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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

House Passes Four Bills Affecting Medicare

On September 12, the U.S. House of Representatives passed four bills related to the Medicare program. The Fighting Fraud to Protect Care for Seniors Act requires the Centers for Medicare & Medicaid Services ("CMS") to pursue a pilot program to evaluate whether Medicare should use "smart card" technology to combat fraud. The pilot program includes the issuance of free smart cart technology to beneficiaries, suppliers and providers.

The text of the bill is available at: https://docs.house.gov/billsthisweek/20180910/HR6690.pdf.

The Comprehensive Care for Seniors Act of 2018 requires CMS to finalize a 2016 proposed rule for Programs for All-Inclusive Care for the Elderly ("PACE") by December 31, 2018. The text of the bill is available at: https://docs.house.gov/billsthisweek/20180910/HR6561.pdf.

The proposed rule includes revisions and updates to PACE, including changes to the application and waiver procedures, sanctions, enforcement actions and termination, administrative requirements, PACE services, participant rights, quality assessment and performance improvement, participant enrollment and disenrollment, and more. The text of the proposed rule is available at: https://www.federalregister.gov/documents/2016/08/16/2016-19153/medicare-and-medicaid-programs-programs-of-all-inclusive-care-for-the-elderly-pace.

The Empowering Seniors' Enrollment Decision Act of 2018 expands an existing special enrollment period for Medicare Advantage. The text of this bill is available at: https://docs.house.gov/billsthisweek/20180910/HR6662-1.pdf.

The Local Coverage Determination Clarification Act of 2018 revises the process for Medicare contractors to issue and reconsider local coverage determinations. The text of this bill is available at: https://docs.house.gov/billsthisweek/20180910/HR3635.pdf.

OIG Report: FDA Should Improve Cybersecurity Checks in Premarket Reviews for Medical Devices

In September, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published a report titled "FDA Should Further Integrate Its Review of Cybersecurity Into the Premarket Review Process for Medical Devices." In light of research showing that networked medical devices approved by the FDA may be susceptible to cybersecurity threats, the OIG undertook to evaluate the measures taken by the FDA to discover and protect against such threats. While OIG did find that FDA obtains and reviews cybersecurity documentation in the pre-market

submissions for medical devices, it recommended that FDA "promote the use of pre-submission meetings to address cybersecurity-related questions, include cybersecurity documentation as a criterion in FDA's Refuse-To-Accept checklists, and include cybersecurity as an element in the Smart template."

The report is available at: https://oig.hhs.gov/oei/reports/oei-09-16-00220.pdf.

CMS Issues Guidance Expanding Individual Mandate Hardship Exemption

On September 12, the Centers for Medicare & Medicaid Services ("CMS") issued guidance that makes it easier for taxpayers to claim a hardship exemption from the individual coverage mandate in the Affordable Care Act ("ACA"). The new guidance allows taxpayers to claim the exemption on their tax returns without having to provide any supporting documents or written explanation. This guidance follows earlier guidance from April that expanded the exemption for taxpayers living in counties with one or no insurers. Although the 2017 tax bill removed the penalty for the individual mandate starting in 2019, the exemption expansions are meant to apply to the 2018 tax year.

CMS' guidance is available at: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf.

$473.69 Million Identified as Improper Medicare FFS Payments for FY 2016

The Centers for Medicare & Medicaid Services ("CMS") gave its annual report to Congress that Recovery Audit Contractors ("RACs") found $473.92 million in improper fee-for-service ("FFS") payments in fiscal year 2016. This amount is $440.69 million, or 7.5% more than was found for fiscal year 2015. Not all of the improper payments were overpayments, as the report states $69.46 million were underpayments and $404.46 million were overpayments. The report also noted that of the total Medicare appeals decided in fiscal year 2016, 41.9% of RAC denials were overturned in the provider's favor.

The report is available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/FY-2016-Medicare-FFS-Report-Congress.pdf

OIG Issues Favorable Advisory Opinion to Surgical Device and Wound Care Manufacturer Warranty Program

On September 10, 2018, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") issued a favorable advisory opinion related to a warranty program for a suite of three products offered to hospital customers by a surgical device and wound care product manufacturer (the "Proposed Arrangement"). Although the OIG stated the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals was present, it would not impose administrative sanctions. Under the Proposed Arrangement, the manufacturer would refund hospitals for the aggregate purchase price of three products (the "Warranty Program"). Certain conditions must be satisfied in order to qualify for a refund under the Warranty Program, including that a patient had joint replacement surgery at the hospital, as an inpatient, and received each of the three products in the product suite; the patient must have been readmitted to the same hospital as an inpatient within 90 days of the surgery due to a surgical site infection or for a revision of the implanted knee or hip system; and each of the three products must have been used in a manner consistent with its instructions for use and other labeling and the hospital must certify that the patient's readmission resulted from the failure of one or more of the products. The manufacturer would refund the hospital the aggregate purchase price regardless of which of the three products failed and regardless of the patient's insurance

status or the third-party payor that covered the surgery. The manufacturer claims that the use of the product suite would reduce the likelihood of a surgical site infection or required revision, and also certified that the three products are not separately reimbursable under the Medicare Inpatient Prospective Payment System ("IPPS"). The OIG concluded that the Proposed Arrangement poses a sufficiently low risk of fraud and abuse because: (1) Medicare reimburses hospitals through one bundled payment for all of the items and services hospitals furnish in connection with an inpatient stay for a joint replacement surgery; (2) Requestor certified it would meet all of the obligations of a seller under the warranties safe harbor; (3) the manufacturer would require each hospital to certify that the physicians performing the surgeries would remain responsible for determining whether a medical device is medically necessary and clinically appropriate for a particular patient; (4) both patients and the Federal health care program would benefit if the Warranty Program works to reduce the incidence of readmissions; and (5) the Warranty Program would contain no exclusivity requirements or quotas, minimums, or any other criteria tied to the volume or value of referrals.

The full OIG advisory opinion, No. 18-10, can be read here: https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-10.pdf

CMS Proposes to Reduce Regulatory Burdens

On September 20, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule aiming to reduce the regulatory burden of Conditions of Participation ("CoPs") and Conditions of Coverage ("CfCs") for providers and suppliers. CMS stated that the regulatory changes put forth by proposed rule, which applies to a broad spectrum of providers and suppliers, can be divided into three types of proposals: (1) those that streamline and simplify processes; (2) those that reduce the frequency of activities and revise timelines; and (3) those aimed at obsolete, duplicative, or unnecessary requirements.

Comments on the proposed rule are due November 19.

The proposed rule can be read here: https://www.gpo.gov/fdsys/pkg/FR-2018-09-20/pdf/2018-19599.pdf

OIG Releases Report Warning of Payment Denials by Medicare Advantage Plans

On September 27, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") released a report in which it raised concerns about service and payment denials by Medicare Advantage Plans revealed during an audit by the Centers for Medicare & Medicaid Services ("CMS"). The CMS audit revealed that Medicare Advantage Organizations ("MAOs") overturned 75% of their own denials over the 2014-2016 period, totaling approximately 216,000 denials. Independent reviewers also overturned denials in favor of providers and beneficiaries at higher levels of the appeals process over the same period. The OIG is concerned that such a high overturn rate means that beneficiaries and providers were denied services and payments that they otherwise should have received, a fact that is made worse when the OIG considered that beneficiaries and providers rarely use the appeals process, citing the statistic that only 1% of denials were appealed to the first level of appeal during 2014-2016. The OIG recommends that CMS "(1) enhance its oversight of MAO contracts, including those with extremely high overturn rates and/or low appeal rates, and take corrective action as appropriate; (2) address persistent problems related to inappropriate denials and insufficient denial letters in Medicare Advantage; and (3) provide beneficiaries with clear, easily accessible information absent serious violations by MAOs." CMS agreed with all of the OIG's recommendations.

The report, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denials*, may be found here: https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf

CMS Announces Reforms to Medicare Local Coverage Determination Process

On October 3, the Centers for Medicare & Medicaid Services ("CMS") announced reforms to Medicare's Local Coverage Determination ("LCD") process. The LCD changes take the form of revisions to the Medicare Program Integrity Manual and are intended to increase transparency and the availability of innovative therapies and devices. The reforms include restructuring Contractor Advisory Committee meetings, an option to request an informal meeting with the Medicare Administrative Contractor ("MAC") to discuss potential LCD requests, and a new process by which interested parties in a MAC jurisdiction can request a new LCD.

The announcement is available at: https://www.cms.gov/newsroom/fact-sheets/summary-significant-changes-medicare-program-integrity-manual-chapter-13-local-coverage.

OIG Report: Medicare Paid $5.7 Billion for Improper Inpatient Rehab Facility Admissions

In September, the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") published a report titled "Many Inpatient Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements." OIG conducted the review of inpatient rehabilitation facility ("IRF") stays based on the results of prior reviews that indicated some facilities did not comply with the IRF requirements. OIG reviewed documents for a sample of 220 IRF stays in 2013 and found that for only 45 of the 220 stays did the IRFs comply with all Medicare coverage and documentation requirements. Based on its findings in the sample size, OIG estimates that Medicare paid IRFs $5.7 billion for care to beneficiaries that was not reasonable and necessary. OIG recommended that CMS educate IRF clinical and billing personnel on coverage and documentation requirements, increase oversight for IRFs, such as post-payment review, work to make sure that coverage and documentation requirements are fairly represented at ALJ hearings, and reevaluate the IRF payment system.

The report is available at: https://oig.hhs.gov/oas/reports/region1/11500500.pdf.

CMS Proposed Rule Would Implement Technical Changes to Medicare Appeals Rules

On October 2, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule containing proposed changes to the Medicare appeals process, with the stated goal of reducing the burden on providers, suppliers, beneficiaries, and adjudicators. The proposed rule contains a number of changes, including removing the signature requirement for appeals requests and small changes to certain timeframes and deadlines. The proposed rule also tweaks provisions of a January 2017 final rule that was meant to help reduce the growing backlog of appeals. Comments on the proposed rule are due December 3.

The proposed rule is available at: https://www.gpo.gov/fdsys/pkg/FR-2018-10-02/pdf/2018-21223.pdf.

NH's Senators Introduce Separate Legislation Aimed at Reducing Health Care Costs

On October 3, U.S. Senator Jeanne Shaheen introduced a bill – the Reducing Costs for Out-of-Network Services Act of 2018 – which would impose caps on the amounts that physicians could charge to uninsured patients and out-of-network patients who receive coverage from the individual marketplace. These protections are similar to those that have existed for Medicare Advantage beneficiaries for several years. Senator Maggie Hassan is a co-sponsor of the bill.

Also on October 3, Senator Hassan announced that she will soon introduce the No More Surprises Medical Bills Act of 2018, which would also address health care costs. The bill would prohibit hospitals and providers from charging out-of-network patients for emergency services more than what they charge in-network patients. The bill would also require hospitals and providers to notify patients in non-emergency circumstances if the services will be out-of-network and then obtain their consent before providing the services. Without such consent, the provider can charge no more than the in-patient amount. Senator Shaheen will be a co-sponsor of the bill.

The text of Senator Shaheen's bill is available at:
https://www.shaheen.senate.gov/imo/media/doc/Shaheen%20Out-of-Pocket%20Costs%20Bill%2010.3.2018.pdf.

STATE DEVELOPMENTS

NH Department of Insurance Hosts Annual Hearing on Health Insurance Premium Rates

The NH Department of Insurance will hold its annual hearing on health insurance premium rates on Tuesday, October 20 from 9am-12:30pm at the University of New Hampshire School of Law in Concord. Limited seating is available and may be reserved in advance. The Department is also offering an opportunity to register to listen to a live stream of the event.

A link to the announcement and for options to participate may be found at:
https://www.nh.gov/insurance/media/pr/2018/documents/2018-annual-hearing-save-the-date-09-05-18.pdf

Open Enrollment Period for Medicaid Programs Announced

On September 28, the NH Department of Health and Human Services announced the open enrollment period this year will be from November 1st through Dec 28th for those enrolled in the Medicaid Care Management Program. Enrollees may choose between NH Healthy Families and Well Sense Health Plan.

The NH Health Protection Program/Premium Assistance Program will become the Granite Advantage Program and enrollees will need to select from one of the two Medicaid Care Management Program Plans. Those who do not make a selection by December 3rd will be assigned a plan but will still have until December 28th to change their selection. Under the new Granite Advantage Plan, enrollees will be required to meet the community engagement requirement by participating in qualifying activities unless they qualify for an exemption. Qualifying activities include employment, education, job search training, caretaking, substance use disorder treatment, and community service.

A link to the notice regarding the changes in the NHHPP may be found at:
https://www.dhhs.nh.gov/ombp/medicaid/documents/gahc-flimsie-092518.pdf

NH DHHS Seeks Public Input on Its 10-Year Mental Health Plan

The NH Department of Health and Human Services is seeking public input on its 10-year mental health plan. The feedback received will inform the development of a plan which will provide a framework to anticipate and address the mental health needs of New Hampshire residents. Sessions were scheduled across the state beginning on September 25th and continuing through October 25th.

A link to the schedule of sessions may be found at https://www.dhhs.nh.gov/dcbcs/bbh/10-year-mh-plan.htm

The NH DHHS Proposes Amendment to Administrative Rules Governing Substance Use Disorder Treatment Services

The NH DHHS has proposed to amend the administrative rules governing Substance Use Disorder and Treatment and Recovery Support Services. The amendments are intended to provide clarity, reflect current best practices, align with recent changes in state and federal law and "adjust expectation with the practical application of the outlined services." The comment period ended on October 4th.

A copy of the proposed amendment may be found at:
https://www.dhhs.nh.gov/oos/aru/documents/hew513ip.pdf

LEGISLATIVE UPDATE

The following Bills were sent to study committees in the last session. We will continue to report any updates.

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. Taken up by House Commerce.

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 1st.

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. Study Committee to file report by November 1st.

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. Study Committee to file report by November 1st.

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

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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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