Health Care Practice Group

Cinde Warmington
Chair
cwarmington@shaheengordon.com

Steven M. Gordon
sgordon@shaheengordon.com

Lucy J. Karl
lkarl@shaheengordon.com

William E. Christie
wchristie@shaheengordon.com

Kara J. Dowal
kdowal@shaheengordon.com

Alexander W. Campbell
acampbell@shaheengordon.com

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

High Participation in Bundled Payment Model

On October 9, the Centers for Medicare & Medicaid Services ("CMS") announced that 1,547 Medicare providers and suppliers signed agreements to participate in the Administration's Bundled Payments for Care Improvement – Advanced (BPCI Advanced) Model. The BPCI Advanced Model provides bundled payments for certain episodes of care as opposed to fee-for-service payments. Participants can also earn an additional payment if all expenditures for an episode of care are below a spending target, which factors in quality measures.

Participants in the BPCI Advanced Model include 832 acute care hospitals and 715 physicians located in 49 states, Washington, D.C., and Puerto Rico. The BPCI Advanced Model qualifies as an Advanced Alternative Payment Model under MACRA, so those providers participating can be exempted from the reporting requirements associated with the Merit-Based Incentive Payment System ("MIPS").

A link to the press release from CMS is here: https://www.cms.gov/newsroom/press-releases/cms-announces-participants-new-value-based-bundled-payment-model

DOJ Requires Divestiture of Aetna's Part D Business to Clear CVS-Aetna Merger

On October 10, the U.S. Department of Justice ("DOJ") announced it is requiring CVS Health Corporation ("CVS") and Aetna Inc. ("Aetna") to divest Aetna's Medicare Part D prescription drug plan business before proceeding with their $69 billion merger. The press release explains that CVS, the country's largest retail pharmacy chain, and Aetna, the country's third-largest health insurance company, are major competitors in the sale of Medicare Part D prescription drug plans, with a combined total of 6.8 million members served throughout the country. The DOJ's Antitrust Division, along with five state attorneys general (California, Florida, Hawaii, Mississippi, and Washington) filed a civil antitrust lawsuit in the U.S. District Court for the District of Columbia to enjoin the proposed merger, which, would cause anticompetitive effects such as increased prices, inferior customer services, and decreased innovation, according to the complaint. The complaint was filed along with a proposed settlement, which proposes that Aetna's Part D business would divest to WellCare Health Plans, Inc., and would also require that Aetna provide transitional assistance to WellCare to operate the business and transfer customers. The settlement would "fully resolve the Department's competition concerns" according to the DOJ's press release.

https://www.justice.gov/opa/pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d

U.S. Supreme Court Declines to Review Ruling that "Improper Motive" Required for EMTALA Screening Claim

On October 9, the U.S. Supreme Court declined to review a Sixth Circuit decision finding that an "improper motive" is required for a claim against a hospital for failing to provide an "appropriate medical screening" in violation of the Emergency Medical Treatment and Labor Act ("EMTALA"). The decision to decline review lets stand a current circuit court split on the issue, as the D.C., First, Fourth, Eighth, and Tenth Circuits have rejected requiring an "improper motive" for a failure to screen claim under EMTALA. In the case, Jamie Elmhirst alleged that McLaren Northern Michigan and McLaren Health Care Corporation failed to perform an appropriate medical screening when she presented in the emergency department with symptoms of the dangerous condition vertebral dissection and requested treatment. Ms. Elmhirst alleges that because the hospital failed to perform the screening, it neither detected the condition nor stabilized her before discharge. She then alleges that the undetected condition caused her to suffer a stroke shortly thereafter, leaving her permanently disabled.

A link to the Sixth Circuit's Opinion, *Elmhirst v. McLaren N. Mich.*, No. 17-1949 (6th Cir. Mar. 9, 2018), can be found here: https://www.supremecourt.gov/DocketPDF/18/18-132/55732/20180727135220488_APPENDIX.pdf

President Trump Signs Laws Prohibiting Private Health Insurers and Medicare Plans from Using "Gag Clauses"

On October 10, President Trump signed legislation which prevents private health insurers and Medicare plans from restricting pharmacists from telling consumers that their prescriptions would be less expensive if paid out of pocket than if they used their health plan. The Patient Right to Know Drug Prices Act (applicable to private insurers and pharmacy benefit managers) and the Know the Lowest Price Act (applicable to Medicare Plans) received overwhelming support in both the House and the Senate.

The Patient Right to Know Drug Prices Act may be read here: https://www.congress.gov/bill/115th-congress/senate-bill/2554/text

The Know the Lowest Price Act may be read here: https://www.congress.gov/bill/115th-congress/senate-bill/2553/text?q=%7B%22search%22%3A%5B%22Know+the+Lowest+Price+Act%22%5D%7D&r=1

CMS Releases Star Ratings for MA and Part D Plans

On October 10, the Centers for Medicare & Medicaid Services ("CMS") announced its release of Star Ratings for 2019 Medicare Advantage and Part D prescription drug plans. CMS publishes the Part C and Part D Star Ratings each year to measure the quality of Medicare Advantage and Part D plans and to reflect the experiences of beneficiaries. CMS's press release noted that in 2019, most areas in the country will have plans with four or more stars. CMS also stated that in 2019, Medicare Advantage will be offering approximately 600 more plans and that 74 percent of enrollees with prescription drug coverage are projected to be in plans with four and five stars in 2019 (compared to 73 percent in 2018).

CMS's star ratings can be accessed here: https://www.medicare.gov/find-a-plan/results/planresults/planratings/compare-plan-ratings.aspx?PlanType=MAPD

HHS Publishes Upcoming Regulatory Agenda, Including RFI for HIPAA Reforms

On October 17, the Office of Management and Budget, Office of Information and Regulatory Affairs ("OIRA") published the fall 2018 "Unified Agenda of Regulatory and Deregulatory Actions," which contains proposed actions for various federal agencies including the Department of Health and Human Services ("HHS"). HHS' agenda includes a number of proposed regulatory actions, including: issuing a proposed rule as a follow-up to the recent Request for Information ("RFI") concerning Anti-Kickback Statute and Stark Law reforms; a second RFI aimed at obtaining input on provisions of the Health Insurance Portability and Accountability Act ("HIPAA") that may be negatively impacting care coordination and case management; proposed rules allowing for increased disclosure of patient information under HIPAA and other privacy laws in cases of incapacitation; proposed rules affecting what plans are available on the Affordable Care Act marketplaces; and a final rule aimed at protecting "conscience rights" in health care.

According to the HHS agenda, the HIPAA RFI will specifically seek comment on the following issues: (1) Methods of accounting of all disclosures of a patient's protected health information; (2) patients' acknowledgment of receipt of a providers' notice of privacy practices; (3) creation of a safe harbor for good faith disclosures of PHI for purposes of care coordination or case management; (4) disclosures of protected health information without a patient's authorization for treatment, payment, and health care operations; (5) the minimum necessary standard/requirement.

The HHS agenda is available at:
https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900&Image58.x=54&Image58.y=6.

The HIPAA RFI is available at:
https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0945-AA00.

OIG Advisory Opinion: Medicaid MCO Payments to Increase EPSDT Services Satisfy AKS Safe Harbor

On October 18, the Office of the Inspector General ("OIG") posted Advisory Opinion 18-11 concerning a proposal by a Medicaid managed care organization ("MCO") to pay its contracted providers and clinics to increase the amount of Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") services that they provide to the health plan's beneficiaries. Under the proposed arrangement, the MCO would enter into contracts with its network providers whereby it would pay per-enrollee incentive payments to providers that met benchmarks for the EPSDT services they provide. The proposed arrangement is intended to increase the amount of EPSDT services provided to the MCO's beneficiaries, thereby lowering health care costs.

OIG found that the proposed arrangement would implicate the Anti-Kickback Statute ("AKS"), however it would satisfy the requirements of the "eligible managed care organization" ("EMCO") safe harbor. The EMOC safe harbor allows for payments between EMCOs and first tier contractors that satisfy certain criteria. The proposed arrangement would satisfy the safe harbor because the MCO is a qualifying EMCO, the providers are first tier contractors, and the incentive payments would be made to "provide or arrange for health care services."

Advisory Opinion No. 18-11 is available at:
https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-11.pdf.

FDA Updates Cybersecurity Guidance for Medical Devices

On October 18, the U.S. Food and Drug Administration ("FDA") issued draft industry guidance on cybersecurity for medical device manufacturers. The guidance builds on previous guidance issued in 2014. FDA provides recommendations to industry regarding cybersecurity device design, labeling, and the documentation to be included in premarket submissions for devices with cybersecurity risk. The guidance establishes two tiers of devices according to their cybersecurity risk: Tier 1 "Higher Cybersecurity Risk," including implantable devices; and Tier 2 "Standard Cybersecurity Risk." The guidance also includes recommendations for design and labeling of devices.

The draft guidance is available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM623529.pdf.

OIG Report: FDA Lacks Policies to Sufficiently Address Postmarket Cybersecurity Risk in Medical Devices

On November 1, the Office of the Inspector General ("OIG") issued a report – "The Food and Drug Administration's Policies and Procedures Should Better Address Postmarket Cybersecurity Risk to Medical Devices" – with recommendations for the U.S. Food and Drug Administration ("FDA"). The report is the result of an audit OIG conducted after it identified that the U.S. Department of Health and Human Services ("HHS") faced challenges ensuring the safety and effectiveness of medical devices and fostering a culture of cybersecurity. OIG found that while FDA does have plans and processes in place to address certain types of medical device problems in the postmarket phase, its plans and processes were deficient in addressing cybersecurity issues. OIG found that FDA was not adequately prepared to address cybersecurity events, and 2 of its 19 district offices lacked written procedures for dealing with recalls of medical devices due to cybersecurity threats. OIG findings were so concerning that it shared them with FDA before issuing its report, and FDA implemented some of the recommendations.

OIG's report contains the following recommendations for FDA: "(1) continually assess the cybersecurity risks to medical devices and update, as appropriate, its plans and strategies; (2) establish written procedures and practices for securely sharing sensitive information about cybersecurity events with key stakeholders who have a "need to know"; (3) enter into a formal agreement with Federal agency partners, namely the Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team, establishing roles and responsibilities as well as the support those agencies will provide to further FDA's mission related to medical device cybersecurity; and (4) ensure the establishment and maintenance of procedures for handling recalls of medical devices vulnerable to cybersecurity threats."

OIG's report is available at: https://oig.hhs.gov/oas/reports/region18/181630530.pdf.

Trump Administration Proposes Expansion of Health Reimbursement Arrangements

On October 23, the Trump Administration proposed a regulation to increase employer and worker health insurance options by permitting employers (including small and mid-sized) to use tax-favored health reimbursement arrangements ("HRAs") to reimburse employees for individual health insurance plan premiums. The proposed rule was issued by the Departments of Labor, Treasury, and Health and Human Services ("HHS") and was published in the *Federal Register* on October 29. It reverses a rule under the Obama administration prevented employers from using HRAs to reimburse employees for the cost of individual health insurance coverage. Additionally, the proposed regulation would allow employers that offer

traditional group coverage to provide an HRA of up to $1,800 per year to reimburse an employee for certain qualified medical expenses.

A fact sheet on the proposed rule may be read here: https://www.dol.gov/sites/dolgov/files/OPA/factsheets/wh-hra-factsheet.pdf

The proposed rule published in the *Federal Register* may be found here: https://www.gpo.gov/fdsys/pkg/FR-2018-10-29/pdf/2018-23183.pdf

CMS Issues Advanced Notice for Proposed Rulemaking for New Payment Model for Medicare Part B Drugs

On October 25, the Centers for Medicare & Medicaid Services ("CMS") issued an Advance Notice of Proposed Rulemaking ("ANPRM") for testing changes to payment for certain separately payable Part B drugs and biologicals. "Specifically, CMS intends to test whether phasing down the Medicare payment amount for selected Part B drugs to more closely align with international prices; allowing private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician and hospital business; and changing the 4.3 percent (post-sequester) drug add-on payment in the model to reflect 6 percent of historical drug costs translated into a set payment amount, would lead to higher quality of care for beneficiaries and reduced expenditures to the Medicare program." CMS says that is considering issuing a proposed rule in the Spring of 2019 on the potential proposed model, called the International Pricing Index ("IPI") Model.

Comments are due by December 31.

A CMS Press Release about the ANPRM is here: https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs

The Advance Notice of Proposed Rulemaking is found here: https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF

CMS Issues Guidance for Innovation with Section 1332 Waivers

On October 22, the Centers for Medicare & Medicaid Services ("CMS") and the Treasury Department issued guidance to help give States more flexibility in designing alternatives to the Affordable Care Act ("ACA") Marketplace. The guidance states that it "intends to expand state flexibility, empowering states to address problems with their individual insurance markets and increase coverage options for their residents, while at the same time encouraging states to adopt innovative strategies to reduce future overall health care spending." The guidance provides supplementary information about the requirements for approval of a State Innovation Waiver under Section 1332 of the ACA, the review procedures of the Secretaries of the Department of Treasury and CMS, the calculation of pass-through funding, analytical requirements, and operational considerations.

Comments are due on December 24.

The guidance may be read here: https://www.gpo.gov/fdsys/pkg/FR-2018-10-24/pdf/2018-23182.pdf

President Trump Signs Bipartisan Opioid Legislation

On October 24, President Trump signed the bipartisan Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT for Patients and Communities Act"). H.R. 6 received a 98-1 vote in the Senate and passed the House with a vote of 393-8. The law has a number of methods intended to combat the opioid crisis, including deterring fentanyl from entering the country, establishing opioid-specific recovery centers, increasing access to housing and work opportunities for people in recovery, expanding access to medication assisted treatment, and increasing Medicare coverage of substance use disorders.

The text of H.R. 6 can be read here: https://www.congress.gov/bill/115th-congress/house-bill/6/text

CMS Publishes Final Physician Fee Schedule Rule

On November 1, the Centers for Medicare & Medicaid Services issued the final rule for the 2019 Physician Fee Schedule ("PFS"). The PFS final rule contains a number of significant changes, including: payment for two newly defined physicians services furnished using communication technology; expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders; adjusting the supervision requirements for radiologist assistants; establishing a new modifier for services provided by therapy assistants; adding a new telehealth services code for prolonged preventive services; reducing the payment amounts for new drugs under Part B; and implementing a number of revisions to the Accountable Care Organization Shared Savings Program. CMS is also soliciting comments on a proposal to create a bundled episode of care for management and counseling treatment for substance use disorders.

One of the most significant updates is to document, coding, and payment requirements for evaluation and management ("E/M") visits. E/M changes include the elimination of the requirement to document the medical necessity of a home visit in lieu of an office visit and allowing physicians to simply update information in the medical record of established patients, rather than re-record the required elements.

A number of provisions of the final rule are delayed until 2021, including: reducing the payment variation for E/M office/outpatient visit levels by paying a single rate for E/M office/outpatient visit levels 2 through 4 for established and new patients; and adopting a new "extended visit" add-on code for use only with E/M office/outpatient level 2 through 4 visits to account for the additional resources required when practitioners need to spend extended time with the patient.

CMS estimates that the changes in the rule will save providers $87 million in administrative costs in 2019 and $843 million over the next decade.

The final rule is available at: https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

CMS' fact sheet on the final rule is available at: https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year.

CMS Issues Final Rule on OPPS, ASC Payments

On November 2, the Centers for Medicare & Medicaid Services issued a final rule on the outpatient prospective payment system ("OPPS") and payments to ambulatory surgery centers ("ASCs"). The final rule includes many changes to the OPPS, including two significant changes: finalizing a proposal to pay for

clinical visits at off-campus provider-based department at the Physician Fee Schedule Rate; and expanding cuts to the 340B discount drug program.

CMS implemented the site-neutral payment policy despite opposition by 48 Senators who argued that it would jeopardize access to care for the nation's seniors. CMS maintains that the change in policy will result in an estimated $380 million in savings in 2019.

The change to the 340B program extends the cuts in payment rates to 340B drugs furnished by non-excepted off-campus provider-based departments. CMS previously cut the reimbursement for 340B drugs from average sales price ("ASP") plus 6% to ASP minus 22.5%. CMS estimates that the cuts resulted in savings to Medicare of $320 million in 2018. CMS' expansion of the cuts comes despite strong opposition from hospitals who say they depend on the higher payments to fund uncompensated care. A federal court rejected a challenge to the 340B payment cuts earlier this year on jurisdictional grounds.

Additional changes in the final rule include: additions to the ASC covered procedures list; reducing the number of measures ASCs and hospital outpatient departments are required to report under quality reporting programs; and changes to the Hospital Consumer Assessment of Healthcare Providers and Systems patient experience of care survey in response to recommendations from the *President's Commission on Combatting Drug Addiction and the Opioid Crisis*.

The final rule increases the OPPS payment rates by 1.35% and the ASC rates by 2.1%.

The final rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24243.pdf.

A fact sheet on the final rule is available at: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center.

OIG Provides Favorable Opinion for Preferred Hospital Network for Medigap Policies

On October 29, the Office of the Inspector General issued Advisory Opinion No. 18-12 concerning a proposed arrangement whereby a Medicare Supplemental Health Insurance ("Medigap") provider would use a preferred hospital network and provide premium credits to beneficiaries to use the in-network hospitals. The network hospitals would also provide discounts on Medicare inpatient deductibles.

OIG stated that it would not impose sanctions under the Anti-Kickback Statute or the prohibition against beneficiary inducements based, in part, on the following factors: the discounts and premium credits were unlikely to affect Medicare payments; the discounts would not increase utilization; the proposed arrangement would be unlikely to affect competition among hospitals; and, since individual providers received no remuneration, it would be unlikely to affect professional medical judgment.

OIG also concluded that the proposed arrangement would fall into the exception to the definition of remuneration for differentials in coinsurance and deductible amounts as part of a benefit plan design.

Advisory Opinion No. 18-12 is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-12.pdf.

After Near 2-year Delay, 340B Ceiling Price Rule Finally Set for Implementation in January

On November 2, the Health Resources and Services Administration ("HRSA") issued a proposed rule to speed up the implementation of a long-delayed final rule concerning the 340B discount drug program. The final rule imposes monetary penalties on drug manufacturers that overcharge safety net providers for discounted drugs sold under the 340B program. The final rule was first issued in January of 2017 under the Obama administration, but its implementation was repeatedly delayed by the Trump administration. The most recent delay pushed implementation out to July 1, 2019. The move to speed up the implementation to January 1, 2019 comes almost two months after hospital groups filed a federal lawsuit asking for an order for HRSA to make the rule effective in 30 days.

The January 5, 2017 final rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf.

The November 2, 2018 proposed rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2018-11-02/pdf/2018-24057.pdf.

CMS Proposes Loosening Requirements for Telehealth Services For Medicare Advantage Beneficiaries

On October 26, the Centers for Medicare & Medicaid Services issued a proposed rule to allow Medicare Advantage ("MA") plans to expand the telehealth benefits they offer beginning in 2020. The rule would expand the circumstances in which a beneficiary could receive telehealth services. Currently, such services are restricted based, in part, by the geographic location of the beneficiary, and the beneficiary is required to receive the telehealth services in a health care facility. The rule would allow beneficiaries to receive services in their homes. CMS is asking for comments on how to implement the statutory provision that if an MA plan covers a Part B service as an additional telehealth benefit, then the MA plan must also provide the enrollee access to such service through an in-person visit.

Comments are due December 31.

The proposed rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2018-11-01/pdf/2018-23599.pdf.

A fact sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/contract-year-cy-2020-medicare-advantage-and-part-d-flexibility-proposed-rule-cms-4185-p.

CMS Issues Final Rule on Medicare Home Health Payments

On October 31, the Centers for Medicare & Medicaid services issued a final rule concerning home health payments under Medicare. The final rule includes a number of changes, including: adopting a new case-mix system; allowing home health agencies ("HHAs") to report remote patient monitoring as allowable costs; and implementing a new "Patient-Driven Groupings Model," which eliminates "therapy thresholds" for determining payment and reduces the episode of care from 60 to 30 days. CMS estimates that the changes in the final rule will result in an overall rate increase of 2.2%, or $420 million, in calendar year 2019, and will save HHAs $60 million annually starting in 2020.

The final rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24145.pdf.

CMS Final Rule Provides Updates to Medicare Payments for DME, ESRD

On November 1, the Centers for Medicare & Medicaid Services issued a final rule regarding the Durable Medical Equipment Prosthetics, Orthotics, and Supplies ("DMEPOS") competitive bidding program. The final rule includes a number of changes to the program, including: establishing lead item bidding, meaning suppliers will only need to submit one bid per product category; finalizing increases in DMEPOS fee schedule rates, using a blend of adjusted and unadjusted fee amounts; and adding new payment classes for oxygen and oxygen equipment.

The final rule also includes changes to payments for end-stage renal disease ("ESRD") facilities. Changes include: increasing the labor-related share of ESRD bundled market basket from 50.673% to 52.3%; allowing new renal dialysis drugs and biologicals as of January 1, 2020 to be eligible for the Transitional Add-on Payment Adjustment; and removing four reporting measures from the ESRD quality incentive program starting in 2021. CMS estimates that the changes in the final rule to ESRD payments will result in a 1.6% overall rate increase in 2019, resulting in $10.5 billion in payments total next year.

The final rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24238.pdf.

Federal Court Again Orders HHS to Clear Medicare Appeals Backlog, This Time by 2022

On November 1, the U.S. District Court for the District of Columbia issued an order requiring the U.S. Department of Health and Human Services ("HHS") to clear a backlog of more than 400,000 Medicare appeals by 2022. This is the latest order in a dispute between hospital groups and HHS over HHS' backlog that has been ongoing for the past few years. In August of 2017, the Court of Appeal for the D.C. Circuit vacated an earlier order that required HHS to clear the backlog by 2021 in accordance with an annual schedule of specific targets. The Court of Appeals held that the previous order had failed to consider whether the targets were impossible to meet. The latest order from the District Court comes after the HHS recently acknowledged that recent funding "has made compliance possible within four years." The District Court's order included the following timeline: 19% reduction by the end of 2019; 49% reduction by the end of 2020; 75% reduction by the end of 2021, and a total reduction by the end of 2022. The court declined to grant an order reducing the interest charged on funds that HHS has not yet recouped from providers on appeals that are currently pending.

The District Court's order is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24238.pdf.

CMS Extends Timeline for Finalizing Rule on Discharge Planning

On November 2, the Centers for Medicare & Medicaid Services published a notice that it was extending the deadline for it to issue a final rule on discharge planning. CMS originally issued a proposed rule on discharge planning in November of 2015 but has cited "the complexity of the rule and scope of public comments" as the basis for the extension. The rule, when finalized, will revise discharge planning requirements for a number of facilities.

The notice is available at: https://www.gpo.gov/fdsys/pkg/FR-2018-11-02/pdf/2018-23922.pdf.

CMS Proposed Rule Increases Oversight of ACA Exchanges

On November 9, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule affecting the Affordable Care Act ("ACA") insurance exchanges. The proposed rule would revise standards

relating to oversight of exchanges established by states, periodic data matching frequency and authority, and the length of a consumer's authorization for the exchange to obtain updated tax information. The proposed rule also includes new requirements for certain issuers related to the collection of a separate payment for the premium portion attributable to coverage for certain abortion services. According to CMS, many of the proposed changes are the result of audits of the state exchanges that revealed "substantial weaknesses" in how the states determined whether beneficiaries are eligible for advance payments of the premium tax credit and cost-sharing reduction.

Comments on the proposed rule are due by January 8, 2019.

The proposed rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2018-11-09/pdf/2018-24504.pdf.

CMS Proposed Rule Would Streamline Medicaid and CHIP Managed Care Regulations

On November 8, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule affecting the Medicaid and Children's Health Insurance Program ("CHIP") managed care regulations. According to CMS, the changes in the proposed rule are meant to address provisions of the 2016 overhaul of the managed care regulations "that many states and stakeholders identified as unnecessarily prescriptive and as adding unnecessary costs and administrative burden." The proposed rule is consistent with the administration's stated goal of easing administrative burdens across all federal departments. Changes in the proposed rule include: providing states with greater flexibility to develop and certify a rate range under specific conditions and limitations, including that the rate range be actuarially sound; requiring CMS to hold itself accountable to issue guidance to help states move more quickly through the federal rate review process and to allow for submission of less documentation in certain circumstances while providing appropriate oversight to ensure patient protections and fiscal integrity; and strengthening Federal requirements to protect federal taxpayers from cost shifting by prohibiting states from retroactively adding or modifying risk-sharing mechanisms and ensuring that differences in reimbursement rates are not linked to enhanced federal match.

The rule will be published on November 14, and comments will be due by January 13, 2019.

The proposed rule is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24626.pdf

CMS' fact sheet about the proposed rule is available at:

https://www.cms.gov/newsroom/fact-sheets/notice-proposed-rulemaking-nprm-medicaid-program-medicaid-and-childrens-health-insurance-program

OIG Would Not Impose Sanctions for Charitable Donation to Research Institute

On November 6, the Office of Inspector General ("OIG") issued Advisory Opinion 18-13, which looked favorably on a proposed arrangement whereby a trust established by a grantor in 1993 when he passed away, would make a sizable charitable donation to a Research Institute. The Research Institute is a public-private partnership between a university and a local health care system. The donation would be made to the university's foundation but earmarked for the Research Institute. The Research Institute is not enrolled in Medicare or Medicaid and does not provide services reimbursable by any Federal health care program; however, the Trustees of the trust – who are members of the grantor's family – all have ownership and financial interests in long-term care facilities that have ongoing business with the health care system.

Because the donation is directed to the Research Institute by the trustees, and the Research Institute is an affiliate of the health care system with which the trustees have financial relationships, the proposed arrangement implicates the Anti-Kickback Statutes ("AKS"). However, OIG concluded that the proposed arrangement would not pose a high risk of fraud and abuse – and therefore it would not impose sanctions under the AKS – for the following reasons: first, the trust certified that the donation would not be explicitly or implicitly conditions on referrals to the trustees' long-term care facilities; second, the health care system would not control how the Research Institute uses the donated money; third, the existence of outside business relationships between entities affiliated with donors and recipient does not make the charitable donations automatically suspect under the AKS; and finally, there are several factors that distinguish the proposed arrangement from other arrangements involving donors motivated to provide improper payment for referrals rather than donation for bona fide charitable purposes, including that the grantor had established the trust and had stated his intention that it be used to support higher learning institutions 30 years prior to the proposed donation.

The advisory opinion is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-13.pdf.

No Rehearing by Federal Circuit on Ending Insurers' Bid for Risk Corridors Payments

On November 6, the Federal Circuit declined to rehear *en banc* a rule against health insurers Moda Health Plan, Inc. and Land of Lincoln Mutual Health Insurance Company. The health insurers were seeking to hold the federal government accountable for millions in unpaid risk corridor payments, however the Federal Circuit's panel determined that although the Affordable Care Act required the government to make the payments, appropriations riders enacted in fiscal years 2015 and 2016 made the program budget neutral, which had the effect of repealing or suspending the government's obligation to pay. The decision was a reversal of the lower court's ruling in *Moda Health Plan, Inc. v. United States*, No. 16-649C (Fed. Cl. Feb. 9, 2017), in which the court held the government owed Moda Health $214 million in unpaid risk corridors payments. On the other hand, the lower court in *Land of Lincoln Mutual Health Ins. Co. v. United States*, No. 16-744C (Fed. Cl. Nov. 10, 2016) found the government didn't have a statutory or contractual obligation to make the full risk-corridors payments on an annual basis. *Moda Health Plan, Inc. v. United States*, No. 2017-1994 (Fed. Cir., petition for reh'g *en banc* denied Nov. 6, 2018).

Trump Administration Removes Contraception Coverage Mandate for Certain Employers

On November 7, the Departments of Health and Human Services, Treasury, and Labor (the "Departments") announced two separate rules that will permit employers with religious or moral objections to the Affordable Care Act's mandate to cover contraceptives to opt out of the requirement. The "conscience protections" are contained in two different rules, one which addresses entities with religious objections and the other which applies to non-profit entities, small business, and individuals and addresses moral objections to services covered by the contraception mandate. "Moral objections", as explained in a fact sheet from the Departments, are those convictions: "(1) that a person "deeply and sincerely holds"; (2) "that are purely ethical or moral in source and content; (3) "but that nevertheless impose … a duty"; (4) and that "certainly occupy … a place parallel to that filled by … God' in traditionally religious persons," such that one could say the "beliefs function as a religion.""

The rules will be published in the November 15 *Federal Register*. They will be effective 60 days after publication.

An unpublished version of the rule can be accessed here: https://www.federalregister.gov/documents/2018/11/15/2018-24512/religious-exemptions-and-accommodations-for-coverage-of-certain-preventive-services-under-the

High Percentage of Physicians Participating in MIPS Received Positive Payment Adjustment

On November 8, the Centers for Medicare & Medicaid Services ("CMS") reported that 93% of physicians participating in the Merit-based Incentive Payment System ("MIPS") under the Quality Payment Program ("QPP") received a positive payment adjustment for 2017 services. CMS reported that 2% of physicians received a neutral adjustment and 5% received a negative adjustment. CMS noted that the positive payment adjustments were modest (the minimum adjustment was 0.28% and the maximum adjustment was 1.88%) but explained that funds available for positive payment adjustments are limited by the budget neutrality requirements of MIPS.

A CMS blog post reporting the results may be found here: https://www.cms.gov/blog/quality-payment-program-qpp-year-1-performance-results

STATE DEVELOPMENTS

Health Insurance Marketplace Open Enrollment Began November 1

Open enrollment in the individual health insurance marketplace will run from November 1-December 15. There are three insurance companies offering individual plans on the NH Marketplace for coverage beginning on January 1, 2019: Anthem, Ambettter (from NH Health Families) and Harvard Pilgrim Health Care.

NH DHHS Posts Interim Rule Governing Granite Advantage Health Care Program

On November 8th, the NH Department of Health and Human Services published its interim rule governing the NH Granite Advantage Health Care Program. Among other things, the rule describes the community engagement requirements for the program, establishes qualifying activities for community engagement, details the impact of noncompliance and establishes how to cure deficit community engagement hours. The Granite Advantage Program, which replaces the NH Health Protection Program, is effective on January 1, 2019 for those enrolled under expanded Medicaid.

The rule may be found at: https://www.dhhs.nh.gov/ombp/medicaid/granite.htm

NH DHHS Holds Public Forums to Introduce Granite Advantage Health Care Program

On November 9th, the NH Department of Health and Human Services announced a series of public forums across the state to introduce the Granite Advantage Health Care Program (GAHCP). The GAHCP replaces the NH Health Protection Program, the plan which provides coverage for those enrolled in expanded Medicaid. The GAHCP includes a community engagement and work requirement for members between the ages of 19-64 unless they are otherwise exempted. Coverage under the new program will be provided through the New Hampshire Medicaid Care Management program which uses two health plans, Well Sense and NH Healthy Families, to manage health care for members. The forums are intended to allow individuals, community organizations, providers and other stakeholders to engage with DHHS on the transition.

Details regarding the 11 forums to be held across the state may be found at https://www.dhhs.nh.gov/media/pr/2018/11092018-ga-forums.htm

LEGISLATIVE UPDATE

The following bills were sent to study committees in the last session.

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 mangers play in the cost, administration, and distribution of prescription drugs.

On November 1, the Study Commission issued its report noting that, during its process, the Commission:

- **Gathered information from the NH Department of Administrative Services, the NH Department of Health and Human Services and to Grafton County.**
- **Heard from patients and patient advocacy groups on the impact of price increases and on how PBM formulary decision impact drug access and price.**
- **Studied legislation passed by other states to bring more transparency to pharmaceutical prices and costs.**
- **Received testimony from representatives of health plans, pharmacies, manufacturers, and PBMs.**

The Commission reported that the task of determining how to achieve greater transparency in pharmaceutical costs was too difficult to accomplish given the timeframe allotted and, accordingly, did not recommend any legislative actions to address the study findings. The final report does include a compilation of ideas that individual Commission members think will help transparency and lower costs.

The link to the full report is at:
http://www.gencourt.state.nh.us/statstudcomm/committees/1414/reports/Final_Report.pdf

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. Interim Study Subcommittee Work Session scheduled for September 18, 2018.

Interim Study Report: Voted Not Recommended for Future Legislation (Vote 15-2).

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 facilities and an increase in licensed capacity in existing facilities, except for rehabilitation facilities whose sole purpose is to treat individuals for substance use disorder or mental health issues. Signed by the Governor on June 25, 2018. Effective upon signing except Section 2 which is effective November 1, 2020. Study Committee to file report by November 1, 2019.

HB 1471: This bill clarifies the law relating to telemedicine services. Introduced and referred to House HHS Committee. Voted Ought to Pass with Amendment by the Committee and by the full House. 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. Signed by the Governor on June 18, 2018. Sections 1-3 effective August 17, 2018. Remainder effective upon signing.

On November 1, the Study Committee submitted its report which provides a survey of the current landscape of reimbursement for telemedicine and telehealth. It concludes that the topic is complex with a wide variance of policy among federal and state governments and among third party payers. It recommends topics for future investigation.

The full report may be found at:
http://www.gencourt.state.nh.us/statstudcomm/committees/1410/reports/Final%20Report.pdf

HB 1782-FN: This bill establishes a committee to study insurance payments to ambulance providers and balance billing by ambulance providers. The committee must report its findings and recommendations on or before November 1, 2018. Passed by the House and Senate. Signed by the Governor on May 25, 2018; Effective upon signing.

On November 1, the Study Committee issued its report finding that current law allowing insurers to either reimburse ambulance service providers directly or by check payable to both the insured and the ambulance service provider leads to a number of problems. It is confusing and inconvenient for the consumer and makes it difficult for the provider to get payment. The Committee recommended deleting the statutory language allowing for the check to be issued to both the insured and the ambulance service provider from both RSA 415: 6-q and RSA 415:18-v. It also recommended encouraging the NH Department of Insurance to continue discussions on network adequacy and better rates for ambulance services, and to explore methods for determining the scope of the problem of balance billing for out-of-network emergency ambulance services.

The full text of the report may be found at:
http://www.gencourt.state.nh.us/statstudcomm/reports/1399.pdf

2019 LEGISLATIVE SERVICE REQUESTS

HB 2019-0024 Title: relative to qualifications for and exceptions from licensure for mental health practice. Sponsors: (Prime) Carol McGuire

HB 2019-0031 Title: permitting the department of health and human services to provide information from the case record to the child's primary health care provider under certain circumstances. Sponsors: (Prime) Skip Berrien

HB 2019-0037 Title: repealing the law relative to providing certain parameters for access to reproductive health care facilities. Sponsors: (Prime) Kurt Wuelper

HB 2019-0039 Title: relative to licensure of health facilities near a critical access hospital. Sponsors: (Prime) William Marsh

HB 2019-0040 Title: relative to the board of medicine. Sponsors: (Prime) Polly Campion

HB 2019-0046 Title: establishing a commission on mental health education programs. Sponsors: (Prime) Patricia Cornell

HB 2019-0091 Title: relative to group and individual health insurance market rules. Sponsors: (Prime) Edward Butler

HB 2019-0128 Title: establishing a New Hampshire health access corporation. Sponsors: (Prime) Peter Schmidt

HB 2019-0129 Title: establishing a commission to examine the feasibility of the New England states entering into a compact for a single payer health care program. Sponsors: (Prime) Peter Schmidt

HB 2019-0130 Title: relative to Medicare for all. Sponsors: (Prime) Peter Schmidt

HB 2019-0131 Title: relative to treatment alternatives to opioids. Sponsors: (Prime) Peter Schmidt

HB 2019-00140 Title: adding opioid addiction, misuse, and abuse to qualifying medical conditions under therapeutic use of cannabis. Sponsors: (Prime) Robert Renny Cushing

HB 2019-0153 Title: prohibiting release of certain information relative to users of therapeutic cannabis to federal agencies. Sponsors: (Prime) Caleb Dyer

HB 2019-0173 Title: relative to funding the New Hampshire granite advantage health care program. Sponsors: (Prime) James McConnell

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

BIOS

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

KARA J. DOWAL, ESQ.
Kara Dowal practices health care law and corporate business law at Shaheen & Gordon, P.A. Kara works with health care providers on a variety of legal issues, including corporate governance, contracting, employment, regulatory compliance, and provider transition matters.

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.