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Tenacity, Creativity and Results are the three words that best describe Shaheen & Gordon's approach to addressing complex legal issues. Our health care team closely monitors the rapidly changing legal environment so that our clients are prepared to meet the challenges of today as well as tomorrow. Relying on a wealth of experience, we offer practical advice and assist in implementing recommendations tailored specifically to meet the needs of both large and small health care clients.

FEDERAL DEVELOPMENTS

Proposed $115 Million Settlement in Anthem Breach

On June 23, Anthem filed a settlement agreement with the U.S. District Court for the Northern District of California, in which it agreed to pay $115 Million to settle a class action from its 2015 data breach involving the personal information of approximately 80 million customers. Many of those customers filed lawsuits in courts across the country alleging violations of state and federal consumer protection laws as a result of the breach which were consolidated in the multi-district litigation. The settlement fund would be used to purchase two years of credit monitoring for class members, reasonable administrative fees, attorneys' fees and costs, and would provide alternative compensation of up to $50 per class member for those customers who had already purchased credit monitoring or out-of-pocket costs deemed reasonably traceable to the data breach. Anthem would also be required to implement certain business practices related to information security as part of the settlement.

Representatives Implore New CMS Administrator to Implement Backlog of OIG Recommendations

On June 23, the House Energy and Commerce Committee sent a letter to Centers for Medicare & Medicaid Services (CMS) Administrator, Seema Verma, asking that CMS use the opportunity of her recent appointment to implement some of the 150 unimplemented recommendations by the U.S. Department of Health and Human Services Office of Inspector General (OIG) – some of which date back almost 30 years. "The start of your term as CMS Administrator provides a tremendous opportunity to bring results-oriented management and accountability to CMS. In that spirit, and in consultation with the HHS OIG, attached is a list of 16 HHS OIG unimplemented recommendations made to CMS in a variety of prior HHS-OIG reports on Medicare and Medicaid." The letter, signed by Committee Chairman Greg Walden (R-OR), Oversight and Investigations Subcommittee Chairman Tim Murphy (R-PA), and Health Subcommittee Chairman Michael C. Burgess, M.D. (R-TX), indicates the Committee's belief that the list of recommendations identified in the letter could be implemented within a year, considering that they are all low cost and not contested by CMS.

A copy of the letter may be accessed online at: https://archives-energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/documents/20170623CMS.pdf

GAO to CMS: Revise Formula for Hospital Bonuses to Prevent Payment to Lower-Quality Hospitals

In June, the U.S. Government Accountability Office ("GAO") issued a report on the Hospital Value-based Purchasing ("HVBP") program titled "CMS Should Take Steps to Ensure Lower Quality Hospitals Do Not Qualify

for Bonuses." The HVBP program was enacted as part of the Affordable Care Act ("ACA") and evaluates hospital performance on quality and efficiency (Medicare spending per beneficiary) measures. Based on those results, the U.S. Department of Health & Human Services ("HHS") Centers for Medicare and Medicaid Services ("CMS") adjusts Medicare payments, supporting bonuses or penalties for hospitals. The ACA provides for the GAO to conduct periodic assessments of the HVBP program.

In conducting its recent assessment, the GAO analyzed CMS documentation and data for all participating hospitals in fiscal years 2013 through 2017, including safety net, small rural, and small urban hospitals. The GAO's most significant finding was that some hospitals with high efficiency scores received bonuses despite having relatively low quality scores, contradicting CMS' stated intention to reward hospitals providing high-quality care at a lower cost. The GAO found that this was an unintended result of CMS' current method of calculating scores and bonus payments, which does not require a complete set of scores for a hospital to participate in the HVBP program. As a result, hospitals with missing quality scores see the weights of those missing scores redistributed to other domains, including efficiency. This has led to some lower-quality hospitals qualifying for and receiving bonuses solely due to their high cost-efficiency.

The report concludes with a recommendation by the GAO that CMS: (1) revise the formula for the calculation of hospitals' total performance score or take other actions so that the efficiency score does not have a disproportionate effect on the total performance score; and (2) revise the practice of proportional redistribution used to correct for missing domain scores so that it no longer facilitates the awarding of bonuses to hospitals with lower quality scores. In its written comments in response to the report, HHS stated that it would evaluate the current methodology for calculating scores and eligibility for bonuses, but that any changes would be subject to noticed and comment rulemaking.

The GAO's report is available at: https://www.gao.gov/assets/690/685586.pdf.

CMS Proposed Rule Adjusts MIPS and AAPM Criteria to Decrease Burden on Clinicians

On June 30, 2017, the U.S. Department of Health & Human Services Centers for Medicare and Medicaid Services ("CMS") published a proposed rule that would modify the criteria for participation in the Merit-Based Incentive Payment System ("MIPS") and Advanced Alternative Payment Models ("Advanced APMs") set forth in the November 4, 2016 final rule implementing the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). MIPS and the AAPMs were established as two tracks intended to further incorporate quality and value measures into the calculation of Medicare provider reimbursement. The changes included in CMS' Proposed Rule would modify or delay the implementation of certain components to increase flexibility to and decrease burdens on providers, thus allowing them additional time to prepare for full participation.

The proposed modifications to MIPS largely involve delaying the changes in weight of the quality and cost components to the MIPS final score. Under the previous final rule, the weight for the quality component was scheduled to decrease from 60% for fiscal year 2017 to 30% for fiscal year 2018, while the weight for the cost component was scheduled to increase from 0% for fiscal year 2017 to 30% for fiscal year 2018. Under CMS' Proposed Rule, the weights of these two components in fiscal year 2018 would remain the same at 60% and 0%, respectively.

CMS also proposes additional changes to the quality component. One change would lower the data completeness threshold for fiscal year 2018 from 60% to 50%, the current threshold for fiscal year 2017, but would only provide one point for clinicians who report less than the 50% threshold, instead of the three

points that were previously awarded in such cases. The Proposed Rule also includes modifications to the quality measure scoring and methods of quality reporting, as well has the addition of new quality bonuses for improvements in quality from the previous year.

CMS also proposes changes to the other two components of the MIPS score – Advancing Care Initiatives and Improvement Activities – that are meant to add flexibility for clinicians.

On the Advanced APMs side, the proposed rule established the following criteria for determining whether an APM qualifies as an Advanced APM: (1) The APM must require participants to use certified electronic health records technology ("CEHRT"); (2) The APM must provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS and; (3) The APM must either require that participating APM entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model expanded under section 1115A(c) of the Social Security Act.

CMS also proposes some changes to the Advanced APMs that would remove or decrease certain regulatory barriers that might otherwise prevent participation. For example, for Advanced APMs that start or end during the Medicare Qualifying APM Participant ("QP") Performance Period and operate continuously for a minimum of 60 days during the Medicare QP Performance Period for the year, CMS is proposing to make QP determinations using payment or patient data only for the dates that APM Entities were able to participate in the Advanced APM per the terms of the Advanced APM, not for the full Medicare QP Performance Period. Additionally, CMS proposes to exempt practices who are participating in Round 1 of the Comprehensive Primary Care Plus from the practice size limit for application of the Medical Home Model financial risk standard.

The Proposed Rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-06-30/pdf/2017-13010.pdf.

CMS Report Shows $8.18 Billion Paid by Drug and Device Manufacturers to Providers in 2016

On June 30, 2017, the U.S. Department of Health & Human Services Centers for Medicare and Medicaid Services ("CMS") released a report of Open Payments data on transactions between drug and medical device manufacturers and physicians and teaching hospitals in 2016. The report indicates that a total of $8.18 billion was paid by drug and device manufacturers in 2016, including approximately $4.36 billion in research payments and $1 billion in ownership or investment interest. Of the 11.3 million transaction records reported, only approximately 657,000 were for research payments and 3,640 were for ownership or investment interest. The report indicates that 1,481 total companies made payments to 631,000 physicians and 1,146 teaching hospitals.

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 for things like travel, research, gifts, speaking fees, and meals. It also includes ownership interests that physicians or their immediate family members have in these companies. This data is then made available to the public each year.

The Open Payments report for 2016 is available at https://openpaymentsdata.cms.gov/summary.

Fifth Circuit Finds Government's Use of Sampling and Extrapolation in Determination of Medicare Overpayment Proper

On June 22, 2017, the Court of Appeals for the Fifth Circuit issued a decision in Maxmed Healthcare, Inc. v. Price, No. 16-50398, finding that the sampling and extrapolation utilized by a contractor for the U.S. Department of Health & Human Services ("HHS") in determining the amount of a Medicare overpayment was proper. The Plaintiff in the case – Maxmed Healthcare, Inc. ("Maxmed"), home health agency that provides home health services to Medicare beneficiaries – challenged the use of extrapolation on the basis that the contractor did not properly document the random numbers used to generate the sample and failed to obtain a sufficiently independent sample of claims.

The Court noted that the Medicare Program Integrity Manual ("MPIM") requires that "[a] record shall be kept of the random numbers actually used in the sample and how they were selected." However, the Court ultimately found that any failure of the HHS contractor to comply with this provision did not invalidate the sampling, because the MPIN also provides that a contractor's failure "to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment." Instead, "[a]n appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted." The Court thus found that Maxmed's argument is inconsistent with the MPIM.

Maxmed's second argument was that the sampling in the case was fatally dependent because the same Medicare beneficiary could have multiple claims or claim lines in the sample. While the Court noted that the ALJ who heard the case agreed with an expert that using multiple claims for one beneficiary in the sample rendered the sampling units not independent, the Court ultimately found that the MPIM does not actually have a strict "independent" requirement, and that it expressly permits a sample to include multiple claims or claim lines from the same beneficiary. The Court therefore held that any lack of independence in the sampling was not fatal.

Finally, Maxmed made a third argument that the use of extrapolation violates the "Rule of Thumb" included in the Medicare Benefit Policy Manual ("MBPM") that a "determination of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs," because extrapolation is not based on an assessment of each beneficiary's individual care needs. The Court found that the Rule of Thumb provided in the MBPM applies to prepayment review of claims, not to post-payment audits of providers, as was the situation at issue.

The Court's decision is available at: http://www.ca5.uscourts.gov/opinions/pub/16/16-50398-CV0.pdf.

CMS Issues Proposed Changes to Outpatient Prospective Payment System

On July 13, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule on the Calendar Year ("CY") 2018 Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgical Center ("ASC") Payment System. The proposed rule includes increases the 2018 OPPS rates by 1.75 percent and would increase ASC payments by 1.9 percent.

One of the major proposed policy changes in the proposed rule is to the 340B discount drug program ("340B Program"). In what is being characterized as an effort to combat rising drug prices, CMS proposes to pay hospitals for discounted drugs purchased through the 340B Program at the average sales price ("ASP")

minus 22.5 percent, rather than ASP plus 6 percent, which is what it pays currently. CMS intends for this move to more closely align CMS payments with the prices at which eligible hospitals obtain discounted drugs through the 340B Program.

CMS' proposal to cut payments under the 340B Program has drawn criticism from 340B participating hospitals. 340B Health, a coalition of hospitals who purchase discounted drugs through the 340B Program, released a statement in opposition to the proposed rule, which cited a past survey of 340B Health members that found that "roughly 60 percent of hospitals would be likely or very likely to withdraw from 340B as a result of a payment cut that would take away all of their 340B savings on Part B drugs, which appears close to what CMS proposed." HHS Secretary Tom Price, however, maintains that the proposed change is "a significant step toward fulfilling President Trump's promise to address rising drug prices."

The proposed rule also includes other policy changes, including: reinstating the non-enforcement of direct supervision enforcement instructions for outpatient therapeutic services for CAHs and small rural hospitals; conditionally packaging payment for low-cost drug administration services into payment for primary services; removing total knee arthroplasty from the inpatient-only list; and removing six measures from the Hospital Outpatient Quality Reporting Program.

The proposed rule can be found at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-14883.pdf.

A CMS fact sheet on the proposed rule can be found at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13.html.

OIG: Reduction of Cost-Sharing for Certain Financially Needy Study Participants Does Not Trigger Penalties

On July 7, 2017, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") issued Advisory Opinion No. 17-02, in which it stated that a hospital outpatient facility's reduction or waiver of cost-sharing for financially-needy patients participating in a clinical research study would not trigger civil monetary penalties ("CMPs"). Although OIG stated that the cost-sharing reduction would implicate the beneficiary inducement CMP and the anti-kickback statute, it would nonetheless be unlikely to impose any penalties for a number of reasons. First, the requestors certified that the cost-sharing reduction would not be offered as part of any advertisement or solicitation for participation in the study, and participants would only be informed of potential cost-sharing reduction if they indicated that they lacked the financial resources to participate in the study. Second, the cost-sharing reductions would not be made routinely, but rather would be made using a financial need application process substantiated through required documentation. Finally, the facility would be making a need-based determination of which participants would receive cost-sharing reduction based on the potential participant's family income level as measured against certain percentages of the Federal Poverty Level. OIG therefore concluded that the proposal to offer cost-sharing reductions for certain financially needy participants satisfied the cost-sharing reduction exception to the beneficiary inducement CMP and would not trigger any penalties.

The Advisory Opinion can be read here: https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-02.pdf.

CMS Delays Home Health CoP Rule for Six Months

On July 10, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services issued a final rule delaying for six months the effective date of new conditions of participation ("CoPs") for home health agencies ("HHAs"). The new CoPs were published in a final rule in January, with an original effective date of July 13, 2017. The new effective date will be January 13, 2018. The delay comes in response to statements from HHAs that implementing the revised CoPs would take longer than the six months originally provided.

The final rule included a comprehensive patient rights CoP, an expanded comprehensive patient assessment requirement, requirements for communications with patients, and an expanded patient care coordination requirement that makes a licensed clinician responsible for all patient care services.

The final rule delaying the implementation can be found at: https://www.gpo.gov/fdsys/pkg/FR-2017-07-10/pdf/2017-14347.pdf.

The January 13 final rule can be found at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-13/pdf/2017-00283.pdf.

OIG Issues Report on Opioid Prescribing in Medicare Part D

In its recent data brief – Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing – the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") shared statistics about opioid prescribing to Medicare Part D beneficiaries. The data brief reports that one in three Medicare Part D beneficiaries received a prescription opioid in 2016 and that about 500,000 beneficiaries received high amounts of opioids. Almost 90,000 beneficiaries are at serious risk; some received extreme amounts of opioids, while others appeared to be doctor shopping. About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk.

The data brief provided various approaches being taken by OIG to combat questionable opioid prescribing in Part D, including educating providers and partnering with federal, state and local law enforcement to follow up on providers with questionable prescribing histories.

The fact brief is available at: https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.

Proposed Rule Boosts Medicare Physician Payments, Aims to Reduce Provider Burdens

On July 13, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule updating the Medicare Physician Fee Schedule ("PFS") for calendar year 2018. The proposed rule increases the PFS by 0.31 percent, which reflects the 0.50 percent update established under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, reduced by 0.19 percent, due to the misvalued code target recapture amount. The proposed rule also reduces by 50 percent the PFS payment rates for certain items and services furnished by certain off-campus hospital outpatient provider-based departments. CMS also proposes to add several codes to the list of telehealth services and to eliminate the required reporting of the telehealth modifier for professional claims in an effort to reduce administrative burden for practitioners.

The proposed rule also includes changes and updates concerning malpractice relative value units, care management services, office-based behavioral health services, payment for care coordination services provided by rural health clinics and federally-qualified health centers, the Medicare Diabetes Prevention

Program, the Physician Quality Reporting System, and more. The proposed rule also solicits comments on updating the evaluation and management visit codes, revaluing emergency department visits, the initial data collection and reporting periods for the Clinical Laboratory Fee Schedule, and payment for biosimilar biological products under Part B.

The proposed rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-14639.pdf.

CMS' fact sheet on the proposed rule is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13-2.html.

New Items Added to 2017 OIG Work Plan

On July 17, and again on August 15, the Department of Health and Human Services Office of Inspector General (OIG) added a number of action items to its November 10, 2017 work plan, a process the OIG previously announced it would do on a monthly basis in an effort to improve transparency. New items include the following:

- Medicare Part B payments for Ambulance Services Subject to Part A Skilled Nursing Facility Consolidated Billing Requirements
- Health and Safety Standards in Social Services for Adults
- Duplicate Drug Claims for Hospice beneficiaries
- Controls Over Opioid Treatment Programs
- Medicare Part B Payments for Psychotherapy Services
- Review of Medicare Payments for Telehealth Services

The complete list of active work plan items can be found on the OIG's website here: https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp

CMS Issues Proposed Rule Implementing Required Cuts to Medicaid DSH Allotments

On July 28, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") issued a proposal rule to implement the requirement in the Affordable Care Act to reduce the amount of Disproportionate Share Hospital ("DSH") allotments. The reductions were initially meant to take place from fiscal year 2014 through 2020, but the implementation was delayed until fiscal year 2018; the reductions will continue through fiscal year 2025. The proposed rule delineates the DSH Health Reform Methodology ("DHRM") to implement annual Medicaid allotment reductions identified in the statute. Taking the statutorily specified factors into account for each state, the proposed DHRM would generate a state-specific DSH allotment reduction amount for each fiscal year specified in statute. The total of all DSH allotment reduction amounts in a specific year would equal the aggregate annual reduction amount identified in statute for that same year. To determine the effective annual DSH allotment for each state, the state-specific annual DSH allotment reduction amount would be applied to the unreduced DSH allotment amount for its respective state.

The proposed rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-07-28/pdf/2017-15962.pdf.

American Hospital Association Urges CMS to Delay Implementation of FY 2018 DSH Allotment Reductions

In an August 23 comment letter to the Administrator of the Centers for Medicare & Medicaid Services (CMS), the American Hospital Association (AHA) advocated for the repeal of the Affordable Care Act (ACA) Medicaid Disproportionate Share Hospital (DSH) allotment reductions. Additionally, citing "significant concerns with the underlying data CMS proposes to use in the DSH Health Reform Methodology (DHRM)," the AHA urged CMS to delay the implementation DSH allotment reductions for fiscal year 2018. The AHA's principal argument for the delay is that "the key components of the DHRM, such as the assessment of how well states target DSH payment sand the determination of the base allotment amount, would be based on data that is not only old and incomplete but largely unavailable to the public." Medicaid DSH payments were cut in the ACA because it was anticipated that hospitals would care for fewer uninsured patients. However, as explained by the hospitals in the letter, "the projected increase in coverage has not been fully realized due to the choice by some states not to expand Medicaid, as well as lower-than anticipated enrollment in coverage through the Health Insurance Marketplaces." Under the ACA, the DSH reductions were originally set to begin in 2014 and continue through 2020. After numerous delays, the reductions are currently set to run from 2018 through 2025.

OCR Unveils New HIPAA Breach Reporting Tool

On July 25, 2017, the U.S. Department of Health and Human Services Office for Civil Rights ("OCR") unveiled a revised Health Insurance Portability and Accountability Act ("HIPAA") Breach Reporting Tool ("HBRT"). The HBRT makes public certain breach information that is required to reported to OCR by covered entities, including the entity's name and location, the number of individuals affected, the type of breach, and the location of the breach. The HBRT allows the public to see recently reported breaches and all breaches under investigation by OCR.

The HBRT is located at: https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf.

D.C. Circuit: Medicare Act Requires Notice-and-Comment Rulemaking for DSH Payment Calculation Rule

On July 25, 2017, in *Allied Health Services v. Price*, the Court of Appeals for the D.C. Circuit found that the U.S. Department of Health and Human Services ("HHS") was required to engage in notice-and-comment rulemaking before deciding to include Medicare Part C days in the Medicare fractions of the disproportionate share hospital ("DSH") payment calculations. In calculating the DSH payments for 2012, HHS announced a policy of including in the calculation patient days attributable to individuals enrolled in Medicare Part C, which would generally result in lower payments to hospitals. This policy was based on the interpretation of the language in the Medicare Act that the Medicare fraction of the DSH payments must incorporate patient days for patients "entitled to benefits under Part A"; HHS interpreted this to include patients enrolled in Part C, as they are still technically eligible under Part A.

The patients in *Allied Health Services v. Price* challenged HHS' implementation of this policy, arguing that the DSH calculations violated the notice-and-comment requirements of the Administrative Procedures Act ("APA") and the Medicare Act. In August of 2016, the United States District Court for the District of Columbia granted summary judgment for HHS, holding that the change in DSH payment calculations was an interpretive rule and therefore HHS was not required to engage in notice-and-comment rulemaking under the APA. The D.C. Circuit Court found, however, that the Medicare Act does not include the APA's exemption from notice-and-comment rulemaking for interpretive rules, and therefore HHS was required to engage in notice-and-comment rulemaking in order to implement this change in policy, regardless of whether it is an

interpretive rule. The D.C. Circuit Court's decision conflicts with the holdings of other circuits, including the First Circuit.

The court's decision is available at: https://www.cadc.uscourts.gov/internet/opinions.nsf/9CD9559D6E45E7EE85258168004F715E/$file/16-5255.pdf.

CMS Published Proposed Rule Regarding Changes to HHA Payments

On July 28, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a proposed rule concerning the home health agency ("HHA") prospective payment system ("PPS"). The proposed rule includes a change in the HHA payment update percentage to align with the requirements of the Medicare Access and CHIP Reauthorization Act ("MACRA"). Under the proposed rule, the percentage for calendar year 2018 will be 1% for those HHAs that submit the required quality data for the Home Health Quality Reporting Program, and -1% for those HHA that do not submit data.

The proposed rule includes a 0.97 percent reduction to the national, standardized 60-day episode rate in 2018 to account for nominal case-mix growth from 2012 to 2014, resulting in an estimated decrease in PPS payments for 2018 of -0.9%. 2018 will be the third year of the three-year phase-in of the reduction to account for nominal case-mix growth.

Also included in the proposed rule are adjustments to the case-mix methodology, including a change in the unit of payment from 60-day episodes of care to 30-day periods of care, to be implemented for 30-day periods of care beginning on or after January 1, 2019. The proposed case-mix methodology refinements – called the home health groupings model ("HHGM") – rely more heavily on clinical characteristics and other patient information to place 30-day periods of care into meaningful payment categories. The proposed HHGM includes changes to the episode timing categories, the addition of an admission source category, the creation of six clinical groups used to categorize 30-day periods of care based on the patient's primary reason for home health care, revised functional levels and corresponding OASIS items, the addition of a comorbidity adjustment, and a proposed change in the Low-Utilization Payment Adjustment threshold.

Immediately following the release of the unpublished proposed rule on July 25, the Partnership for Quality Home Healthcare ("Partnership") issued a statement urging CMS to work collaboratively with HHAs to refine the HHGM, which the Partnership says would "dramatically alter[] Medicare payments for skilled home health services." Keith Myers, Chairman of the Partnership, noted that the HHGM represents a "major reform to home health reimbursement" and stated that "We question whether CMS has the unilateral authority to make such a proposed change without action by Congress." The Partnership plans to release an analysis of the impacts of the proposed HHGM.

The proposed rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-07-28/pdf/2017-15825.pdf.

A CMS fact sheet on the proposed rule is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-25.html.

The statement by the Partnership for Quality Home Healthcare is available at: http://homehealth4america.org/media-center/390.

CMS Published Final Rule on Medicare Payments to IPPS Hospitals

On August 14, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a final rule on payments to hospitals under the inpatient prospective payment system ("IPPS").

Under the final rule, IPPS payments will increase by approximately $2.4 billion in 2018, which is less than the $3.1 billion that was anticipated in the proposed rule on this issue that was released in April. This increase includes a 1.2% increase in operating payment rates to general acute care hospitals that successfully participate in the Hospital Inpatient Quality Reporting ("IQR") Program and are meaningful electronic health record users, as well as the projected hospital market basket update of 2.7% adjusted by a -0.6 percentage point required for productivity, -0.6% adjustment to remove the one-time adjustment of 0.6% made in FY 2017 for the FYs 2014–2016 effect of the adjustment to offset the estimated costs of the two midnight policy, a +0.4588 percentage point adjustment required by the 21st Century Cures Act, and the -0.75 percentage point adjustment to the update required by the Affordable Care Act.

The final rule also includes the distribution of approximately $6.8 billion in uncompensated care payments in 2018, up from approximately $6 billion in 2017. The final rule also finalizes CMS' earlier proposal to begin incorporating uncompensated care cost data from Worksheet S-10 of the Medicare cost report in the methodology for distributing these funds. Specifically, for FY 2018, CMS will use Worksheet S-10 data from FY 2014 cost reports in combination with Medicare and Medicaid low income days data from the two preceding cost reporting periods to determine the distribution of uncompensated care payments.

In addition to updating payments to acute care hospitals, the final rule also increases the PPS payment rate to long-term care hospitals ("LTCHs") by 1%. However, as a result of other changes in the final rule, including the continued phase-in of the dual payment system, CMS expects that PPS payments to LTCHs will decrease by approximately 2.4%, or $110 million, in fiscal year 2018. In addition to this payment update, the final rule also imposes a one-year moratorium on the implementation of the 25% threshold policy for fiscal year 2018 while it conducts an evaluation of whether the threshold is still needed.

In the final rule, CMS implements changes to the payment adjustment factor for the Hospital Readmissions Reduction Program, in accordance with the 21st Century Cures Act. CMS will assess penalties based on a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and full-benefit Medicaid. CMS also specifies the applicable time period and the methodology for the calculation of aggregate payments for excess readmissions for fiscal year 2018 and updates the program's Extraordinary Circumstance Exception policy.

In addition to the above, the final rule also includes important updates or changes to various other programs and areas, including: changes to instructions for the review of the critical access hospital 96-hour certification requirement; hospital-acquired conditions reduction program; electronic health record incentive programs for eligible hospitals; and the Hospital Inpatient Quality Reporting (IQR) Program.

The final rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-05-03/pdf/2017-08428.pdf.

CMS' fact sheet on the final rule is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-08-02.html.

New DOJ Unit to Focus on Combatting Opioid Fraud

On August 2, 2017, U.S. Attorney General Jeff Sessions announced that the U.S. Department of Justice ("DOJ") will be launching the Opioid Fraud and Abuse Detection Unit, which will focus on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to this prescription opioid epidemic. The Unit will consist of twelve Assistant United States Attorneys from twelve districts who will serve three year terms and will focus solely on investigating and prosecuting health care fraud related to prescription opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes. The District of New Hampshire is not one of the twelve districts chosen to participate in the program.

A DOJ press release on the Opioid Fraud and Abuse Detection Unit is available at: https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit.

CMS Published Final Rule on Medicare Payments to IRFs for 2018

On August 3, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a final rule concerning payments to inpatient rehabilitation facilities ("IRFs"). The final rule includes a 0.9% increase factor in Prospective Payment System ("PPS") payment rates, reflecting a 1.0% statutory increase and a 0.1% decrease due to updating the outlier threshold. The 0.9% increase will increase payments by $75 million. Under the final rule, CMS will continue to maintain the facility-level adjustment factors at current levels as it continues to monitor the most current IRF claims data available to assess the effects of the changes made in fiscal year 2014.

In addition to payment updates, the final rule also includes some other changes relevant to IRFs. CMS has finalized the removal of the 25% payment penalty to IRF patient assessment instrument submissions that are not timely transmitted to its data repository. Additionally, following a comprehensive analysis of the presumptive methodology lists in ICD-10-CM, CMS is refining these lists to ensure that they accurately reflect the types of patients that should count presumptively toward the 60 percent rule, by: counting certain ICD-10-CM diagnosis codes for patients with traumatic brain injury and hip fracture conditions; and revising the presumptive methodology list for major multiple trauma by counting IRF cases that contain two or more of the ICD-10-CM codes from three major multiple trauma lists in the specified combinations. Finally, the final rule also includes important changes to the IRF Quality Reporting Program concerning an update to the current pressure ulcer measure and the removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from IRFs.

The final rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-08-03/pdf/2017-16291.pdf.

CMS' fact sheet on the final rule is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-31-2.html.

CMS Published Final Rule on Medicare Payments to SNFs

On August 4, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a final rule concerning Medicare payments to skilled nursing facilities ("SNFs"). In the final rule, CMS finalized the statutory 1.0% market basket increase, and expects that this will result in an increase in aggregate payments to SNFs of $370 million, which is $20 million less than what CMS had initially projected in the proposed rule it published in April.

The final rule also makes changes to the SNF Quality Reporting Program, including updating the current pressure ulcer measure and adopting four new measures that address functional status beginning with the 2020 program year. The final rule also states that CMS will begin reporting six new measures for display by the fall of 2018.

The final rule includes some scoring and operational updates to the SNF Value-Based Purchasing Program, performance and baseline periods for the FY 2020 Program year, updated values for performance standards for FY 2020, additional details for the Review and Correction process for SNFs' performance information to be made public on Nursing Home Compare, and a revision to the previously-adopted rounding policy for SNF performance scores.

The final rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-08-04/pdf/2017-16256.pdf.

CMS' fact sheet for the final rule is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-31.html.

CMS Published Final Rule Concerning Medicare Payments to Hospices

On August 1, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a final rule concerning Medicare payments to hospices serving Medicare beneficiaries. In accordance with the Medicare Access and CHIP Reauthorization Act of 2015, payments to hospices will increase by 1.0% in 2018 for an aggregate increase of $180 million. In accordance with the Improving Medicare Post-Acute Care Transformation Act of 2014, the cap on aggregate annual payments to a hospice will also increase by 1.0%, resulting in an aggregate cap of $28,689 in 2018.

The final rule also adopts certain measures of the Hospice CAHPS Experience of Care Survey, which is a part of the Hospital Quality Reporting Program ("HQRP"), including two global measures and six composite survey-based measures. According to CMS, "Hospice CAHPS® is important for the hospice community because the results of the survey allow comparisons among hospices nationally," which CMS believes "will help beneficiaries and their families select a hospice program." To that end, the final rule announces that CMS will begin publicly reporting hospice quality reporting program data via a Hospice Compare Site in August 2017 to help customers make informed choices. While the HQRP includes both the Hospice Item Set ("HIS") and Hospice CAHPS® Survey data, this new website will initially display only HIS data. The public display of the Hospice CAHPS® Survey data will be added in winter 2018.

The final rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-08-04/pdf/2017-16294.pdf.

CMS' fact sheet for the final rule is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-08-01.html.

CMS Projects that Medicare Part D Premiums Will Decrease in 2018

On July 31, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") issued a memorandum announcing that the average basic premium for a Medicare Part D prescription drug plan in 2018 is projected to decline to an estimated $33.50 per month, representing a decrease of approximately $1.20 from the actual average premium in 2017. CMS notes that this decrease comes despite the fact that spending for the Part D program continues to increase faster than

spending for other parts of Medicare. The projection for the average premium for 2018 is based on bids submitted by drug plans for basic drug coverage for the 2018 benefit year and calculated by the independent CMS Office of the Actuary.

The memorandum is available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2018.pdf.

CMS' press release concerning the memorandum and the Part D premiums is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-08-02-3.html.

IPFs to See $45 Million Medicare Bump in 2018

On August 7, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a notice in the Federal Register concerning Medicare payments and policy updates for inpatient psychiatric facilities ("IPFs"). The notice contains proposed updates to IPF payments, including an increase in payments by 0.99% or $45 million in 2018. This increase reflects a 2.6% market basket update reduced by the productivity adjustment of 0.6%, a statutory reduction of 0.75%, and a reduction of 0.26% due to an update to the outlier fixed-dollar threshold amount. CMS seeks comments on the proposed changes on or before October 6, 2017.

The notice is available at https://www.gpo.gov/fdsys/pkg/FR-2017-08-07/pdf/2017-16430.pdf.

CMS' fact sheet for the notice is available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-08-02-2.html.

Government Found Liable for Risk Corridors Payments

On August 4, a U.S. Federal Claims Court found the government liable to pay Molina Healthcare of California Inc. full risk corridors program payments totaling over $52 million for the years 2014 and 2015. Judge Thomas C. Wheeler found that the Affordable Care Act (ACA) requires full annual payment to insurers under the risk corridors program. Section 1342 of the ACA established the temporary risk corridors program for sharing in insurers' gains or losses that result from inaccurate rate setting from 2014 through 2016 between the federal government and qualified health plans. In October 2015, the Centers for Medicare and Medicaid Services announced that it would only pay 12.6% of the $2.87 billion in risk corridor payments requested by insurers. In this case, the government attempted to argue that the risk corridors program was "budget neutral" was unsuccessful, with the Court concluding that Congress did not expressly intend that it be so in either the ACA or the appropriations riders. There has been disagreement on this issue within the Federal Claims Court, with a judge in *Maine Community Health Options v. United States* (Fed. Cl. July 31, 2017) holding that the risk corridor program was "budget neutral."

The Court's opinion may be read in full here: https://ecf.cofc.uscourts.gov/cgi-bin/show_public_doc?2017cv0097-25-0

Hospice Compare Website Now Available

On August 16, the Centers for Medicare & Medicaid Services released its Hospice Compare website. The website provides a tool for patients, family members, caregivers, and healthcare providers to compare hospice providers based on quality of care. Quality metrics include the percentage of patients that were

screened for pain or uncomfortable breathing, and whether patients' preferences were being met. In a press release, CMS promoted the website, stating "[b]y ensuring patients have the information they need to understand their options, CMS is helping individuals make informed healthcare decisions for themselves and their families based on objective measures of quality."

The Hospice Compare website can be accessed here: https://www.medicare.gov/hospicecompare/

CMS Announces Targeted Probe and Educate Medical Review Strategy

On August 14, the Centers for Medicare & Medicaid Services (CMS) announced it Medicare Administrative Contractors (MACs) would focus on specific providers/suppliers within a service rather than all providers/suppliers billing a particular service when performing medical review. CMS refers to this strategy as a "Targeted Probe and Educate" or "TPE" explaining that is a way to improve on a process that can be burdensome to providers. TPE involves review of 20-40 claims per provider, per item or service, per round, for a total of up to three rounds of review. Each round of 20-40 claims is a "probe". Once a probe is finished, providers are offered individualized one-on-one education based on their review results. Providers with moderate and high error rates in the first probe will continue on to a second round of 20-40 reviews, followed again by provider-specific education, and followed again by a third and final round if the second round reveals high error rates. Providers/suppliers with continued high error rates after three rounds of TPE may be referred to CMS for 100% prepay review, extrapolation, referral to a Recovery Auditor, or other action. Conversely, providers/suppliers may be removed from TPE if they demonstrate low error rates or sufficient improvement in error rates.

IRS Revokes Tax Exempt Status of Small, Rural Hospital

In February 2017, the Internal Revenue Service (IRS) revoked the 501(c)(3) tax-exempt status of a non-profit hospital for failure to comply with the requirements of 501(r) under the Affordable Care Act (ACA). The IRS cited that the hospital, described by the IRS as a "small, rural facility," failed to complete and adopt an implementation strategy for its community health needs assessment (CHNA) and that it failed to make the CHNA available to the public. The IRS called the hospital's failures "egregious" and "willful." During the audit process, the hospital acknowledged it did not have the "will, financial resources, nor the staff to follow through with the CHNA process required under section 501(r) on a triannual basis." The hospital, although its name was redacted in the Final Adverse Determination Letter posted to the IRS website, is operated by a local county governmental agency and is designated as a "critical access hospital" for Medicare. Prior to this revocation, enforcement of Section 501(r) has been the imposition of a $50,000 excise tax.

OIG Issues Advisory Opinion Approving Pharmaceutical Manufacturer's Plan for Free Replacements of Spoiled Products

On August 25, 2017, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") published Advisory Opinion 17-03 concerning a pharmaceutical manufacturer's proposal to replace products that require specialized handling that could not be administered to patients for certain reasons, at no additional charge to the purchaser. The pharmaceutical manufacturer manufactures certain biological and other products that are sensitive to temperature changes, direct sunlight, or movement, and may require reconstitution in a controlled environment. To ensure quality and patient safety, the products' labeling includes limitations on the amount of time that may elapse between when a product is reconstituted and when it is administered to a patient, as waiting too long can result in product spoilage. Under the proposed arrangement, the manufacturer would replace spoiled products at no charge, as long as they were not administered to patients and became spoiled because of one or more specific events or conditions. The

proposed arrangement is limited to replacement of the spoiled products; providers could not receive credit for spoiled products or replacement for free samples.

After first determining that the proposed arrangement would not fit into the safe harbor for warranties, OIG concluded that the proposed arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute for the following reasons: replacement would be restricted to certain unintentional, unplanned circumstances, and could increase patient safety and quality of care; the risk is low that the proposed arrangement would lead to increased costs or overutilization, because it would only apply to products that customers already selected and intended to use but did not administer or bill for, and so would not result in overutilization; the proposed arrangement would only cover individual claims for spoiled products, not large losses, and would have a minimal effect on competition; and the proposed arrangement would bear some similarity to an insurance policy, the cost of which the manufacturer certified would be bundled into the price of the products.

The advisory opinion is available at:
https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf.

OIG Issues Advisory Opinion Approving Preferred Hospital Networks for Medigap Policies

On August 31, 2017, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") published Advisory Opinion No. 17-04 concerning the use of a "preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies. Under the proposed arrangement, a group of offerors of Medigap policies ("Requestors") entered into an agreement with a preferred hospital organization ("PHO") which has contracts with hospitals throughout the country ("Network Hospitals"). The Network Hospitals provide discounts of up to 100% of the Medicare Part A inpatient deductible for Requestors' Medigap policyholders that would otherwise be payable by the Requestors. Each time Requestors receive this discount from a Network Hospital, Requestors pay the PHO a fee for administrative services. The PHO's hospital network is open to any accredited, Medicare certified hospital that meets the requirements of applicable state laws and that contractually agrees to discount all or a portion of the Part A deductible for Medigap policies. Requestors certified that the Policyholders' physicians and surgeons do not receive any remuneration under the Arrangement in return for referring patients to a Network Hospital.

After first determining that the proposed arrangement did not fit into either the safe harbor waivers of beneficiary coinsurance and deductible amounts, or the safe harbor for reduced premium amounts offered by health plans, OIG concluded that the proposed arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute for the follow reasons: neither the discounts nor the premium credits increase or affect per-service Medicare payments; the arrangement is unlikely to increase utilization, since the discounts are effectively invisible to policyholders, because they apply only to the portion of the individual's cost-sharing obligations that the individual's supplemental insurance otherwise would cover; the arrangement does not unfairly affect competition among hospitals, because membership in the PHO's hospital network is open to any accredited, Medicare-certified hospital that meets the requirements of applicable state laws; the arrangement is unlikely to affect professional medical judgment, because the Policyholders' physicians and surgeons receive no remuneration, and the Policyholders remain free to go to any hospital without incurring any additional out-of-pocket expense for their inpatient hospital stay; and the arrangement operates transparently Requestors make clear that policyholders have the freedom to choose any hospital without incurring additional liability or a penalty.

The advisory opinion is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-04.pdf.

OIG Finds that SNFs Are Failing to Report Abuse and Neglect of Residents

On August 24, 2017, the U.S. Department of Health and Human Services ("HHS") Office of the Inspector General ("OIG") issued a memorandum to the Centers for Medicare & Medicaid Services ("CMS") alerting it of the preliminary results of OIG's ongoing review of potential abuse or neglect of Medicare beneficiaries in skilled nursing facilities ("SNFs"). OIG states in the memorandum that its review has so far identified 134 Medicare beneficiaries in 33 different states whose injuries may have been the result of potential abuse or neglect that occurred in 2015 and 2016. Of these incidents, OIG states that up to 15% were not reported to the appropriate state agencies, and up to 28% were not reported to law enforcement agencies, despite state mandatory reporting laws.

OIG identified certain CMS failures that may be contributing to the lack of reporting of abuse and neglect of Medicare beneficiaries in SNFs. OIG determined that CMS does not match Medicare claims for reimbursement of emergency room visits with claims for reimbursement of SNF services to identify instances of potential abuse or neglect, and suggested that CMS take immediate action to implement procedures to compare these claims. OIG also determined that CMS has not taken any enforcement action under Section 1150B of the Social Security Act (42 U.S.C. § 1320b-25), although it notes CMS' position that it has not yet been granted authority to enforce Section 1150B. OIG suggests that CMS work with the HHS Office of the Secretary to obtain enforcement authority so that it may enforce Section 1150B relative to penalties for failing to report abuse and neglect of beneficiaries at SNFs.

OIG's memorandum is available at: https://oig.hhs.gov/oas/reports/region1/11700504.pdf.

Congressional GOP Effort to Repeal or Replace ACA Fails in Senate; Path Forward Unclear

Following the successful passage of the American Health Care Act ("AHCA") – the House GOP bill to repeal and replace parts of the Affordable Care Act ("ACA") – in the House of Representatives on May 4, the Senate next took up the issue in June. On June 22, the Senate GOP unveiled the Better Care Reconciliation Act of 2017 ("BCRA"), which, like the AHCA, would make cuts to Medicaid funding and repeal certain ACA consumer protections.

Almost as soon as the bill was announced, Democrats and Republicans alike spoke out against it. A handful of Republicans came out against the bill over their belief that it did not go far enough to repeal the ACA. Democrats and some moderate Republicans opposed the bill's significant cuts to Medicaid. Following the release of a score by the Congressional Budget Office indicating that the bill would result in 22 million individuals losing coverage over ten years, Senate leadership was forced to postpone a procedural vote due to concerns that the Republicans did not have enough votes to pass the bill.

Following the increased opposition to the BCRA after the release of the CBO score, Senate Republicans revised the bill in early July in an effort to gain additional support of moderate Republicans. The changes included additional funding to address rising premiums, an option for individuals to purchase low-cost, fewer benefit plans, additional funding to combat the ongoing opioid epidemic, and the retention of certain ACA taxes on high earners. While the revised plan was able to move the needle slightly within the Republican party, opposition from stakeholders and interest groups continued to mount.

The repeal and replace effort collapsed on July 17 when two conservative GOP senators announced that they could not support the BCRA because they felt it did not go far enough in repealing the ACA. On July 18, Sen. Mitch McConnell announced plans to pursue a straight repeal of the ACA rather than a repeal and immediate replacement. On July 19, the Senate Budget Committee released a draft of the Obamacare Repeal Reconciliation Act of 2017 ("ORRA"), which was almost identical to a similar bill passed by both houses and vetoed by President Obama in 2015. On the same day, the CBO updated their previous score of the 2015 bill to show that the 2017 version would result in an additional 32 million uninsured Americans.

On July 25, the Senate held votes on both the BCRA and the ORRA. The first was rejected, but the motion to begin debate on the ORRA passed. However, the repeal effort ultimately failed days later on July 28 when the Senate rejected Sen. McConnell's last-minute "skinny repeal" bill. The bill's failure was primarily the result of "no" votes from GOP Senators McCain, Collins, and Lisa Murkowski. Following the failure of the skinny repeal bill, Senators from both parties called for bipartisan discussions on improving the existing framework under the ACA.

OIG Issues Advisory Opinion Approving Retail Pharmacy Membership Discount Program

On September 7, 2017 the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") published Advisory Opinion 17-05 in response to a retail pharmacy chain's proposal to allow Federal health care program beneficiaries to participate in a paid membership program that includes discounts on certain prescriptions and clinic services. Under the proposed arrangement addressed in the Advisory Opinion, the retail pharmacy chain – which offers retail pharmacy items and services as well as clinic services – would expand its current members-only benefits program to include Federal health care program beneficiaries, who previously have been excluded from the program. The benefit program would offer beneficiaries three categories of benefits: 1) access to discounts on the pharmacy's retail prices for specific items for which members pay entirely out-of-pocket; 2) access to a 10% discount on any clinic service when the member pays for the service entirely out-of-pocket; and 3) the ability to earn a 10% credit toward future eligible retail purchases when they purchase certain branded products and in-store photo-finishing.

OIG analyzed the proposed arrangement under the beneficiary inducements civil monetary penalty ("CMP") and the anti-kickback statute. OIG first concluded that the discount program would satisfy the "retailer rewards" exception to the beneficiary inducements CMP and OIG would therefore not impose any CMP. While there is no parallel exception to the anti-kickback statute, OIG did determine that the proposed discount program would pose a minimal risk of fraud and abuse and that OIG would not impose any sanctions. OIG's determination was based the following combined factors: 1) the proposed arrangement would not include any features to specifically steer beneficiaries to the retail pharmacies or clinics to purchase federally-reimbursable items or services; 2) the proposed arrangement would be unlikely to result in overutilization or otherwise increase costs to federal health care programs, in part because the discounts would only be available on items and services that are not reimbursable by any federal health care program, and the pharmacies would not submit any bills to any federal health care program; 3) membership in the discount program would be offered on equal terms to all customers over the age of 18; and 4) the offer or transfer of the rewards under the proposed arrangement would not be tied to the provision of other items or services reimbursed in whole or in part by any federal health care program.

The Advisory Opinion is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-05.pdf.

STATE DEVELOPMENTS

Minuteman Withdraws from NH Marketplace

On June 23, the NH Department of Insurance announced that Minuteman Health, Inc. will no longer sell insurance in New Hampshire effective January 18, 2018. Minuteman currently insures approximately 27,000 individual members. Executives for the company initially stated they were attempting to re-launch as a for-profit insurance company but later indicated that effort had failed.

Department of Insurance Seeks to Stabilize the Individual Insurance Marketplace and Reduce Rate Increases

Three insurance companies have confirmed that they will offer coverage through the marketplace in 2018 including, Anthem, Harvard Pilgrim and Ambetter. On August 1, 2017, the federal government published information indicating rate increases for individuals insured through the marketplace may increase more than 40% in 2018. On July 19, 2017, the Department of Insurance announced its plan to stabilize the individual insurance market and reduce rate increases. The plan includes creating a state-operated reinsurance program and filing a waiver application with the federal government to receive "pass-through" funding in the estimated amount of $8.2M equivalent to what the federal government will save as a result of the reinsurance program. The Department also proposed an assessment on all health insurance companies totaling over $36M, a plan that was later rejected by the NH Joint Legislative Committee on Administrative Rules. This rejection leaves the NH individual marketplace at significant risk.

NH Medicaid Expansion In Jeopardy Due to Hospital Donations

On July 25, CMS notified Jeffrey Meyers, the Commissioner of the NH Department of Health and Human Services of its concerns regarding the state's current arrangement of funding the non-federal share cost of the New Hampshire Medicaid expansion program (New Hampshire Health Protection Program) using donations from healthcare providers. Federal law governing the Medicaid program generally prohibits provider-related donations. A permissible provider donation is one that has no direct or indirect relationship to Medicaid payments made to the donating provider, provider class, or any related entity. CMS believes that under the current arrangement, "there is a relationship between the donations and Medicaid payments because Medicaid expansion is conditioned on the receipt of donations as articulated in New Hampshire legislation." Recognizing that this determination will significantly impact the NH Medicaid expansion program, CMS acknowledged the need for a transition period to allow New Hampshire to bring the State's non-federal share financing into compliance with federal law. It stated its expectation that such changes be made by the end of the next legislative session to be effective for the 2019 fiscal year. Failure to make such changes may result in financial consequences that would end the NH Medicaid expansion program which currently provides coverage for over 52,000 New Hampshire residents.

NH Seeks Federal Approval to Add Work Requirement to NH Health Protection Program

On August 30, the New Hampshire Department of Health and Human Services released a proposed amendment to the already approved CMS 1115 waiver seeking once again to add work requirements to the Medicaid expansion program. The proposal would require that those seeking coverage under the Medicaid expansion program show that they are employed, in training or in school,

with certain exceptions, such as for those caring for young children or those suffering from a temporary illness or injury. CMS rejected a similar proposal last year, but there is some expectation that the new administration will have a different perspective. On June 28, Governor Sununu signed into law House Bill 517 (a budget trailer bill), which includes a provision requiring DHHS to seek a waiver or plan amendment establishing work requirements. Public hearings on the proposal are scheduled for September 14 and September 21.

More information may be found at https://www.dhhs.nh.gov/media/pr/2017/09012017-nhhpp-work-reqs.htm.

State Develops Plan to Address the Due Process Rights of Mental Health Patients Held in Hospital Emergency Rooms

In a letter dated August 31, Jeffrey Meyers, Commissioner of the New Hampshire Department of Health and Human Services, outlined a plan to address the due process rights of mental health patients held in hospital emergency rooms. Currently, patients certified for involuntary admission to a psychiatric facility receive a hearing within three days after admission to the New Hampshire Hospital or another designated receiving facility. But with the current lack of available beds, patients are often held for days and even weeks in hospital emergency rooms without consent and without a hearing. Earlier this year, the legislature passed House Bill 400 requiring, among other things, that Commissioner Meyers submit a plan to address the problem by September 1. The plan, which was developed by the Commissioner in conjunction with the New Hampshire Hospital Association and other stakeholders, provides that patients being held at hospital emergency rooms for involuntary admission be provided a hearing within 72 hours. It provides for a 90 day pilot program starting November 1, 2017 at four hospitals (Dartmouth Hitchcock Medical Center, Southern NH Medical Center, Catholic Medical Center and Speare Memorial Hospital) before implementation becomes statewide. In order to comply with the due process requirements, hospitals will need to provide space for lawyers to meet with clients and a secure a video link to conduct hearings. The estimated cost of the program is nearly $1 million including the cost of a program coordinator, attorneys' fees, technical support and additional emergency room staffing.

Employers May Pay Employees Bi-weekly Without Prior Approval

Under a newly enacted law, New Hampshire employers may now opt to pay employees bi- weekly without seeking prior approval from the New Hampshire Department of Labor. Previously, employers were required to pay wages within eight days of the end of each work week unless they obtained prior written approval from the New Hampshire Department of Labor to pay less frequently. Under the new law, employers may pay employee wages weekly or bi-weekly without prior approval. Employers must still seek approval to pay employees less frequently than bi-weekly, however wages must may be paid at least monthly.

2017 Legislative Updates

HB 157: This bill adds moderate to severe chronic pain to the definition of qualifying medical conditions under therapeutic use of cannabis. **Status: Signed by the Governor effective August 15, 2017.**

HB 160: This bill adds post-traumatic stress disorder to the qualifying medical conditions under therapeutic use of cannabis. **Status: Signed by the Governor effective August 27, 2017.**

HB 208: This bill establishes a commission to study current mental health procedures for involuntary

commitment. **Status: Voted Out to Pass with Amendment by the House and Senate. Amendments changed the composition of the commission. The House concurred with the Senate amendment. Signed by the Governor effective partially on June 28, 2018 and partially on November 1, 2018**

HB 291: This bill removes veterinarians from the requirements of adopting rules for prescribing opioids and querying the controlled drug prescription health and safety program. **Status: Voted Ought to Pass with Amendment by the House and Senate. The Amendment changes the training/continuing education requirements for veterinarians. Signed by the Governor effective August 15, 2017.**

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: Voted Ought to Pass by the House. Senate Voted Ought to Pass with Amendment. The Amendment allows the State Office of Rural Health to receive and collect data regarding the surveys. The House concurred with the Amendment. Signed by the Governor effective June 16, 2017.**

HB 334: This bill exempts from licensure by the board of medical imaging and radiation therapy persons who perform sonography in certain circumstances. **Status: Voted Ought to Pass with Amendment by the House. Amendment changes the exemption to an exemption from licensure for any "person who is regulated in another profession [and] acting within the scope of that person's license, registration, or certification." Senate voted Ought to Pass with amendment. The amendment expands the Medical Imaging and Radiation Therapy Exemptions. The House concurred with the Senate Amendment. Signed by the Governor effective September 8, 2017**

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: Voted Ought to Pass with Amendment by the House; Voted Ought to Pass by Senate. The final amended bill states that nothing in RSA 141-C:20-a will require an immunization or vaccine requirement for diseases that are noncommunicable. Signed by the Governor effective August 15, 2017.**

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: Voted Ought to Pass by the House. Voted Ought to Pass in the Senate with a provision repealing the prohibition on May 1, 2018. The House concurred with the Senate amendment. Passed into law without signature, partially effective July 11, 2017; partially effective May 1, 2018.**

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: Voted Ought to Pass by the House; Voted Ought to Pass with Amendment by the Senate. The Senate clarified the language of the Bill. The House concurred with the Senate amendment. Signed by the Governor effective September 8, 2017.**

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: Voted Ought to Pass by the House. Voted Ought to Pass with Amendment in the Senate. The amendments are substantial and include expanding the types of vaccines that can be administered by pharmacists and adds provisions to the insurance**

regulations concerning federal health care reform and repeals these same provisions on July 1, 2020. The House concurred with the Senate amendments. Signed by the Governor. Partially effective July 10, 2017 with various sections becoming effective later. Bill repeals on July 1, 2020.

HB 511: This bill establishes a commission to study creating a public health oversight program within the department of health and human services. **Status: Voted Ought to Pass with Amendments by both the House and the Senate. Amendments change the size and scope of commission to study environmentally-triggered chronic illness. House concurred with Senate amendments. Signed by the Governor. Partially effective June 28, 2017; Repeals on November 1, 2018.**

HB 575-FN: This bill allows the board of acupuncture to certify individuals as acupuncture detoxification specialists. **Status: House voted Ought to Pass with Amendment. Amendment clarifies requirements for board certification. Senate voted Ought to Pass with Amendment. The amendment adds additional certification requirements. The House voted to nonconcur with the Senate amendment and went to a Committee of Conference which agreed to adopt the Bill as amended by the House. Signed by the Governor effective July 1, 2017.**

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: Voted Ought to Pass with Amendment by the House. Voted Ought to Pass with Amendment by Senate. Senate Amendment adds procedural requirements for board hearings. House concurred. Signed by the Governor effective July 1, 2017.**

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. Voted Ought to Pass by House. Signed by the Governor effective June 16, 2017.**

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. Voted Ought to Pass by House. Signed by the Governor effective July 11, 2017.**

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. **Senate voted Ought to Pass with Amendment. The amendments provide that qualified alcohol and drug counselors from other states are able to practice in NH not more than 60 days after making an application for licensure and require the certain regulatory boards and commissions provide information on their websites regarding reciprocity for those holding licenses in other states. House voted Ought to Pass.**

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: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House HHS Committee. Amendments clarify the bill's applicability to nurses, physicians and physician assistants, individuals who give aid at the scene of an emergency; require private insurance to pay for such testing for those not covered by workers compensation, and also make other non-substantive changes. Senate voted to concur**

with the House amendments. Signed by the Governor. Partially effective August 29, 2017. Establishment of study commission at January 1, 2018.

SB 61: This bill clarifies the procedure for receipt of medical records of a deceased spouse or next of kin. **Status: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House. Amendments clarify criteria for determining who may receive a deceased individual's medical records and how. Senate voted to concur with House amendment. Signed by the Governor effective January 1, 2018.**

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: Voted Ought to Pass by Senate. Voted Ought to Pass by the House. The bill has been enrolled but note contingencies in SB 150 and HB469 which affect implementation.**

SB 137: This bill requires the Board of Nursing to grant licenses to applicants for license by endorsement for persons holding licenses issued by Vermont, Massachusetts, New York or Connecticut. **Status: House amended the bill to provide for temporary licenses (120 days). Signed by the Governor effective August 9, 2017; Repeals July 1, 2019.**

SB 150: Under this bill, a pharmacy intern under the direct supervision of a pharmacist may administer immunizing vaccines. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by the House. Signed by the Governor effective July 11, 2017.**

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: Voted Ought to Pass with Amendment by Senate. Voted Ought to Pass with Amendment by House. Amendments impose additional restrictions on the temporary license. Senate concurred with House amendments. Signed by the Governor effective September 3, 2017; Repeal and reenactment with new requirements effective June 30, 2019.**

SB 155: This bill declares that step 2 of the Medicaid managed care program shall not be implemented until July 1, 2019. **Status: Senate voted Ought to Pass with Amendment. The Amendment provided that nursing facility services would be incorporated into the Medicaid managed care program beginning January 1, 2019. The Commissioner of HHS would procure contracts with a program start date of January 1, 2019. The House voted Ought to Pass with Amendment reversing the Senate amendment and requiring that Step 2 of the program not be implemented before July 1, 2019 and to require the Commissioner of HHS to re-procure contracts with vendors to administer the Medicaid Managed Care program, provided that the program shall not be implemented before July 1, 2019. The Senate voted to nonconcur with the amendment. The bill went to a Committee of Conference. Passed into law without signature, effective July 22, 2017.**

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: Senate voted Ought to Pass with Amendment. House voted Ought to Pass with Amendment. Amendment alters the language of the consumer rights notification. The Senate concurred with the House amendment. Signed by the Governor effective January 1, 2018.**

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: Voted Ought to Pass with Amendment by Senate. Introduced in House and referred to House HHS Committee. Amendment changes authorization renewal frequency from once every 24 months to once every 12 months. House voted Ought to Pass. Signed by the Governor effective August 28, 2017.**

SB 212: This bill adopts the physical therapy licensure compact, implemented by the physical therapy governing board. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass with Amendment. The amendment did not substantially alter the bill. The Senate concurred with the House amendment. Signed by the Governor effective July 1, 2017.**

SB 237-FN: This bill allows medical providers who practice in metropolitan areas to be reimbursed by Medicaid for telehealth services. **Status: Voted Ought to Pass by Senate. Voted Ought to Pass by the House; Signed by the Governor effective July 8, 2017.**

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Cinde Warmington, Kara J. Dowal, 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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