

**Health Care  
Practice Group**

Cinde Warmington  
Chair  
[cwarmington@  
shaheengordon.com](mailto:cwarmington@shaheengordon.com)

William E. Christie  
[wchristie@  
shaheengordon.com](mailto:wchristie@shaheengordon.com)

Steven M. Gordon  
[sgordon@  
shaheengordon.com](mailto:sgordon@shaheengordon.com)

Lucy J. Karl  
[lkarl@  
shaheengordon.com](mailto:lkarl@shaheengordon.com)

Kara J. Dowal  
[kdowal@  
shaheengordon.com](mailto:kdowal@shaheengordon.com)

Alexander W. Campbell  
[acampbell@  
shaheengordon.com](mailto:acampbell@shaheengordon.com)

[www.shaheengordon.com](http://www.shaheengordon.com)

*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****Government Nets \$2.6 Billion in Fraud and Abuse Collections in FY 2017**

On April 6, 2018, the U.S. Department of Health & Human Services ("HHS") and Department of Justice ("DOJ") published the "Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2017." The Annual Report states that for Fiscal Year 2017, the Federal government recovered \$2.6 billion as a result of its fraud and abuse efforts. This amount includes over \$2.4 billion in health care fraud judgments and settlements. According to the Annual Report, "Of this \$2.6 billion, the Medicare Trust Funds received transfers of approximately \$1.4 billion during this period, and \$406.7 million in Federal Medicaid money was similarly transferred separately to the Treasury as a result of these efforts."

DOJ opened 967 new criminal health care fraud investigations, filed criminal charges in 439 cases, and obtained 639 convictions for health care fraud-related crimes. DOJ also opened 948 new civil health care fraud investigations in Fiscal Year 2017 and had over 1,000 civil cases pending at the end of the year. On the HHS side, the Office of the Inspector General ("OIG") initiated 788 criminal actions and 818 civil actions. OIG also excluded 3,244 individuals and entities from participation in Federal health care programs.

The Annual Report is available at:  
<https://oig.hhs.gov/publications/docs/hcfac/FY2017-hcfac.pdf>

**CMS Final Rule Increases Flexibility for States and Issuers in ACA Marketplace**

On April 9, 2018, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") published the Notice of Benefit and Payment Parameters final rule, which applies to health insurance plan years beginning on or after January 1, 2019. The final rule aims to increase flexibility for states by allowing them to select from the 50 essential health benefits ("EHB")-benchmark plans used for the 2017 plan year in other states around the country. This increased flexibility is meant to allow insurers to offer more affordable health plans. The final rule also returns oversight of network adequacy to the states.

Other items included in the final rule are: amendment to the risk adjustment program to reduce the burden on issuers; improvements to the Advanced Premium Tax Credit program integrity; standardization of and other changes to special enrollment periods; and reduction in quality improvement activity reporting burdens on insurers.

The final rule is available at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-07355.pdf>

CMS' press release on the final rule is available at:  
<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-04-09.html>

### **Trump Signs Executive Order Directing Agency Heads to Implement Work-Oriented Reforms to Entitlement Benefits**

On April 10, 2018, President Trump issued an executive order requiring the heads of eight executive departments to take steps to implement reforms consistent with a list of enumerated "Principles of Economic Mobility," which includes strengthening work requirements and reducing the size of bureaucracy. The principle aim of the executive order is to enact reforms to the federal welfare system, which, according to President Trump, "traps many recipients, especially children, in poverty and is in need of further reform and modernization in order to increase self-sufficiency, well-being, and economic mobility." The Executive Order gives agency heads 90 days to submit recommendations to the Office of Management and Budget.

The Executive Order follows recent approval by the Centers for Medicare & Medicaid Services for Arkansas to implement work requirements for its Medicaid program. Arkansas is the third state to obtain approval for such a requirement.

The Executive Order is available at: <https://www.whitehouse.gov/presidential-actions/executive-order-reducing-poverty-america-promoting-opportunity-economic-mobility/>

### **OIG Reports \$3.7 Million in Improper Telehealth Claims**

On April 6, 2018, the U.S. Department of Health & Human Services Office of Inspector General ("OIG") published results of its recent audit of 100 claims for telehealth services provided in 2014 and 2015. Out of the sample, the OIG found that 69 claims met Medicare requirements for telehealth services while 31 did not. Out of the 31 that did not meet Medicare requirements, 24 claims were for beneficiaries who received services at non-rural originating sites, 7 were billed by ineligible institutional providers, 3 were for services provided at unauthorized originating sites, 2 were provided with services through an unauthorized means of communication, 1 claim was for a non-covered service, and 1 claim was for services provided by a physician outside the United States. Based on the results of the audit, the OIG estimated that \$3.7 million was improperly paid by Medicare.

The OIG recommended that CMS conduct post-payment reviews to disallow payments for which claim edits cannot be implemented (such as unallowable originating sites or communications); work with Medicare contractors to implement all telehealth claims edits listed in the *Medicare Claims Processing Manual*, and offer training and education on Medicare telehealth requirements to practitioners. CMS concurred with all recommendations.

The report, titled *CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements*, is available at: <https://oig.hhs.gov/oas/reports/region5/51600058.pdf>.

### **Review of "Particularity" Requirement for FCA Claims Declined by Supreme Court**

On April 16, 2018, the U.S. Supreme Court denied a petition to review a decision from the First Circuit seeking that the Court decide whether a False Claims Act ("FCA") relator can satisfy Federal Rule of Civil Procedure 9(b)'s requirement to "state with particularity the circumstances constituting fraud" without alleging details of any specific false claims submitted to the government. The question is currently split

under federal appeals courts. In the case underlying the petition to the Supreme Court, the First Circuit had applied a “relaxed” pleading standard under the FCA, holding that a medical device manufacturer used latently defective versions of its Food and Drug Administration (FDA)-approved device, which resulted in physicians submitting false claims.

The original qui tam complaint was brought by two British physicians against Medical Device, Inc. (f/k/a DePuy Orthopaedics, Inc., a subsidiary of Johnson & Johnson) who are expert witnesses in ongoing product liability actions against DePuy. The district court dismissed the complaint for failure to plead fraud with particularity under Rule 9(b). On appeal, although the First Circuit affirmed the dismissal of claims alleging the company made false statements to the FDA to secure FDA-approval of the device, it revived claims that DePuy often sold defectively manufactured products to providers that materially differed from the FDA-approved device. In applying its more “relaxed” pleading standard, the First Circuit stated that, “where the complaint essentially alleges facts showing that it is statistically certain that DePuy caused third parties to submit many false claims to the government,” the relators did not need to plead the false claims with more particularity. *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, No. 16-1442 (1st Cir. July 26, 2017).

The petition for certiorari can be found here: [https://www.supremecourt.gov/DocketPDF/17/17-1108/34429/20180205155210528\\_Petition%20for%20Writ%20of%20Certiorari%20-%20Medical%20Device%20Business%20Ser....pdf](https://www.supremecourt.gov/DocketPDF/17/17-1108/34429/20180205155210528_Petition%20for%20Writ%20of%20Certiorari%20-%20Medical%20Device%20Business%20Ser....pdf).

### **Sessions Announces DEA to Put Annual Limits on Opioid Production and Will Share Painkiller Prescription Information with States**

On April 17, in two companion press releases, U.S. Attorney General Jeff Sessions announced a notice of proposed rulemaking by the Drug Enforcement Administration (“DEA”) that would put annual production limits on specific opioids based on its history of drug diversion and that an information-sharing agreement had been reached among the DEA and 48 Attorneys General that would allow for the sharing of information on prescription painkillers.

Under the proposed rule, the DEA would use information about drug diversion that it gathers from its Automation of Reports and Consolidated Orders (“ARCOS”) system, from the Department of Health and Human Services, the Food and Drug Administration, the Centers for Disease Control and Prevention, Medicare and Medicaid, and the states. Attorney General Sessions stated: “Under the proposed rule, DEA’s opioid production limits would be more responsive to the risk of drug abuse by explicitly taking diversion into account. It’s a common-sense idea: the more a drug is diverted, the more its production should be limited. Today’s proposed rule will give DEA more information to help the agency protect law-abiding Americans from the threat of drugs—and that makes all of us safer.”

According to the press release, the agreement on information sharing allows the DEA to share with the Attorneys General information collected by its ARCOS system, including 80 million annual transaction reports from manufacturers and distributors of prescription drugs. The states will also share their information taken from prescription drug monitoring programs (PDMPs) to the DEA. The information will be used to investigate and prosecute those engaged in pill diversion and trafficking.

Attorney General Sessions’ Press Release on the DEA Proposed Rule can be read here: <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-changes-dea-opioid-limit-rules>

A copy of the Proposed Rule can be found here: <https://www.justice.gov/opa/press-release/file/1053681/download>.

Attorney General Sessions' Press Release on the Information Sharing Agreement can be found here: <https://www.justice.gov/opa/pr/dea-share-painkiller-prescription-information-48-attorneys-general>.

### **FDA Publishes Medical Device Safety Action Plan**

On April 17, the Food and Drug Administration ("FDA") published a plan to help "enhance and modernize" the agency's approach to medical device safety and innovation. In the *Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health*, the FDA sets out five areas of focus: (1) Establish a robust medical device patient safety net in the United States; (2) Explore regulatory options to streamline and modernize timely implementation of postmarket mitigations; (3) Spur innovation towards safer medical devices; (4) Advance medical device cybersecurity; and (5) Integrate the Center for Devices and Radiological Health's (CDRH's) premarket and postmarket offices and activities to advance the use of a TPLC (Total Product Life Cycle) approach to device safety.

In a statement from FDA Commissioner Scott Gottlieb, MD, he highlighted the novel aspects of the Plan, including the integration of the FDA's Center for Devices and Radiological Health (CDRH) pre-market and post-market offices, exploring regulatory options to streamline timely implementation of post-market mitigation, and programs like its Breakthrough Device Program, that helps facilitate patient access to innovative medical devices. "Our aim is to make sure that the new advances in technology that are enabling better capabilities and benefits are also harnessed to bring added assurances of safety, so that more patients can benefit from new devices and address unmet needs."

The FDA's Plan can be read in full here:

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf>.

FDA Commissioner Gottlieb's Statement can be read here:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604672.htm>.

### **OIG Finds CMS Generally Effective at Preventing Capitation Payments After Beneficiary Death**

On April 18, the U.S. Department of Health & Human Services Office of Inspector General ("OIG") issued a report of its findings from its review of whether the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") policies and procedures ensured that capitation payments were not made to prescription drug plan sponsors on behalf of beneficiaries after the beneficiaries' deaths. OIG found that as of March 7, 2017, CMS failed to recoup \$1.1 million in improper capitation payments. OIG recommends that CMS recoups the \$1.1 million and continue to implement system enhancements to identify, adjust, and recoup improper capitation payments.

The report can be found at: <https://oig.hhs.gov/oas/reports/region7/71605088.pdf>.

### **HHS Releases Mental Health and Substance Use Disorder Parity Action Plan**

On April 23, the U.S. Department of Health & Human Services ("HHS") released a Mental Health and Substance Use Disorder Parity Action Plan, required by Section 13002 of the 21<sup>st</sup> Century Cures Act. The Action Plan implements the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") based on written comments from stakeholders and input from a public listening

session held in July 2017 and includes recent and planned actions from HHS, the Department of Labor (“DOL”), and the Department of the Treasury to maintain momentum on parity enforcement and implementation. MHPAEA requires that limitations on benefits under employment-based large group health plans and health insurance issuers that provide mental health and substance use disorder coverage not be more restrictive than limitations on medical and surgical benefits. Among the planned actions, the DOL will annually release data on closed federal parity investigations, results, and violations, and devote resources to the review of employer-sponsored health plans. The DOL also plans to update its self-compliance checklist on its website used to determine whether a group health plan is in compliance with federal law.

The Action Plan can be read in full here:

<https://www.hhs.gov/sites/default/files/parity-action-plan-b.pdf>.

### **CMS Sets IPPS and LTCH Rates for FY 2019**

On April 24, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (“CMS”) issued a proposed rule to increase payment to hospitals under the Inpatient Prospective Payment System for fiscal year (FY) 2019 by approximately \$4 billion and reduce the payments under Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) by approximately \$5 million. The rule was published in the *Federal Register* on May 7 (83 Fed. Reg. 20164). The proposed changes would apply to approximately 3,330 acute care hospitals and approximately 420 LTCHs, affecting discharges occurring on or after October 1, 2018. Comments on the proposed rule are due June 25.

In FY 2019, rates for inpatient stays paid under the IPPS for acute care hospitals that successfully participate in the Hospital Inpatient Quality Reporting Program and demonstrate meaningful use of electronic health records (“EHRs”) would increase by about 1.75%, which results from a 2.8% market basket update offset and a 0.5% adjustment required by legislation, a -0.8% multi-factor productivity adjustment, and a -0.75% adjustment mandated by the Affordable Care Act. CMS projects the rate increase will increase IPPS operating payments by about 2.1%. CMS proposes an increase of \$1.5 billion from FY 2018 in uncompensated care payments in FY 2019, distributing approximately \$8.25 billion in FY 2019. CMS projects that proposed changes in uncompensated care payments, capital payments, and the changes to the low-volume hospital payments will increase IPPS payments by an additional 1.3%, resulting in a total increase in IPPS payments of 3.4%.

For LTCHs, the proposed rule updates the Federal payment rate for the PPS by 1.15%. CMS projects that LTCH PPS payments would decrease by approximately 0.1%, or \$5 million in FY 2019.

A significant focus of the proposed rule includes promoting interoperability of EHRs, and CMS is proposing substantial changes to the “Meaningful Use” program (Medicare and Medicaid Electronic Health Record Incentive Programs) to, according to a CMS fact sheet: “make the program more flexible and less burdensome; emphasize measures that require the exchange of health information between providers and patients, and incentivize providers to make it easier for patients to obtain their medical records electronically.” CMS is also proposing to change the name of the program from “Meaningful Use” to “Promoting Interoperability.” The proposed rule keeps the requirement to use the 2015 Edition of certified electronic health record technology in 2019 to qualify for incentive payments and avoid reductions to Medicare payments.

Another focus of the rule is price transparency. The proposed rule would require hospitals to make a list of their standard charges accessible to the public on the internet. Stressing a concern for challenges that

patients face due to insufficient price transparency, such as being surprised by out-of-network bills for physicians providing services at in-network hospitals, CMS is requesting information from the public about the barriers that exist to giving patients price information and how price transparency can be improved.

A fact sheet on the proposed rule can be found here:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-24.html>.

The proposed rule can be read in full here:

<https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-08705.pdf>.

### **CMS Published Proposed Rule with FY 2019 Updates for SNF Payments**

On April 27, 2018 the Centers for Medicare & Medicaid Services (“CMS”) published a proposed rule outlining the proposed Fiscal Year 2019 Medicare payment updates and proposed quality program changes for skilled nursing facilities (“SNFs”). The proposed rule includes three major provisions: proposed changes to the case-mix classification system used under the SNF Prospective Payment System (“PPS”), the SNF Value-Based Purchasing Program (“VBP”), and the SNF Quality Reporting Program (“QRP”). The rule is intended to further promote the shift in Medicare payments from volume to value.

The proposed rule changes the case-mix classification system from the existing Resource Utilization Group, Version IV (“RUG-IV”) to the new Patient-Driven Payment Model (“PDPM”). The PDPM would focus on clinically relevant factors, rather than volume-based service, and would adjust Medicare payments based on each aspect of a resident’s care at the SNF. CMS also made efforts to simplify the PDPM as compared to the RUG-IV and another previously-proposed system. The proposed case-mix classification system would be effective October 1, 2019.

The proposed rule includes updates to the VBP, which applies positive or negative incentive payments to SNFs based on their performance on certain readmission measures. The proposed rule would also add a new cost-benefit factor to be considered when evaluating whether to remove a measure from the QRP measure set. CMS estimates that the changes in the proposed rule will have an aggregate impact on an increase of \$850 million in payments to SNFs, based on the FY 2019 market basket update of 2.4 percent required by the Bipartisan Budget Act of 2018. Comments to the proposed rule are due to CMS by June 26, 2018.

The proposed rule is available at: <https://www.federalregister.gov/documents/2018/05/08/2018-09015/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities>.

CMS’ fact sheet on the proposed rule is available at:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-27-4.html>.

### **Despite Court Decision, Agencies Maintain “Usual, Customary, and Reasonable” Rule for Payments for Out-of-Network Emergency Services**

On May 3, 2018, the U.S. Departments of Treasury, Labor, and Health and Human Services published a clarification meant to address concerns about the Departments’ decision to retain the so-called “usually, customary, and reasonable” (“UCR”) rates that are available to health insurers as a method of paying providers. The UCR rates were one of three rates included in a 2015 final rule that required insurers

to pay the greatest of three possible amounts for emergency services: the amount negotiated with in-network providers; the UCR rate; or the amount that Medicare would pay for the same services.

During the comment period for the 2015 final rule, several commenters – including the American College of Emergency Physicians (“ACEP”) – criticized the inclusion of UCR rates, saying that there would be the potential for insurers to manipulate the UCR rates for payment to out-of-network providers who provided EMTALA emergency services. The Departments responded to the comments by noting that the concerns about the UCR were adequately addressed by the requirement that insurers pay the greatest of the possible three amounts.

ACEP then filed a lawsuit challenging both the payment requirements and the Departments’ response to its comments on the inclusion of the UCR rate. In August of 2017, the U.S. District Court for the District of Columbia held that the Departments’ failure to seriously address ACEP’s concerns was arbitrary and capricious, and remanded back to the Departments to adequately address the comments and propose alternatives to the UCR rates. The Departments’ latest clarification retains the UCR rate and explains that the agencies “continue to believe that the implementing regulations provide a reasonable and transparent methodology to determine appropriate payments” by insurers for out-of-network emergency services.

The Departments’ clarification is available at: <https://www.gpo.gov/fdsys/pkg/FR-2018-05-03/pdf/2018-09369.pdf>.

The 2015 final rule which established the UCR rate is available at: <https://www.gpo.gov/fdsys/pkg/FR-2015-11-18/pdf/2015-29294.pdf>.

### **CMS Proposed Rule Would Decrease Burden on IRFs**

On April 27, 2018, the Centers for Medicare & Medicaid Services (“CMS”) issued a proposed rule which includes an estimated 0.9% increase to prospective payment rates for inpatient rehabilitation facilities (“IRFs”) for fiscal year 2019 and also proposed changes to the coverage requirements to ease the burden on IRFs. Proposed changes include: allowing the post-admission physician evaluation to count as one of the face-to-face physician visits; allowing the rehabilitation physician to lead the interdisciplinary team meeting remotely without any additional documentation requirements; and removing the admission order documentation requirement in an effort to reduce duplicative documentation requirements. CMS is also soliciting comments on whether rehabilitation physicians should have the flexibility to determine when a patient needs to be assessed face-to-face and when the assessment can be successfully accomplished remotely via another mode of communication. Comments must be received by June 26, 2018.

The proposed rule is available at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-08961.pdf>.

CMS’ fact sheet on the proposed rule is available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-27.html#anthony>.

### **OIG Opines No Violation of Antikickback Statute for Free Ostomy Samples and Customer Satisfaction Surveys**

On May 7, the U.S. Department of Health & Human Services Office of Inspector General (“OIG”) issued Advisory Opinion 18-02, in which it reviewed an arrangement where a medical device and

pharmaceutical products company (“Requestor”) provides a limited number of free samples to patients and contracts with a third party to conduct follow-up customer satisfaction surveys (the “Arrangement”). Under the Arrangement, upon request of either the patient or the patient’s health care provider, the Requestor will send only one free sample of a particular size and configuration ostomy product to a patient. Although the Requestor distributes and sells the ostomy products, it certified to the OIG that it does not own or operate, directly or indirectly, any entity that files claims for the ostomy products or any other reimbursable products or services to Medicare or state health programs. Additionally, the free sample is not contingent on the purchase of additional products.

The Requestor also contracts with a third party to process sample requests and to administer a customer satisfaction survey that evaluates customer satisfaction with the products; helps patients identify support services or other general information about ostomy; and provides basic information about the products, upon request.

The OIG found that although the Requestor did not meet the definition of a provider, practitioner, or supplier under the antikickback statute, the provision of free samples may be intended to induce Federal health care program beneficiaries to self-refer to the products in the future and therefore the antikickback statute is implicated. However, the OIG found that the Arrangement poses a low risk of fraud and abuse under the antikickback statute because (1) the Arrangement should not increase costs to patients or federal health care programs (neither patients nor Federal health care programs incur costs because the Requestor does not bill a third-party payor for the samples); (2) risk of inappropriate patient steering is low because future purchases remain a matter of a patient’s personal preference; (3) the Arrangement is unlikely to result in inappropriate utilization; and (4) the Arrangement contains safeguards to limit the risk that the third-party contractor is paid for referrals (the contractor does not sell the products, is not allowed to recommend the products or any other items sold in connection with administering the survey, and is not paid based on future sales. Also, the Request only receives the data from the survey in an aggregate and de-identified form.

Advisory Opinion 18-02 can be found here:

<https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-02.pdf>.

### **CMS Releases First Rural Health Strategy and Increases Rates for Rural DME**

On May 10, the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services (“CMS”) announced its first Rural Health Strategy with the aim to ensure access to high quality, affordable healthcare to rural Americans. Based on input from rural providers and beneficiaries, the Rural Health Strategy has five main objectives: (1) Apply a rural lens to CMS programs and policies; (2) Improve access to care through provider engagement and support; (3) Advance telehealth and telemedicine; (4) Empower patients in rural communities to make decisions about their healthcare; (5) Leverage partnerships to achieve the goals of the CMS Rural Health Strategy.

May 9, CMS announced an interim final rule with comment period, published May 11 in the Federal Register ([83 Fed. Reg. 21912](#)), increasing the fee schedule rates of durable medical equipment (“DME”) items and services in rural and non-contiguous areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (“CBP”). Under the rule, blended rates of 50 percent of the amount based on the competitive bid rates and 50 percent of the traditional fee schedule amounts that were in effect in 2016 prior to the fully adjusted fee schedule rates went into effect, will be resumed from June 1, 2018 to December 31, 2018. According to a CMS press release, the rule comes in response to stakeholder concerns about “significant financial challenges” that the

current DME adjusted fee schedule poses to suppliers and the decline in the number of suppliers in rural and non-contiguous areas as a result. CMS stated the aim of the rule is to protect access to needed DME in these areas. Comments on the interim final rule are due July 9, 2018.

The interim final rule may be accessed here: <https://www.gpo.gov/fdsys/pkg/FR-2018-05-11/pdf/2018-10084.pdf>.

A fact sheet on CMS' Rural Health Strategy can be read here: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-05-08.html>.

### **OIG Updates Work Plan**

The U.S. Department of Health & Human Services ("HHS") Office of Inspector General ("OIG") has released its updated work plan for May 2018. Updates include examining the extent to which Healthcare Coalitions ensure "a successful whole community response" by integrating non-hospital-based facilities into emergency preparedness activities and technological strategies; reviewing the impact of authorized generic drugs on Medicaid drug rebates; and reviewing HHS' oversight of recovery and response efforts related to hurricanes Harvey, Irma, and Maria in 2017, along with assessing and auditing HHS' primary risks for hurricane preparedness and response. In response to reports from States that they have had issues with private contractors who design, develop, and operate the States' Medicaid Management Information System ("MMIS"), the OIG also plans to determine if selected States followed Federal and State requirements related to procuring private MMIS contracting services and claiming Federal Medicaid reimbursement.

You can view the updated work plan here: <https://oig.hhs.gov/reports-and-publications/workplan/updates.asp>.

### **D.C. Circuit Court Dismisses Challenge to ACA Insurer Payments**

On May 16, the Court of Appeals for the D.C. Circuit dismissed the appeal in the action between the administration and the House of Representatives challenging payments to insurers under the Affordable Care Act's (ACA's) cost-sharing reduction (CSR) program. Although the parties agreed to settle the lawsuit in December 2017, the settlement stalled in March 2018 when the Court of Appeals ordered the parties to file a supplement to their joint motion to remand the case to District Court, seeking an explanation of the "exceptional circumstances" the parties cited in their joint motion. The case was filed in November 2014 and was based on the Obama administration's interpretation of Section 1402 of the ACA, which authorizes the federal government to provide payments to insurers to offset CSR payments for certain beneficiaries. The House of Representatives argued that such payments can only be made in accordance with a Congressional appropriation of funds, which never occurred.

### **President Trump Signs Right-to-Try Bill into Law**

On May 30, 2018, President Trump signed the "Right to Try Act" into law, which allows terminally ill patients to access experimental medical treatments that have not yet been approved by the Food and Drug Administration ("FDA"). Implementing the "right to try" for terminally ill patients had been one of the President's major priorities. Some House Democrats opposed the bill over concerns about exposing vulnerable patients to treatments that had not yet been proven safe or effective, and concerns that increasing access to unapproved treatments would negatively affect ongoing clinical trials.

Information about the bill is available at: <https://www.congress.gov/bill/115th-congress/senate-bill/204>.

### **U.S. Supreme Court Declines to Review Dismissal of False Claims Act Claim on Alleged Off-Label Marketing**

On May 21, 2018, the U.S. Supreme Court declined to review the decision by the Court of Appeals for the Fifth Circuit in *U.S. ex rel. King v. Solvay Pharmaceuticals, Inc.*, a False Claims Act (“FCA”) case concerning off-label promotion. The case was originally brought by relators John King and Tammy Drummond, who formerly worked at Solvay and who alleged that the company was involved in an off-label marketing campaign involving its drugs Aceon, Luvox, and AndroGel. The district court dismissed the claims because the AndroGel claims were subject to the public disclosure bar, and the relators’ claims about Aceon and Luvox were based only on circumstantial evidence. The Fifth Circuit affirmed the district court’s ruling. The relators had petitioned the Supreme Court to determine whether circumstantial evidence was sufficient to support an FCA claim, and to resolve a circuit split over the requirements for qualifying as an “original source” of a fraudulent claim.

The Fifth Circuit’s decision is available at: <https://caselaw.findlaw.com/us-5th-circuit/1873696.html>.

### **Pfizer Settles AKS Beneficiary Inducement Claim with \$23.85 Million Payment and Corporate Integrity Agreement**

On May 24, 2018, U.S. Attorney for the District of Massachusetts Andrew Lelling announced that Pfizer had entered into a settlement agreement that included its payment of \$23.85 million and a five-year corporate integrity agreement. The pharmaceutical giant had agreed to settle allegations that it had unlawfully induced beneficiaries in violation of the Anti-Kickback Statute by using a charitable foundation to cover Medicare beneficiaries’ copayments for three Pfizer drugs. The government claims that Pfizer bypassed its own free drug program and used a third-party specialty pharmacy to move beneficiaries over to the foundation. The government also claimed that Pfizer coordinated the use of the foundation to coincide with an increase in the price of one of the drugs.

U.S. Attorney Lelling’s statement on the settlement is available at: <https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay>.

### **CMS Issues Memo to Part D Sponsors on Unacceptable “Gag Clauses”**

On May 17, 2018, Centers for Medicare & Medicaid Services (“CMS”) Administrator Seema Verma issued a memorandum to Medicare Part D plan sponsors notifying them of CMS’ position that the use of so-called “gag clauses” in contracts with pharmacies is unacceptable. Some plan sponsors include gag clauses in their contracts with pharmacies that prevent the pharmacies from notifying Part D beneficiaries that the amount they pay for a drug’s copay is more than if they paid for the drug in cash.

In her memo, Administrator Verma states: “We are committed to empowering patients with the information they need to make informed decisions about their care. This includes ensuring that all patients have access to drug price information that can help them save money and get the most value from their insurance coverage. In Medicare Part D, our existing policy requires plan sponsors to ensure enrollees pay the lesser of the Part D negotiated price or copay, or be subject to CMS compliance actions.”

Administrator Verma's memo is available at:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/Other-Content-Types/2018-05-17.pdf>.

### **GAO Recommends that CMS Continue Its Application of Prior Authorization**

In an April 2018 report titled "CMS Should Take Action to Continue Prior Authorization Efforts to Reduce Spending," the U.S. Government Accountability Office ("GAO") published its findings from a study it conducted on the Center for Medicare & Medicaid Services' ("CMS") prior authorization programs. GAO examined: 1) the changes in expenditures and the potential savings for items and services subject to prior authorization demonstrations; 2) reported benefits and challenges of prior authorization; and 3) CMS's monitoring of the programs and plans for future prior authorization. The GAO found that CMS' recent fixed-length demonstrations to measure the effectiveness of prior authorization have resulted in a decrease in expenditures for the items subject to the demonstrations. Although GAO notes some challenges identified by provider and supplier group officials, it recommended that CMS take steps, based on results from evaluations, to continue prior authorization beyond the expiration of the current demonstrations.

GAO's report is available at: <https://www.gao.gov/assets/700/691381.pdf>.

### **CMS Requests Comment on Home Health Claim Review Demonstration Project**

On May 31, 2018, the Centers for Medicare & Medicaid Services published a request for comments on a proposed demonstration project to develop procedures for identifying, investigating, and prosecuting Medicare fraud by home health agencies ("HHAs"). The proposed demonstration project will take place in Illinois, Ohio, North Carolina, Florida, and Texas. States in the demonstration states will have a choice of participating in 100% pre-claim review or 100% postpayment review. The providers will be subject to review until they reach their target affirmation or claim approval rate, after which they can choose to be relieved from claim review, except for spot checks. Providers may decline to participate in the project, but they would face a 25% payment reduction on all claims.

Comments must be received by July 30, 2018. The request for comments is available at:

<https://www.gpo.gov/fdsys/pkg/FR-2018-05-31/pdf/2018-11492.pdf>.

### **Walmart Agrees to Pay \$825,000 to Resolve Medicaid Fraud Allegations Involving Prescription Auto Refills**

On May 29, 2018 the U.S. Attorney for the District of Minnesota and the Minnesota Attorney General announced that Walmart had agreed to pay \$825,000 to resolve allegations that it had violated Minnesota's Medicaid program's prohibition against automatic refill prescriptions. The allegations were brought by a relator in a False Claims Act qui tam action. According to the allegations in the complaint, Walmart pharmacies routinely enrolled Medicaid beneficiaries in the companies' auto-refill program, and billed Medicaid for prescriptions in violation of state rules and regulations. In addition, according to the allegations, pharmacy employees reported the violation to company managers, yet Walmart continued to automatically refill the prescriptions.

The U.S. Attorney's press release on the settlement is available at: <https://www.justice.gov/usao-mn/pr/walmart-sam-s-club-pay-825000-resolve-fraud-allegations-concerning-auto-refilling>.

***OIG Report Identifies Missed Opportunities by HRSA to Help Health Centers Reduce Risks***

On May 30, 2018, the U.S. Department of Health and Human Services Office of the Inspector General (“OIG”) published a report on the Health Resources & Services Administration’s (“HRSA”) oversight of health centers who were recipients of Service Area Competition grants in 2014: “HRSA Helped Health Centers With Elevated Risks and Can Continue to Take Additional Steps.” HRSA’s Service Area Competition Grants are awarded to health centers in underserved areas, including some that are at risk because of non-compliance with multiple program requirements or are financially unstable, and therefore require additional oversight to ensure that patients receive quality care. OIG’s review identified these at-risk grant recipients and analyzed data for 2.5 years after they received the grants to assess HRSA’s oversight. OIG determined that 25% of the health centers that were awarded a grant were at risk. OIG found that while HRSA did take steps to help these health centers improve – and while many of them did improve – HRSA missed opportunities to minimize risk. OIG identified the following as steps that HRSA should have taken to further minimize the risk of these health centers: limit project periods; restrict funding; conduct site visits; withhold further funding from health centers that failed to show improvement.

OIG’s report includes two specific recommendations to HRSA: (1) use risk management interventions in accordance with its policies to help health centers reduce elevated risks; and (2) explore additional steps it could take to help health centers reduce elevated risks.

OIG’s report is available at: <https://oig.hhs.gov/oei/reports/oei-05-14-00470.pdf>.

***OIG Expects to Recover \$1.46 Billion in First Half of FY 2018***

In its recent semiannual report to Congress, the U.S. Department of Health and Human Services Office of the Inspector General (“OIG”) stated that it expects to recover \$1.46 billion in investigative recoveries for the first half of fiscal year 2018, down from an expected recovery of \$2.04 billion for the same period in fiscal year 2017. OIG reports that during the first half of fiscal year 2018, it initiated criminal actions against 424 individuals or entities and civil actions against 349 individuals or entities. It also excluded 1,588 individuals and entities from federal health care programs.

OIG’s report is available at: <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2018/sar-spring-2018.pdf>.

***OIG Approves Free Telemedicine Services to County HIV Clinic***

On May 24, 2018, the U.S. Department of Health & Human Services, Office of the Inspector General (“OIG”) issued Advisory Opinion 18-03, in which it concluded that an arrangement consisting of free telemedicine services in exchange for referrals of HIV consultations would present a low risk of fraud and abuse under the anti-kickback statute. Under the proposed arrangement, a provider would use grant funds it received from the state health department to provide free telemedicine services to a county clinic for use in telemedicine encounters related to HIV prevention. In exchange, the provider would receive the opportunity to earn the originating site fees for telemedicine services furnished and could potentially receive referrals from the clinic of business for virtual PrEP and PEP consultations and follow-up items and services.

The OIG concluded that, despite the existence of remuneration for which purpose would be to induce referrals of Federal health care program business, the proposed arrangement would present a low risk of fraud and abuse under the anti-kickback statute because: 1) it would include safeguards intended to prevent inappropriate patient steering; 2) it would be unlikely to result in inappropriate patient steering to the

Provider's pharmacy; 3) it would be unlikely to inappropriately increase costs to Federal health care programs; and 4) the primary beneficiaries of the arrangement would be the clinic patients who would be able to receive HIV prevention services more conveniently.

Advisory Opinion 18-03 is available at:

<https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-03.pdf>.

### **Administration Announces Additional Delay of 340B Rule**

On June 5, 2018, the U.S. Department of Health and Human Services, Health Resources and Services Administration ("HRSA") announced another delay to the implementation of its final rule on changes to the 340B discount drug program. The final rule adjusts the ceiling for reimbursements from the federal government for drugs obtained at a discount under the 340B program. It was finalized in January of 2017 and originally scheduled to go into effect in March of that year, but has been delayed several times by the Trump Administration in the face of vocal criticism of 340B hospitals who argue that the new reimbursement rates will have significant negative financial consequences for hospitals. The latest delay pushes the effective date out to July 1, 2019.

The final rule is available at: <https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf>.

The notice of the delay is available at: <https://www.gpo.gov/fdsys/pkg/FR-2018-06-05/pdf/2018-12103.pdf>.

### **OIG Review Finds Significant Increase in Part D Costs, Despite Decrease in Prescriptions**

In a recent report, "Increases in Reimbursement for Brand Name Drugs in Part D," the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") detailed its findings of a review of Medicare Part D drug reimbursement. OIG conducted its review of prescription drug event records from 2011 to 2015 following media reports of recent increases in prescription drug prices. OIG found that total reimbursement for brand-name Part D drugs increased 77 percent from 2011 to 2015, despite a 17 percent decrease in the number of prescriptions written. Even accounting for manufacturer rebates, reimbursement still increased by 62 percent in this timeframe. OIG also found that the percentage of beneficiaries responsible for out-of-pocket costs of at least \$2,000 per year for brand-name drugs nearly doubled in this period.

OIG's report is available at: <https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf>.

### **Medicare Trustees Report that Medicare Expected to Become Insolvent Three Years Earlier Than Previously Projected**

On June 5, 2018, the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds published their 2018 Annual Report on the state of the trust funds. The report states that the Hospital Insurance trust fund – which pays for Medicare Part A – is expected to run out by 2026, three years earlier than was projected last year. The Trustees cite lower payroll taxes and lower income from taxation of SSI benefits as contributing factors. The report includes a suggestion that legislation be implemented soon to address the projected shortfall.

The Trustees' report is available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>.

**STATE DEVELOPMENTS**

**NH Medicaid Expansion Bill headed to the Governor's Desk**

After months of negotiation, the NH Senate and House have come to agreement on a bill to continue the Medicaid expansion program that provides coverage for over 50,000 NH residents. Senate Bill 313 will now proceed to the Governor's desk for signature. Under the bill, the New Hampshire Health Protection Program will be replaced by the Granite Advantage Health Care Program. The new program will use a managed care model which is expected to result in significant cost savings to the state. The bill applies "work" and "community engagement" requirements on enrollees of the program. On May 7, the state received approval from CMS for its proposal that enrollees between the ages to 19 and 64 be required participate in at least 100 hours per month of community engagement activities, which may include employment, community service or job training. The Department of Health and Human Services has submitted an application to CMS to amend and extend its current Demonstration Waiver in order to provide coverage to the state's Medicaid expansion population consistent with the legislation passed by the House and Senate. The comment period for the Demonstration Waiver has been extended until 5pm on June 29, 2018.

The Demonstration Waiver Public Notice may be found at;

<https://www.dhhs.nh.gov/ombp/medicaid/documents/ga-public-notice-05302018.pdf>

**HHS Proposes New Rules for Home Health Care and Hospice Provider Licensing**

The NH Department of Health and Human Services has proposed new rules governing the licensing of Home Health Care Providers and Home Hospice Care Providers. The proposed rules update the licensing requirement consistent with other licensing rules that have recently been updated. There are extensive changes such as changes in initial inspection requirements, changes to the license renewal process and clarification of the requirements in the event of a closure or a change of ownership.

The proposed rules may be found at:

Home Health Care Providers Licensing: <https://www.dhhs.nh.gov/oos/aru/documents/hep809ip.pdf>

Home Hospice Care Providers Licensing: <https://www.dhhs.nh.gov/oos/aru/documents/hep823ip.pdf>

Comments for both are due by June 19, 2018 at 4:30pm.

**2018 LEGISLATIVE UPDATES**

**HB 1102-FN** This bill authorizes the commissioner of the department of health and human services to contract with a physician certified by the Academy Society of Addiction Medicine to review medication assisted treatment in New Hampshire. Passed by the House with Amendment. The amendment allows the HHS Commissioner to contract with multiple physicians, permits the physician(s) to be certified from one of multiple accrediting bodies, and describes the consultant's role in more general terms. **The bill was introduced in the Senate which passed the bill with amendment on non-related new provisions. The House did not concur with the Senate amendments. A Committee of Conference was convened and voted to adopt the version of the bill passed by the House. Both the House and Senate voted to adopt the Committee of Conference report.**

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

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

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

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

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

**HB 1506-FN** This bill: I. Establishes the regulation and licensure of assistant physicians by the board of medicine. II. Regulates their practice through assistant physician collaborative practice arrangements. III. Establishes a grant program in the department of health and human services to provide matching funds for primary care clinics in medically underserved areas utilizing assistant physicians. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment replaces "assistant physicians" with "graduate physicians." Introduced and

referred to the Senate HHS Committee which voted Ought to Pass with Amendment. The Amendment completely eliminates the text of the original bill and replaces it with language amending RSA 126-T, a statute related to the Commission on Primary Care Workforce Issues. It expands the membership of the commission, changes the scope of the review and extends the due dates for a report. **Voted Ought to Pass with Amendment by the Senate. The House concurred with the Senate amendment and the bill was enrolled.**

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

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

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

**HB 1606:** This bill makes various changes to the regulation of doctors of naturopathic medicine including the scope of practice of naturopaths and the procedures of the naturopathic board of examiners. Introduced and referred to House Executive Departments and Administration Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The amendment provides for the election of a chairperson of the board of examiners, changes the quorum for the board from four members to three, and increases the frequency of submission by the licensee of proof of continuing education. **Voted Ought to Pass by the Senate.**

**HB1654:** This bill prohibits holding an injured driver or passenger responsible for medical costs determined to not be reasonable. Introduced and referred to House Commerce Committee. Voted Ought to Pass by the Committee and the full House. **Introduced and referred to Senate Commerce Committee. Voted Ought to Pass by the Senate. Signed by the Governor. Effective July 24, 2018.**

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

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

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

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

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

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

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

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

**HB 1769-FN:** This bill prohibits discrimination against physicians based on maintenance of certification. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the

Committee and the full House. The amendment makes a small change to those entities that are prohibited from differentiating between physicians based on a physician's maintenance of certification. **Introduced and referred to Senate HHS. Senate referred the bill for interim study.**

**HB 1791-FN:** This bill declares that a contract between an insurance carrier or pharmacy benefit manager and a contracted pharmacy shall not contain a provision prohibiting the pharmacist from providing certain information to an insured. Introduced and referred to House Commerce Committee. Voted Ought to Pass by Committee. Voted Ought to Pass by the Committee and the full House. **Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by the Senate. The House concurred with the Senate amendment and the bill was enrolled. The amendment establishes requirements for the dispensing and substitution of biological products by pharmacists.**

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

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

**HB 1816-FN:** This bill requires the commissioner of the department of health and human services to adjust the Medicaid managed care program by requesting a certain waiver from the Centers for Medicare and Medicaid Services, implementing enhanced eligibility screening, and requiring managed care organizations to meet the federal medical loss ratio provision with any surplus to be deposited into the general fund. This bill also eliminates certain provisions under step 2 of the program. Introduced, referred to House HHS Committee and sent to subcommittee. Voted Ought to Pass with Amendment by the Committee. The bill as amended declares that the remaining unimplemented phases of step 2 of the program shall not be implemented and requires the commissioner to implement enhanced eligibility screening and require managed care organizations to meet the Federal medical loss ratio provision with any nonfederal surplus to be deposited into the general fund. Introduced and referred to Senate HHS Committee. **The Senate voted Ought to Pass with Amendment. The House concurred with the amendment and the bill was enrolled. The amended bill as passed removes the requirement that managed care organizations meet the federal medical loss ratio. It also permits HHS to develop a plan to offer on a voluntary basis PACE and/or ACO models to provide non-fee-for-service basis nursing facility and home care services.**

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

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

**SB 313-FN:** This bill establishes the New Hampshire Granite Advantage Health Care Program which shall replace the current New Hampshire health protection program. Under this program, those individuals eligible to receive benefits under the Medicaid program and newly eligible adults shall choose coverage offered by one of the managed care organizations contracted as vendors under the Medicaid program. Introduced and referred to Senate Finance Committee. Voted Ought to Pass with Amendment by the Committee and the full House. The bill as amended provides for the establishment of the Granite Workforce Pilot Program and increases the amount of liquor revenues to be deposited into the Alcohol Abuse Prevention and Treatment fund and provides that moneys deposited into the fund shall be transferred to the Granite Advantage Health Care Trust Fund for substance use disorder prevention, treatment, and recovery. **Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by House. Senate concurred with House amendment. Bill was enrolled. The final bill is discussed in more detail above.**

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

**SB 332:** This bill requires insurers offering health insurance policies with prescription drug coverage to allow covered persons to synchronize the dispensing dates of their prescription drugs. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by the Committee and the full Senate. The amendment revises the bill by adding specificity to the circumstances under which the synchronization is available. Introduced and referred to House Commerce Committee. **Voted Ought to Pass by House. Signed by Governor to be effective January 1, 2019.**

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

**House. The Senate did not concur with the House amendment and the bill went to a Committee of Conference. No Committee of Conference report was filed. Some of the changes sought in this Senate bill were addressed in House Bill 1791.**

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

**SB 377:** This bill makes various changes to the regulation of dentists and dental hygienists, including requiring criminal history records checks for new applicants and establishing a professionals' health program for impaired dentists. This bill is a request of the board of dental examiners. Introduced and referred to Senate HHS Committee. Voted Ought to Pass by the Committee and the full Senate. **Introduced and referred to House Executive Departments and Administration. Voted Ought to Pass with Amendment by House. The Senate concurred with the House amendment and the bill was enrolled. The amendment deleted the provision regarding dentists advertising as a specialist.**

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

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

**SB 383:** This bill establishes a commission to study the benefits and costs of a "health care for all" program for New Hampshire. Introduced and referred to Senate HHS Committee. Voted Ought to Pass with Amendment by the Senate. The amendment changes the purpose of the study commission to one which will recommend policies that will enhance access to affordable health care for all New Hampshire residents. Introduced in the House Commerce Committee. **Voted Inexpedient to Legislate by the House.**

**SB 421:** This bill clarifies insurance coverage for prescription contraceptive drugs and prescription contraceptive devices and for contraceptive services. Introduced and referred to Senate Commerce Committee. Voted Ought to Pass by the Senate; Introduced and referred to House Commerce Committee. **The House voted Ought to Pass with Amendment. The Senate concurred with the**

**House amendment and the bill was enrolled. The amendment relates primarily to the provision of generic contraceptive drugs.**

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

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

**SB 477:** This bill establishes the therapeutic cannabis medical oversight board which shall monitor and contribute to the oversight of the clinical, quality, and public health related matters of the use of cannabis for therapeutic purposes law under RSA 126-X. **Passed by the House and Senate. Signed into law by the Governor. Effective 60 days after passage.**

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

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

**SB 573-FN-A:** This bill allows the chief medical examiner and designees to register and access the controlled drug prescription health and safety program. This bill also makes an appropriation to the controlled drug prescription health and safety program. This bill is a request of the controlled drug prescription health and safety program, established in RSA 318-B:32. Introduced and referred to Senate HHS Committee which voted Ought to Pass with Amendment. Senate voted Ought to Pass with Amendment. The amendment clarifies the access by the Chief Medical Examiner and delegates. **House voted Ought to Pass. The Bill was enrolled and signed by the Governor to be effective July 29, 2018.**

**SB 576-FN:** This bill repeals the provision suspending home health services rate setting established in 2017, 156. After being laid on the table and removed, Senate voted Ought to Pass with Amendment. The

amended bill requires the Department of Health and Human Services to review Medicaid reimbursement for home health services. Introduced and referred to House Finance Committee. **House voted Inexpedient to Legislate.**

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

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

\*~\*~\*

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.

#### **ALEXANDER W. CAMPBELL, ESQ.**

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

The information provided in this update is for general information purposes only. It is not intended to be taken as legal advice for any individual case or situation. The receipt or viewing of this information is not intended to create, and does not constitute, an attorney-client relationship between Shaheen & Gordon, P.A. or any of its attorneys and the receiver of this information, nor, if one already exists, does it expand any existing attorney-client relationship. Recipients are advised to consult their own legal counsel for legal advice tailored to their particular needs and situation.