee, Senator Mike Enzi (R-WY), introduced a budget resolution to repeal the Affordable Care Act (ACA). In a press release, Chairman Enzi noted that the ACA has "clearly failed hardworking Americans" and that the resolution "promises relief" and "provides the tools necessary to repeal this failed law." The resolution provides:

- Reconciliation instructions to authorizing committees so that repeal legislation can move through a fast-track process and can pass with only a simple majority in the Senate, as in the House;
- Reconciliation instructions to four authorizing committees—Ways and Means and Energy and Commerce in the House, Finance and Health, Education, Labor, and Pensions in the Senate—to achieve at least $1 billion each in deficit reduction over 10 years; and
- Reserve funds necessary to accommodate legislation to repeal and replace the ACA.

Chairman Enzi stated, "These instructions to committees are provided to facilitate immediate action on repeal, with the intent of sending legislation to the new President's desk as soon as possible."

The Senate approved the resolution on January 4 with a 51-48 party-line vote. Authorizing committees are required to report legislation to their Budget Committee by January 27. The legislation will then be combined for consideration on the floors of both the House and the Senate.

To review the resolution, visit: http://www.budget.senate.gov/imo/media/doc/HEN17065.pdf.

Final Rule on 340B Ceiling Prices and CMPs Published and 340B "Mega-Guidance" Proposal Withdrawn

On January 5, 2017, the Department of Health & Human Services (HHS) published a final rule related to the 340B Drug Pricing Program. The rule applies to all drug manufacturers that are required to make their drugs available to covered entities under the program and provides the calculation of the 340B ceiling price and the appropriate application of civil monetary penalties (CMPs).

Under the final rule, a drug manufacturer that "knowingly and intentionally" overcharges a 340B covered entity may be fined up to $5,000 for each instance of overcharging. The rule further permits a manufacturer to sell a drug at $0.01 if the ceiling price calculation results in a price of $0.00, and requires manufacturers to offer refunds for overcharges on new drugs.

Finally, the final rule provides authority to the HHS Office of Inspector General (OIG) to bring 340B actions. "[A]s a general principle, HHS will defer to OIG to determine whether a given situation constitutes a 'knowing and intentional' 340B drug overcharge based on the specific case being investigated," the rule said.

The final rule (82 Fed. Reg. 1210) is effective March 6, 2017 and may be viewed at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf.

On January 30, 2017, the White House Office of Management and Budget (OMB) withdrew the HHS Health Resources and Services Administration's (HRSA) 340B "mega-guidance" that HRSA proposed on August 27, 2015. OMB's withdrawal of the 340B mega-guidance was in response to President Trump's freeze on pending regulatory changes on January 20, 2017.

FDA Guidance: Postmarket Management of Cybersecurity in Medical Devices

On December 28, 2016, the Food and Drug Administration (FDA) issued guidance on the postmarket management of cybersecurity in medical devices, clarifying postmarket recommendations and emphasizing the need to monitor, identify, and address cybersecurity vulnerabilities as part of premarket development and postmarket management.

The Agency encourages manufacturers to implement comprehensive cybersecurity risk management programs and documentation consistent with the Quality System Regulation (21 CFR § 820). The guidance establishes a risk-based framework for assessing when cybersecurity changes to medical devices require reporting to FDA. It recommends that manufacturers report vulnerabilities to FDA that involve uncontrolled risks to safety and essential performance, and develop programs that monitor, identify, and analyze the exploitability of the vulnerability and the severity of patient harm if the vulnerability were to be exploited.

The document is not intended to provide guidance on reporting to FDA when a device has or may have caused or contributed to a death or serious injury as required by 21 USC § 519 and 21 CFR § 803. Nor does the guidance document establish legally enforceable responsibilities.

The guidance document may be viewed at:

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf#sthash.jV71YDQT.dpuf.

Materials from the January 12 guidance webinar may be accessed at:

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm534592.htm#sthash.jV71YDQT.dpuf.

Final Rule Expands OIG Exclusion Authority

On January 12, 2017, the Department of Health and Human Services Office of Inspector General (OIG) finalized regulations that expand OIG exclusion authority. The final rule (82 Fed. Reg. 4100) implements new and revised exclusion authority under the Affordable Care Act of 2010 and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, including new authority for conviction of an offense in connection with obstruction of both investigations and audits, and expanding those subject to exclusion to individuals or entities who refer patients or certify the need for items or services. OIG stated in response to the comments that it anticipates minimal economic impact and believes the likely aggregate economic effect of these regulations will be significantly less than $100 Million.

The rule goes into effect on February 13, 2017. It may be read at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-12/pdf/2016-31390.pdf.

New Home Health Care Rules Finalized by CMS

On January 13, 2017, the Centers for Medicare and Medicaid Services (CMS) published rules governing home health agencies. The final rule (82 Fed. Reg. 4506) revises the conditions of participation (CoPs) that home health agencies (HHAs) are required to meet to participate in Medicare and Medicaid. The requirements focus on interdisciplinary patient care delivery and give HHAs greater flexibility in meeting quality standards. Among its several requirements, the final rule includes:

- A comprehensive patient rights CoP that clearly enumerates the rights of home health agency patients and the steps that must be taken to assure those rights;
- An expanded comprehensive patient assessment requirement that focuses on all aspects of patient wellbeing; and
- A requirement that assures that patients and caregivers have written information about upcoming visits, medication instructions, treatments administered, instructions for care that the patient and caregivers perform, and the name and contact information of a home health agency clinical manager.

The rule goes into effect on July 13, 2017. It may be read at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-13/pdf/2017-00283.pdf.

Requirements Proposed for Qualified Providers and Suppliers of Prosthetics and Custom Orthotics

On January 12, 2017, the Centers for Medicare and Medicaid Services (CMS) proposed a rule that would implement statutory requirements of Section 1834(h) of the Social Security Act. The proposed rule specifies the necessary qualifications for qualified practitioners and suppliers to obtain an order to furnish and fabricate prosthetics and custom orthotics for reimbursement.

CMS seeks comments on the proposed rule, including on the following specific areas:

- The requirement that qualified practitioners and qualified suppliers must meet specific state licensing conditions, be certified by the American Board for Certification in Orthotics and Prosthetics, Inc. (ABC) or by the Board for Orthotist/Prosthetist Certification Intl. (BOC), or be credentialed and approved by a specialized training program.
- Proposed criteria for facilities at which qualified practitioners and qualified suppliers can fabricate items of prosthetics and custom-fabricated orthotics.
- A proposed alternative for supplier credentialing that an organization employing an individual who has been certified by the ABC or the BOC be authorized to make the decision about accreditation for a particular supplier.
- The timeline for when qualified practitioners and qualified suppliers would need to meet the requirements included in the final rule.

Comments are due by 5:00 p.m. on March 13, 2017. A CMS fact sheet detailing these and other provisions of the proposed rule may be found here:

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-11.html#sthash.X4PMqnrI.dpuf.

The proposed rule may be read at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-12/pdf/2017-00425.pdf.

Potential Violation of HIPAA Breach Notification Rule Yields $475K Settlement

On January 9, 2017, the Department of Health and Human Services Office for Civil Rights (OCR) announced a $475,000 settlement of potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Breach Notification Rule.

The settlement arose from an untimely reporting of a breach of unsecured protected health information (PHI) by Presence Health, an Illinois-based healthcare network. Presence Health failed to notify the affected individuals, major media outlets, and OCR within 60 days of discovering that paper operating room schedules were missing. The schedules included the names, dates of birth, medical record numbers, and medical procedure information of 836 individuals scheduled for surgery. Presence Health discovered the breach on October 22, 2013 and notified OCR of the breach on January 31, 2014.

"Common Rule" Revised for Human Research Subjects

On January 19, 2017, the Department of Health and Human Services (HHS) and 15 other agencies published a final rule updating the Federal Policy for the Protection of Human Subjects (also referred to as the "Common Rule"), originally promulgated in 1991. The final rule (82 Fed. Reg. 7149) recognizes considerable changes to the volume, landscape, and diversity of human subject research since the Common Rule was last amended in 2005. In the preamble to the final rule, the agencies stated the intent was "to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators." (82 Fed. Reg. 7149, 7149, January 19, 2017).

On July 26, 2011, an Advanced Notice of Proposed Rulemaking (ANPRM) was published to request comment on how to modernize the current regulations. On September 8, 2015, a Notice of Proposed Rulemaking (NPRM) was published requesting similar comment. The preamble to the final rule summarized the following as significant changes made to the Common Rule:

- "Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process.
- Allows the use of broad consent (i.e., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens….
- Establishes new exempt categories of research based on their risk profile….
- Creates a requirement for U.S.-based institutions engaged in cooperative research to use a single IRB [institutional review board] for that portion of the research that takes place within the United States, with certain exceptions….
- Removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care." (*Id.* at 7150).

The final rule goes into effect January 19, 2018 and may be read at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf.

CMS Limits Medicaid Managed Care Pass-Through Payments

On January 18, 2017, the Center for Medicare and Medicaid Services (CMS) published a final rule finalizing changes to pass-through payments under Medicaid managed care contract(s) and rate certification(s). The final rule (82 Fed. Reg. 5415) prevents both increases in pass-through payments as well as the addition of new pass-through payments beyond those in place when the pass-through payment transition periods were effective in July 2016. The final rule incorporates the provisions of the November 22, 2016 proposed rule including limiting the ability to continue pass-through payments for hospitals, physicians, or nursing facilities to states that can demonstrate that they had such pass-through payments; prohibiting retroactive adjustments or amendments to managed care contract(s) and rate certification(s) to increase or add new pass-through payments; and establishing a new maximum amount of permitted annual pass-through payments.

The final rule goes into effect on March 20, 2017 and may be read at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00916.pdf.

More Time to Report Electronic Clinical Quality Measure Data

On January 17, 2017, the Centers for Medicare and Medicaid Services (CMS) announced in a blog post an extension for eligible hospitals participating in the Hospital Inpatient Quality Reporting (IQR) and/or the Medicare Electronic Health Record (EHR) Incentive Programs to submit electronic Clinical Quality Measure (eCQM) data for the 2016 reporting period. Hospitals now have until 11:59 p.m. PT on March 13, 2017 to submit their eCQM data pertaining to the fiscal year (FY) 2018 payment determination.

CMS also announced their intention to modify the eCQM requirements to reduce reporting burdens in the FY 2018 IPPS proposed rule, which CMS anticipates to be published in the late spring of 2017. More specifically, “CMS plans to address stakeholder concerns regarding challenges associated with hospitals transitioning to new EHR systems or products, upgrading to EHR technology certified to the 2015 Edition, modifying workflows, and addressing data element mapping, as well as the time allotted for hospitals to incorporate updates to eCQM specifications in 2017.”

More information about eCQM reporting for the Hospital IQR and EHR Incentive Programs can be found at: https://www.qualitynet.org/ and https://www.cms.gov/.

SAMHSA Updates Substance Use Disorder Confidentiality Requirements

On January 18, 2017, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a final rule to modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations, 42 C.F.R. Part 2 (commonly referred to as “Part 2”) in order to address the substantial changes in the U.S. healthcare system, such as the use of integrated care models and electronic medical records, since the last substantive update was made in 1987.

The final rule amends 14 major provisions of the Part 2 regulations, including revising the requirements for reporting violations of the regulations by opioid treatment programs, revising and updating definitions, revised the consent requirements, clarifying how discontinued programs should dispose of records, revising audit and evaluation requirements, facilitating the sharing of information within the healthcare system, and revising the research provision.

The final rule goes into effect on February 17, 2017 and may be read at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00719.pdf.

CMS Reports $7.33 Billion in 2015 Open Payment Data

On January 17, 2017, the Centers for Medicare and Medicaid Services (CMS) updated the 2015 Open Payment Data. Open Payments is a federal program, required by the Affordable Care Act, that collects information about the payments drug and device companies make to physicians and teaching hospitals, including for travel, research, gifts, speaking fees, and meals. It also identifies ownership interests that physicians or their immediate family members have in these companies. In 2015, the total U.S. dollar value reached $7.33 billion, nearly double that from 2013.

For more information on the Open Payment program visit: https://www.cms.gov/openpayments/

Final Rule to Attempt to Reduce HHS Medicare Appeals Backlog

On January 17, 2017, the Department of Health and Human Services (HHS) published a final rule to revise its Medicare appeals procedures to address the growing backlog of Medicare appeals. In the preamble to the final rule, HHS describes its "three-prong approach" to the problem, which includes (1) requesting new resources to increase adjudication capacity; (2) administrative actions and strategies, and (3) legislative reforms for additional funding and new authorities. The final rule (82 Fed. Reg. 4974) expands the pool of available adjudicators (giving authority to attorney adjudicators to issue decisions) and streamlines the processes for adjudicators to reduce time spent on repetitive issues or procedural matters. HHS is under court order to reduce its Medicare appeals backlog by 30% at the end of 2017, by 60% at the end of 2018, by 90% at the end of 2019, and in full by December 31, 2020. (*American Hosp. Ass'n v. Burwell*, No. 14-851 (JEB) (D.D.C. Dec. 5, 2016).

The final rule goes into effect March 20, 2017 and may be viewed at:

https://www.gpo.gov/fdsys/pkg/FR-2017-01-17/pdf/2016-32058.pdf#sthash.S5mMDWbK.dpuf.

Aetna's Acquisition of Humana Blocked

On January 23, 2017, the U.S. District Court for the District of Columbia issued an order enjoining Aetna's proposed acquisition of Humana. The $37 million acquisition was first announced by the two health insurance companies on July 2, 2015. On July 21, 2016, the United States Department of Justice (DOJ), along with six states and the District of Columbia, filed an action seeking to stop the acquisition. The government alleged that the transaction violates Federal anti-trust law because its effect "may be to substantially lessen competition" in a number of markets: (1) the market for individual Medicare Advantage plans in 364 counties across 21 states; and (2) the market for individual insurance sold on the public exchanges in 17 counties across three states (Florida, Georgia, and Missouri).

The Court rejected Aetna and Humana's arguments that federal regulation would be sufficient to prevent the merged firm from raising prices or reducing benefits, and that entry by new competitors or the proposed divestiture to another insurer would suffice to replace competition eliminated by the merger. The Court concluded that any efficiencies generated by the merger would not be enough to overcome the anticompetitive effects for consumers.

The DOJ in a press release called the Court's decision "a victory for American consumers – especially seniors and working families and individuals." Media sources report that Aetna and Humana are considering an appeal of the Court's decision.

The District Court's decision can be read in full at:
:
https://www.justice.gov/opa/press-release/file/930361/download

President Trump Issues Executive Order to Roll Back ACA

On January 20, 2017, after being inaugurated as the 45th President of the United States, President Trump signed his first executive order: "Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal." The Order requires the Secretary of Health and Human Services "and the heads of all other executive departments and agencies . . . with authorities and responsibilities under the [ACA]" to:

> "exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications."

The Order also charges the heads of executive department agencies to utilize available discretion and take actions to assist states with encouraging the development of a free and open insurance market, up to and including promulgating new regulations.

Although Congress has not yet passed a repeal of any part of the ACA, President Trump's executive order sets the stage for the executive department's full cooperation in the dismantling of the ACA's many provisions.

The executive order may be viewed at https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and. .

Anthem Ends Its Policy of Requiring Prior Authorization for Medication-Assisted Treatment for Opioid Use Disorder

On January 19, 2017, New York Attorney General Eric Schneiderman announced that his office had reached an agreement with Anthem for it to stop requiring prior authorization for medication-assisted treatment (MAT) for opioid use disorder, a policy change that Anthem will apply nationally. Prior to this announcement, Anthem had required providers -- who had already received specific training regarding MAT and federal authorization to prescribe these drugs -- to submit a prior approval form for MAT coverage requests, which required them to answer numerous questions about the patient's current treatment and medication history. Schneiderman's investigation found that New York's Empire BlueCross BlueShield denied nearly 8% of MAT authorization requests in 2015 and the first half of 2016.

MAT, when prescribed and monitored properly, has proved effective in helping patients recover from opioid use disorder, and is both safe and cost-effective to reduce the risk of overdose. Unlike methadone treatment, which must be administered in a highly structured clinic, MAT medications, usually containing buprenorphine and naloxone, may be prescribed or dispensed in physicians' offices to treat opioid use

disorder, provided the treating physician has obtained the appropriate certification and has been issued a special DEA license.

This is the second such agreement that Schneiderman's office has reached with a health insurer. In October of 2016, Schneiderman announced a similar agreement with Cigna whereby it would cease requiring prior authorization for MAT for opioid use disorder.

To view Schneiderman's announcement of the Anthem agreement, visit:

https://ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-anthem-discontinue-pre-authorization.

To view Schneiderman's announcement of the Cigna agreement, visit:

https://ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-cigna-discontinue-pre-authorization.

CMS Issues Proposed Changes to Medicare Advantage and Part D for 2018

On February 1, 2017, the Center for Medicare & Medicaid Services (CMS) issued the 2018 Advance Notice and Draft Call Letter, outlining its proposed changes to Medicare Advantage and Medicare Part D. In 2018, CMS proposes continuing to use a blend of encounter data-based risk scores with Risk Adjustment Processing System (RAPS)-based risk scores, and is soliciting comments on whether and how to apply a uniform industry-wide adjustment to the encounter data-based portion of the blended risk score for payment to Medicare Advantage organizations. CMS also proposes to continue waiving the requirement for Medicare Advantage Employer Group Waiver Plans to submit Part C bid pricing information and instead continue the policy of administratively setting rates for these plans.

CMS proposes to continue to adjust the Star Ratings to account for the impact of dual-eligible and disabled status on plans' Star Ratings. CMS is also proposing modifications to the current "beneficiary access and performance problems" measure to reflect the magnitude of any civil money penalties and to use more recent data.

In an effort to build upon recent success in reducing beneficiary overutilization of opioids, CMS is proposing a number of updates to earlier drug utilization policies, including revisions to the utilization review criteria to better align with CDC guidelines, and establishing an expectation that Part D sponsors implement formulary-level safety edits based on a cumulative morphine equivalent dose approach.

The 2018 Advance Notice and Draft Call Letter can be read in full at:

https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2018.pdf#sthash.4O09MUnC.dpuf.

CMS' Fact Sheet on the Advance Notice and Draft Call Letter can be found at:

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-02-01.html#sthash.4O09MUnC.dpuf.

President Trump's Executive Order Travel Ban Impacts Health Care

On January 27, 2017, President Trump signed an executive order barring entry into the country for 90 days of immigrants from seven Muslim-majority countries – Iran, Iraq, Libya, Syria, Somalia, Sudan, and Yemen. The executive order also suspends the issuance of visas to persons from these countries, and imposes other restrictions and immigration requirements.

The executive order sparked protests and the filing of numerous legal actions. Federal judges in New York, Massachusetts, and elsewhere issued preliminary injunctions, although the District Court in Massachusetts later ruled against an extension of the stay. Following the issuance of a temporary restraining order by the District Court for the District of Washington on February 3, the Department of Homeland Security suspended all enforcement of the travel ban nationwide. The White House announced that the Justice Department would file a motion to stop the halt and reinstate the ban.

Although the travel ban was only in effect for one week, it had a significant impact in the medical community, and would continue to do so if reinstated. According to statistics from the American Medical Association, over 8,400 physicians working in the United States are from Syria and Iran, only two of the seven countries affected by the ban. If reinstated, the ban could impact physician recruitment and doctors who are completing residency training in the United States, as they would likely be unable to change their visa status from J-1 to H-1B. The ban would also prevent patients from the seven countries from traveling to the country to receive specialty medical care. The international medical community at-large will also be affected, as physicians from the seven countries – as well as physicians from other countries who may boycott travel to the United States out of protest – would be absent from medical conferences held in the United States.

Since DHS suspended the travel ban, those whose visas were revoked are now able to have them reinstated, but must go to an embassy or consulate to do so.

The executive order may be viewed at https://www.whitehouse.gov/the-press-office/2017/01/27/executive-order-protecting-nation-foreign-terrorist-entry-united-states.

President Trump Signs Executive Order Cutting Regulations

On January 30, 2017, President Trump signed an executive order: "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs." The executive order's stated purpose is to "manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations."

The executive order's most controversial provisions are the requirement that agencies repeal two regulations for every new regulation finalized, and the mandate that the total incremental cost of all new regulations and repealed regulations finalized in 2017 to be no greater than zero.

Explicitly excepted from the executive order are regulations related to military, national security, or foreign affairs, agency organization, management, or personnel, and any other category of regulations exempted by the Director of the Office of Management and Budget.

The executive order can be viewed at:
https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling#sthash.FIuyiHB2.dpuf.

Florida Supreme Court Holds That State's Right to Know Law Is Not Preempted by PSQIA

On January 31, the Florida Supreme Court issued a ruling that the Federal Patient Safety Quality Improvement Act (PSQIA) does not preempt an amendment to the Florida Constitution protecting the right of patients to access information about adverse medical incidents. In *Charles v. Southern Baptist Hosp. of Fla., Inc.*, No SC15-2180 (Fla. Jan 31, 2017), the plaintiff in a medical negligence action against Southern Baptist Hospital sought access to reports of adverse medical incidents occurring at the hospital. Southern Baptist refused to produce the reports and argued that such reports were privileged and protected from discovery by the PSQIA. As the case moved through the Florida courts, each court's decision depended on an interpretation of whether the reports of adverse medical incidents fell under the PSQIA definition of "patient safety work product," which is protected under PSQIA. The Florida Supreme Court held that the adverse medical incident reports were not protected under the PSQIA because they fell under an exception to the definition of patient safety work product for information "collected, maintained, or developed separately, or exists separately, from a patient evaluation system," because providers have an independent obligation under Florida law to create the reports.

The Florida Supreme Court's decision may be viewed at:

http://www.floridasupremecourt.org/decisions/2017/sc15-2180.pdf.

OIG Issues Advisory Opinion on Cost-Share Waivers and Stipends for Research Participants

On December 13, 2016, the Department of Health and Human Services Office of Inspector General (OIG) issued an advisory opinion (*Advisory Opinion 16-13*) on (1) a proposed arrangement to waive cost-sharing obligations for participants in a government-funded clinical research study (the "Proposed Arrangement") and (2) a current arrangement for payments of stipends to the same study participants to participate in study visits (the "Current Arrangement"). The research study involved in both the current and proposed arrangements involves a strategy trial (as opposed to a treatment trial) in which the strategy of treating anal high-grad squamous intraepithelial lesions ("HSIL") is effective in reducing the incidence of anal cancer in HIV-infected persons. The Requestor of the Advisory Opinion certified in its request that enrollment and retention in the study require multiple visits over five years or more, that diagnostic procedures and treatments (for those study participants in the treatment arm of the study) will be uncomfortable, and that cost-sharing obligations for the health care services related to the study could be a substantial burden to the participants. The Requestor also certified that reimbursements for cost-sharing obligations (including copayments, coinsurance, and deductibles) would come from the National Cancer Institute (NCI). The Requestor certified that NCI approved the expenditure of grant funds on both the Proposed Arrangement as well as on the Current Arrangement of payment of $100 and $25 per visit stipends to study participants (depending on the procedures performed at the visit).

The OIG concluded that both the Proposed Arrangement and the Current Arrangement present a minimal risk of fraud and abuse under the anti-kickback statute and although they could potentially generate prohibited remuneration if the requisite intent were present, that it would not impose administrative sanctions. It reasoned that both arrangements are consistent with NCI policy objectives and subject to government oversight because they are performed as an NCI AIDS Malignancy Consortium (AMC) protocol; they are funded exclusively via the Public Health Service grant awarded by NCI to the AMC; NCI approved the use of grant funds for the arrangements; and NCI appointed an independent entity with no financial interest in the outcome of the study to monitor compliance with the protocol. OIG also found that waiving the cost-sharing obligations is a necessary and reasonable way to encourage participants to enroll in and remain compliant in the study. Finally, the OIG mentioned that because the study was neither commercial nor

product-specific, it was not designed to benefit a particular commercial product or entity and that the "unique nature" of the medical services received by participants in the study was not likely to induce them to receive unnecessary services at the study sites.

The advisory opinion may be read in full:

https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-13.pdf

STATE DEVELOPMENTS

REMINDERS:

- **Annual Reports for New Hampshire business entities are due to the Secretary of State by April 1, 2017.**
- **Annual Breach Notification Reports must be made to the Office of Civil Rights by March 1, 2017 at:** https://ocrportal.hhs.gov/ocr/breach/wizard_breach.jsf?faces-redirect=true.

NH Department of Insurance Issues its Annual Report on Health Insurance Costs

On December 20, 2016, the NH Department of Insurance released its Annual Report on Health Insurance Costs. The report analyzes 2015 data from health insurers operating in New Hampshire. Its key findings as set forth in the Department's Press Release, are as follows:

- Pharmacy costs increased almost 9 percent and comprised 19 percent of all medical costs.
- The number of residents without health insurance decreased, from 120,000 (9 percent) in 2014 to 83,000 (6 percent) in 2015
- The individual market grew from 52,000 members as of December 2014 to 107,000 in April 2016, largely due to the NH Premium Assistance Program (NH PAP).
- The individual market now represents 38 percent of the total number insured lives in New Hampshire.
    - 46 percent of individual market members received their coverage through the exchange
    - 37 percent were part of the NH PAP
    - 17 percent obtained their individual coverage outside of the exchange
- Average premium increases were under 2 percent in 2015.

The full report is available on the Insurance Department's website:

http://www.nh.gov/insurance/reports/documents/nhid-2015-medical-cost-drivers-final-report.pdf

Hospitals and Insurance Companies Provide Funding for Medicaid Expansion Plan

In a deal that was struck with legislators last year, hospitals and insurers are making voluntary contributions to fund the costs of the Medicaid expansion program that are not covered by the federal government. DHHS Commissioner Jeffrey Meyers reported to lawmakers on December 30, 2016 that the contributions made thus far are sufficient to cover the cost of the program through the first quarter of 2017. In the event sufficient voluntary donations are not received, the program will face repeal within 180 days leaving many thousands of people in New Hampshire without health insurance. There are competing bills currently being considered by the legislature, both to repeal Medicaid expansion and to make the program permanent.

NH Department of Health and Human Services Reports Significant Data Breach

On December 27, 2016, Department of Health and Human Services Commissioner, Jeffrey Meyers, issued a Press Release reporting a security breach involving DHHS client data. The Department learned of the breach, which exposed the protected health and personal information of up to 15,000 DHHS clients, on November 4, 2016. The breach arose when a patient at NH Hospital allegedly accessed the confidential information using a computer in the library at NH Hospital and later posted the information to a social media site. The information included names, addresses, Social Security numbers and Medicaid identification numbers of DHHS clients The Department took corrective action to remove the information from the site within 24 hours and to prevent future unauthorized access. DHHS clients affected by the breach were notified as required by federal and state law.

NH Attorney General Brings Action Against Makers of Fentanyl Drug

On January 18, Attorney General Joseph Foster announced that an enforcement action has been brought against Insys Therapeutics, Inc., the maker of the fentanyl spray product which is sold under the name Subsys. The Attorney General's Office concluded in its investigation that Insys engaged in aggressive marketing including a scheme to provide payments through its speaker program to induce prescribers to write Subsys prescriptions. According to a Press Release issued by the Attorney General's Office, Insys cooperated in the investigation and, while admitting no wrongdoing, entered into an agreement to resolve the matter. Under the terms of the Agreement, Insys agrees not to engage in false, misleading or deceptive marketing practices and agrees to certain restrictions on its Subsys speaker program. In addition, Insys has paid the State $2.9 Million and will also make a direct payment to the NH Charitable Foundation in the amount of $500K to be used to prevent or remediate programs associated with the abuse, misuse or misprescribing of opioids.

2017 Legislative Updates

We are currently tracking the following Bills:

HB 157: This bill adds chronic pain to the qualifying medical conditions under therapeutic use of cannabis. **Status: Introduced and referred to House HHS Committee.**

HB 158: This bill adds opioid addiction to the qualifying medical conditions under therapeutic use of cannabis. **Status: Introduced and referred to House HHS Committee.**

HB 159: This bill adds fibromyalgia to the qualifying medical conditions under therapeutic use of cannabis. **Status: Introduced and referred to House HHS Committee.**

HB 160: This bill adds post-traumatic stress disorder to the qualifying medical conditions under therapeutic use of cannabis. **Status: Introduced and referred to House HHS Committee.**

HB 162: This bill establishes a procedure for the annulment of a mental health record. **Status: Introduced and referred to Science, Technology and Energy Committee.**

HB 184-FN: This bill repeals RSA 328-J, the regulation of medical imaging and radiation therapy under the board of medical imaging and radiation therapy. **Status: Introduced and referred to House Executive Departments and Administration Committee.**

HB 197: This bill adds myelitis disorder or disease to the qualifying medical conditions under therapeutic use of cannabis**. Status: Introduced and referred to House HHS Committee.**

HB 200: This bill authorizes heath care facilities and physicians to dispense medication and use equipment and therapies which are not Food and Drug Administration approved. **Status: Voted Inexpedient to Legislate by the House.**

HB 208: This bill establishes a commission to study current mental health procedures for involuntary commitment. **Status: Introduced and referred to House HHS Committee. Sent to subcommittee.**

HB 222: This bill makes certain changes to the law regarding use of cannabis for therapeutic purposes, including broadening the definition of "qualifying medical condition." **Status: Introduced and referred to House HHS Committee.**

HB 250: This bill establishes a commission to study the benefits and costs of a "health care for all" program for New Hampshire. **Status: Introduced and referred to House Commerce and Consumer Affairs. Sent to subcommittee.**

HB 256: This bill authorizes a person to self-order laboratory testing without a health care provider's request under certain circumstances. **Status: Voted inexpedient to legislate by the House.**

HB 291: This bill removes the requirement that the board of veterinary medicine adopt rules regarding prescribing opioids and that veterinarians query the controlled drug prescription monitoring program when prescribing such drugs. **Status: Introduced and referred to House Environmental and Agriculture.**

HB 295: This bill repeals the prohibition against assigning medical payments under motor vehicle liability policies to health care providers. **Status: Introduced and referred to House Commerce and Consumer Affairs. Sent to subcommittee.**

HB 321: This bill establishes a commission to study a public option program for health insurance in New Hampshire. **Status: Introduced and referred to House Commerce and Consumer Affairs. Sent to subcommittee.**

HB 322: This bill declares that certain licensing boards for health care providers may adopt rules to require completion of a certain survey as part of the license renewal process. This bill is a result of the commission established in 2016, 252. **Status: Introduced and referred to House Executive Departments and Administration.**

HB 329: This bill establishes a committee to study balance billing by health care providers. **Status: Introduced and referred to House Commerce and Consumer Affairs. Sent to subcommittee.**

HB 334: This bill exempts from licensure by the board of medical imaging and radiation therapy persons who perform sonography in certain circumstances. **Status; Introduced and referred to House Executive Departments and Administration.**

HB 361: This bill deletes the authority of the commissioner of the department of health and human services to adopt rules regarding certain child immunizations/vaccines. **Status: Introduced and referred**

to HHS Committee.

HB 362: This bill declares that immunization/vaccine requirements shall not be established for diseases that are noncommunicable in a child care or school setting, including hepatitis B. **Status: Introduced and referred to House HHS Committee.**

HB 442: This bill prohibits employers from asking a job applicant about his or her criminal history prior to an interview. **Status: Introduced and referred to House Labor Committee.**

HB 443: This bill prohibits prescription drug manufacturers from offering to pay or reimburse an individual for his or her insurance copayment. **Status: Introduced and referred to House Commerce Committee. Sent to subcommittee.**

HB 455-FN: This bill prohibits pharmacy benefit managers from requiring providers to attain accreditation, credentialing, or licensing other than by the pharmacy board or other state or federal entity. **Status: Introduced and referred to House Commerce Committee. Sent to subcommittee.**

HB 468-FN: This bill allows persons licensed as mental health practitioners in other states to practice in this state 60 days after application to the board of mental health practice, pending final approval. **Status: Introduced and referred to House Executive Departments and Administration.**

HB 469: This bill requires licensed pharmacies to establish continuous quality improvement programs to identify weaknesses in processes and systems and make appropriate corrections. This bill is a request of the pharmacy board. **Status: Introduced and referred to HHS.**

HB 471-FN: This bill requires the department of health and human services to publish an annual report consisting of an aggregate statistical summary of all induced terminations of pregnancy performed in New Hampshire. This report shall be available to the public. Data submitted by providers shall be for statistical purposes only and not public records. **Status: Introduced and referred to House HHS.**

HB 472: This bill permits qualifying patients and registered caregivers to cultivate cannabis for therapeutic use. **Status: Introduced and referred to House HHS Committee.**

HB 510: This bill declares that with the insured's permission, medical payments under a motor vehicle liability policy may be assignable to a health care provider. **Status: Introduced and referred to House Commerce Committee. Sent to subcommittee.**

HB 511: This bill establishes a commission to study creating a public health oversight program within the department of health and human services. **Status: Introduced and referred to House HHS Committee.**

HB 572-FN: This bill extends the suspension of prior authorization requirement for a community mental health program on drugs used to treat mental illness. **Status: Introduced and referred to House HHS Committee.**

HB 575-FN: This bill allows the board of acupuncture to certify individuals as acupuncture detoxification specialists. **Status: Introduced and referred to House Executive Departments and Administration.**

HB 578-FN: This bill prohibits an abortion of a viable unborn child, except in cases of medical emergency. **Status: Introduced and referred to House Judiciary Committee.**

HB 589-FN: This bill repeals the law relative to providing certain parameters for access to reproductive health care facilities. **Status: Introduced and referred to House Judiciary Committee.**

HB 596-FN: This bill permits a person who has been involuntarily committed to a treatment facility under RSA 135-C to request a review hearing every 2 years. **Status: Introduced and referred to House Judiciary Committee.**

HB 602-FN-A: This bill prohibits the placement of certain persons with mental illness in the secure psychiatric unit. The bill establishes a commission to develop plans and oversee the establishment of a secure psychiatric hospital to treat such persons who would present a serious likelihood of danger to themselves or others. This bill also makes an appropriation for the purposes of the bill. **Status: Introduced and referred to House Judiciary Committee.**

HB 606-FN-A: This bill establishes a scholarship fund for health care providers who stay in New Hampshire for 5 years and makes an appropriation therefor. **Status: Introduced and referred to House Finance.**

HB 611: This bill clarifies premium rates for individuals and small employers under the law relating to portability, availability and renewability of health care coverage. **Status: Introduced and referred to House Commerce Committee. Sent to subcommittee.**

HB628-FN: This bill establishes a system of paid family and medical leave insurance. **Status: Introduced and referred to House Labor.**

HB 630-FN-A: This bill establishes the state health information and analysis program. Under this bill, the commissioner of the department of health and human services, the insurance commissioner, the commissioner of the department of corrections, and the attorney general shall enter into a memorandum of understanding to collaborate in the development of publicly available information on health care system patient safety, cost, quality, access to coverage and care, system performance, and efficiency and information pertaining to the delivery and financing of the health care system in New Hampshire, including information on new health system projects and associated costs. The bill establishes a health information and analysis planning council to provide consultation for the development of a public data resource for New Hampshire. The bill also establishes a fund for the implementation and administration of the requirements of the program. **Status: Introduced and referred to House HHS.**

HB 633-FN: This bill allows health insurance policies without mandates to be sold to New Hampshire residents. Under this bill, if the policy or certificate does not include certain mandated coverages, it must be submitted to the insurance commissioner for approval. **Status: Introduced and referred to House Commerce Committee. Sent to subcommittee.**

HB 638-FN-LOCAL: This bill repeals the New Hampshire health protection program. **Status: Introduced and referred to House HHS.**

HB 650-FN: This bill makes various changes to the regulation of psychology practitioners including the

requirements of the board of psychologists relating to investigation and hearings concerning disciplinary proceedings, the form of complaints against licensees, and the disclosure of patient records. **Status: Introduced and referred to House Executive Departments and Administration.**

SB 15: This bill adds a new qualifying medical condition for the purposes of receiving cannabis for therapeutic use**,** severe pain that has not responded to previously prescribed medication or surgical measures or for which other treatment options produced serious side effects. **Status: Voted Ought to Pass by Senate.**

SB 17: This bill clarifies hepatitis C as a qualifying medical condition for the use of cannabis for therapeutic purposes. **Status: Voted Ought to Pass by Senate.**

SB 26: This bill clarifies the definition of "facility caregiver" for purposes of the use of cannabis for therapeutic purposes law to include community living facilities certified under RSA 126-A:19 and RSA 126-A:20. **Status: Voted Ought to Pass by Senate.**

SB 54: This bill increases the number of hours of alcohol and drug use education required for initial licensure as a master license alcohol and drug counselor or as a licensed alcohol and drug counselor. **Status: Introduced and referred to Senate Executive Departments and Administration.**

SB 59: This bill creates a process for certain individuals to request a blood testing order when they have been exposed to a source individual's bodily fluids. **Status: Introduced and referred to Senate HHS.**

SB 61: This bill clarifies the procedure for receipt of medical records of a deceased spouse or next of kin. **Status: Introduced and referred to Senate HHS.**

SB 65: This bill adds certain vaccines to the law which allows licensed pharmacists to administer vaccines including hepatitis A, hepatitis B, Tdap, MMR, and meningococcal vaccines. **Status: Introduced and referred to Senate HHS.**

SB 126: This bill requires the public utilities commission to award funds from the renewable energy fund to hospitals with renewable energy projects. **Status: Introduced and referred to Senate Energy.**

SB 139: This bill modifies the requirements for licensure of magnetic resonance technologists by the board of medical imaging and radiation therapy. **Status: Introduced and referred to Senate Executive Departments and Administration.**

SB 144-FN: This bill clarifies the definition of "qualifying medical condition" to include certain conditions which trigger certain medical symptoms. This bill also deletes the requirement that a medical provider document how the injury affects activities of daily living. **Status: Introduced and referred to Senate HHS.**

SB 146-FN: This bill requires the commissioner of the department of health and human services to develop a centralized state system for transporting persons subject to involuntary emergency admission. This bill is a result of the committee established in 2016, 101. **Status: Introduced and referred to Senate HHS. Committee reported bill as Ought to Pass.**

SB 149: 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. **Status: Introduced and referred to Senate HHS.**

SB 150: Under this bill, a pharmacy intern under the direct supervision of a pharmacist may administer immunizing vaccines. **Status: Introduced and referred to Senate HHS.**

SB 151: This bill prohibits a nursing facility from requiring that a patient sign a mandatory arbitration agreement. **Status: Introduced and referred to Senate HHS.**

SB 152: This bill allows for temporary employment in a residential care facility or as a licensed nursing assistant by persons awaiting the results of a criminal history background check. **Status: Introduced and referred to Senate HHS.**

SB 154: This bill allows pharmacies to dispense oral contraceptives to persons 18 years of age or older without a prescription. **Status: Introduced and referred to Senate HHS.**

SB 155: This bill declares that step 2 of the Medicaid managed care program shall not be implemented until July 1, 2019. **Status: Introduced and referred to Senate HHS.**

SB 156: This bill clarifies the process of paying for filling prescriptions for covered persons. The bill also adds authority for the pharmacy board to adopt rules for enforcement of requirements for the price of filling prescriptions. **Status: Introduced and referred to Senate HHS.**

SB 157: This bill adds rulemaking for persons with substance use disorder for the purposes of the managed care law. This bill also requires health carriers to notify covered persons of their rights as a managed care consumer. **Status: Introduced and referred to Senate HHS.**

SB 158: This bill declares that if substance use disorder services are a covered benefit under a health benefit plan, no prior authorization shall be required for prescribed medications for a substance use disorder. **Status: Introduced and referred to Senate HHS.**

SB 159: This bill adds Ehlers-Danlos syndrome to the definition of "qualifying medical conditions" for the purposes of therapeutic cannabis. **Status: Introduced and referred to Senate HHS.**

SB 189-FN: This bill requires insurance policies to cover 3-D tomosynthesis mammography. **Status: Introduced and referred to Senate Commerce.**

SB 212: This bill adopts the physical therapy licensure compact, implemented by the physical therapy governing board. **Status: Introduced and referred to Senate Executive Departments and Administration.**

SB 220-FN: This bill changes the definition of mental illness for the purpose of involuntary commitment to include ingestion of opioid substances. **Status: Introduced and referred to Senate HHS.**

SB 236: This bill makes the Medicaid expansion law permanent. The program would currently expire December 31, 2018. **Status: Introduced and referred to Senate HHS.**

SB 237-FN: This bill allows medical providers who practice in metropolitan areas to be reimbursed by Medicaid for telehealth services. **Status: Introduced and referred to Senate HHS.**

SB 238-FN: This bill clarifies the term "usual and customary price" for the purposes of filling prescriptions to mean the price an individual would pay for a prescription at a retail pharmacy if that individual did not have a prescription drug benefit or insurance. **Status: Introduced and referred to Senate HHS.**

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

BIOS

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

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