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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

OIG Reports that Remaining CO-OPs are Not Financially Viable

On September 12, 2017 the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") issued a report on the current status of the Consumer Operated and Oriented Plans ("CO-OPs") that were established under the Affordable Care Act titled *CMS Oversight Must Continue Because All Remaining Consumer Operated and Oriented Plans Were Not Profitable and May Not Be Viable and Sustainable*. The report was issued following OIG's review of the 11 CO-OPs that were operational as of January 1, 2016. Of these 11 CO-OPs, 5 had ceased or planned to cease operations by the end of the 2016 plan year, and the remaining 6 CO-OPs had all reported net losses and as of December 31, 2016 had drawn down almost all of the CO-OP loan funds that were available to them. OIG reports that the 6 remaining CO-OPs did not appear to be financially viable and sustainable following the 2016 plan year. CO-OPs are non-profit health insurers who were eligible to receive start up and solvency loans under the Affordable Care Act.

OIG's review and report comes after the Centers for Medicare & Medicaid Services ("CMS") placed 10 of the 11 CO-OPs on corrective action plans or enhanced oversight plans in 2015 and 2016 because of concerns over their finances, operations, or market strategies. However, OIG reports that CMS oversight was not able to stop the collapse of almost half of all CO-OPs. OIG provides the following recommendations for CMS oversight moving forward: (1) continue to work with operational CO-OPs to improve their financial condition; (2) continue the use of corrective action and enhanced oversight plans, especially for those CO-OPs with net losses and no remaining CO-OP loan funds to be drawn down; and (3) continue to work with States to ensure that CO-OP plan participants receive continuous coverage and access to plan providers and services.

OIG's report is available at:
https://oig.hhs.gov/oas/reports/region5/51600027.pdf

CMS Issues Guidance Clarifying Requirement that Hospitals Be "Primarily Engaged" in Providing Inpatient Services

On September 6, 2017, the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services ("CMS") published a memorandum explaining the requirement under Section 1861(e) of the Social Security Act that a facility must be "primarily engaged" in the provision of inpatient services to qualify as a hospital under Medicare.

The memorandum – which was sent to state survey agency directors – states that "CMS considers multiple factors and will make a final determination based on an evaluation of the facility in totality." The memorandum goes on to provide a non-exhaustive list of such factors, including the number of off-campus outpatient locations, the number of

provider based emergency departments, the number of inpatient beds related to the size of the facility and scope of services offered, volume of outpatient surgical procedures compared to inpatient surgical procedures, and staffing patterns. The memorandum explains that having the capacity to provide inpatient care is not the same as actually providing inpatient care to patients, and that survey agencies should not conduct surveys for compliance where there are less than two inpatients receiving care at the facility. In such situations, a review of the facility's admissions data will instead be conducted to determine whether the facility had an average daily census ("ADC") of two or more and an average length of stay ("ALOS") of at least two or more midnights. According to the memorandum: "If the facility does not have a minimum ADC of two inpatients and an ALOS of two over the last 12 months, the facility is most likely not primarily engaged in providing care to inpatients . . . ." CMS retains the final authority to determine whether a facility qualifies as a hospital for Medicare purposes.

CMS' memorandum is available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-44.pdf

Bipartisan Coalition of State Attorneys General Addresses Insurers and Expands Investigation of Opioid Crisis

On September 18, 2017, 37 state attorneys general, including New Hampshire Attorney General Gordon MacDonald, sent a letter to health insurers encouraging them to review and revise their payment and coverage policies so that providers are incentivized to prioritize non-opioid pain management prescriptions. The letter, addressed to Marilyn Tavenner, the President and CEO of America's Health Insurance Plans, stated, "[T]he opioid epidemic is the preeminent public health crisis of our time. . . .The unnecessary over-prescription of opioid painkillers is a significant factor contributing to the problem."

The following day, the bipartisan coalition of state attorneys general announced it was expanding its investigation into opioid manufactures and distributors to determine whether the companies engaged in unlawful practices in the marketing and distribution of opioids. The coalition served subpoenas and document requests on the following five pharmaceutical manufacturers: Endo International plc; Janssen Pharmaceuticals; Teva Pharmaceutical Industries Ltd./Cephalon Inc.; and Allergan Inc. New York Attorney General Eric T. Schneiderman noted in its announcement of the expanded investigation that it also demanded documents from distributors AmerisourceBergen, Cardinal Health, and McKesson, remarking that together they account for approximately 90 percent of the nation's opioid distribution and make nearly $500 billion a year in revenue.

A link to the full text of the September 18, 2017 letter is available at: http://www.naag.org/assets/redesign/files/sign-on-letter/Final%20NAAG%20Opioid%20Letter%20to%20AHIP.pdf

New Items Added to 2017 OIG Work Plan

On September 15, 2017, the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") added a number of action items to its work plan as part of its ongoing effort to increase transparency through monthly updates. New items include: examination of the federal marketplace enrollment systems to focus on operational readiness, internal controls, and IT security; investigating whether HHS has sufficiently implemented incident response capabilities for detecting, reporting, and responding to security incidents; reviewing Medicaid health home programs for compliance with relevant Federal and State requirements; determining whether long term care facilities complied with new Federal requirements for life safety and emergency preparedness for the period May 4, 2016 through November 15,

2017; and examining whether Part D sponsors complied with Medicare requirements for reporting direct and indirect remuneration.

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

Medicare Paid New England Providers Twice for Non-physician Outpatient Services Provided Shortly Before or During Inpatient Stays

On September 21, 2017, the Department of Health and Human Services Office of Inspector General (OIG) issued an audit report for Medicare Part A Inpatient Prospective Payment System ("IPPS") Hospitals. The audit looked at Medicare payments made by National Government Services ("NGS") for non-physician outpatient services provided within 3 days prior to the date of admission, on the date of admission, or during IPPS stays (excluding date of discharge). Audit findings revealed that NGS payments were correct for 54 of the 129 non-physician outpatient services that were sampled. However, for 75 services that were sampled, NGS paid 41 providers twice—as part of the IPPS payment and the Part B payment—which resulted in total overpayments of $287,655. The errors were attributed to hospitals not understanding Medicare billing requirements, controls that failed to prevent or detect incorrect billing, and/or providers being unaware that the beneficiaries were inpatients at other hospitals. Additionally, Medicare payment system controls, at the time of each hospital's claim submissions, did not prevent or detect overpayments for such incorrectly billed services. On the basis of the sample results, the OIG estimated that at least $1.3 million in overpayments were made to outpatient hospitals during calendar years 2013 and 2014 because of these errors.

The OIG and NGS recommend that all IPPS hospitals exercise reasonable diligence to investigate their Medicare claim payments from calendar years 2013 through the present, return any identified overpayments to Medicare (in accordance with the 60-day rule), and identify/track any returned overpayments made based on this recommendation.

The full report can be found at https://oig.hhs.gov/oas/reports/region1/11500511.asp

Vulnerabilities Remain in Medicare Hospital Outlier Payments

On September 22, 2017, the Department of Health and Human Services Office of Inspector General ("OIG") issued a report stating that Medicare contractors have not consistently referred qualified hospital cost reports for reconciliation. Furthermore, the Centers for Medicare & Medicaid Services ("CMS") did not consistently ensure that Medicare contractors reconciled the outlier payments associated with the cost reports that were referred. The result is nearly $426 million in funds due to Medicare. The OIG advised CMS to: 1) ensure that Medicare contractors follow through with the OIG's recommended corrective actions (including overpayments made to Medicare or hospitals); 2) Determine whether cost reports that exceeded the three-year reopening limit may be re-opened due to similar fault, and if so, work with the Medicare contactors to re-open them; 3) Ensure that Medicare contractors review all cost reports submitted since the end of the audit periods in the OIG's previous reviews and ensure that those whose outlier payments qualified for reconciliation are correctly identified, referred, and reconciled in accordance with Federal guidelines; 4) Maintain a system that identifies and tracks referred cost reports and that recalculates outlier payments on the basis of claim submissions made by hospitals.

The full report may be accessed here: https://oig.hhs.gov/oas/reports/region7/71402800.pdf

OIG Reports that States Improperly Determined Eligibility for ACA Marketplaces

On September 28, 2017, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") issued a report stating that, "CMS failed to effectively ensure that states' Affordable Care Act marketplaces always properly determined individuals' eligibility for qualified health plans and insurance affordability programs." The OIG said that the Centers for Medicare & Medicaid Services ("CMS") provided oversight and technical assistance, however, it did not ensure that all State marketplaces (1) had the system functionality to verify individuals' eligibility for qualified health plans ("QHP"s) and insurance affordability programs; or (2) had or used the system to determine ineligibility for individuals who had not filed a tax return to reconcile the premium tax credit. Furthermore, CMS failed to ensure that all of the marketplaces completed required independent audits. The OIG explained that without effective oversight, CMS cannot confirm that State marketplaces properly determine individuals' eligibility or reduce the risk that individuals receive undue financial assistance. The OIG also identified three weaknesses in CMS's procedures for SMART reviews (a reporting document that State marketplaces submit annually to CMS to demonstrate that they meet program integrity standards.) The OIG recommended that CMS set deadlines for marketplaces to develop eligibility systems and seek legislative authority to establish them; monitor marketplaces' progress with the systems; require independent audits for marketplaces. Procedural recommendations were made for CMS' SMART reviews.

The full OIG report may be accessed here: https://oig.hhs.gov/oas/reports/region9/91601002.asp

HRSA Delays Effective Date for 340B Ceiling Price and Civil Monetary Penalties Rule

On September 29, 2017, the Health Resources and Services Administration ("HRSA") published a delay in the effective date of a January 5, 2017 final rule that set forth the calculation of the ceiling price and application of civil monetary penalties under section 340B of the Public Health Service Act ("PHSA"), known as the ''340B Drug Pricing Program'' or the ''340B Program.'' The final rule applied to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. HRSA has decided to delay the implementation and enforcement of the rule until July 1, 2018 in order to provide regulated entities with more time to implement the rule's requirements, allow for a more deliberate consideration of alternative and supplemental regulatory provisions, and ensure there is sufficient time for additional rulemaking.

More information about the rule and the delay can be found here: https://www.gpo.gov/fdsys/pkg/FR-2017-09-29/pdf/2017-20911.pdf

CMS Withdraws Proposed Rule on New Part B Drug Payment Model

On October 4, 2017 the Centers for Medicare & Medicaid Services ("CMS") withdrew a proposed rule issued on March 11, 2017 titled, ''Medicare Program; Part B Drug Payment Model'' (81 FR 13230). The rule proposed the Part B Drug Payment Model as a two-phase model that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. CMS withdrew the rule because of "the complexity of the issues related to the proposed model design and the desire to increase stakeholder input."

More information about the proposed rule and the decision to withdraw it can be found here: https://www.gpo.gov/fdsys/pkg/FR-2017-10-04/pdf/2017-21420.pdf

OIG Says MACs Should be Tracking and Collecting More Overpayments

On September 27, 2017, the Department of Health and Human Services Office of Inspector General ("OIG") issued a report titled *Enhancements Needed in the Tracking and Collection of Medicare overpayments Identified by ZPICs and PSCs*, in which it noted that Medicare Administrative Contractors (MACs), had failed to collect approximately 80% of the overpayment amounts identified for fiscal year 2014. For 2014, the MACs sought to collect $482 million from providers, however, as of September 2015, they had only collected $96 million. The MACs cited that some of their difficulties with collections were due to providers declaring bankruptcy, providers who were no longer in business, and providers who were revoked from Medicare or on a payment suspension. The OIG found that the MACs along with the Zone Program Integrity Contractors ("ZPIC"s) and the Program Safeguard Contractors ("PSC"s) have difficulties tracking referrals and collections, explaining that often the referral data reported by the ZPICs and PSCs did not match the MACs' data. The OIG made a number of recommendations, including for the Centers for Medicare & Medicaid Services ("CMS") to use a unique identifier for each overpayment; to create a standard report format for both overpayment referral reports and overpayment collections, and to require a surety bond for home health providers (as those providers accounted for the largest overpayment referral dollars for FY 2014). Overall, CMS agreed with the OIG's recommendations, however it stated it was evaluating the surety bond requirement because it wanted to avoid undue burden on providers.

The report may be read in full at:
https://oig.hhs.gov/oei/reports/oei-03-13-00630.pdf

OIG Report Approves of Further Expansion of Part B Drug Price Substitution Policy

On October 2, 2017, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") published a report, *Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2015 Average Sales Prices*. The report analyzed the effectiveness of the price substitution policy utilized by the Centers for Medicare & Medicaid Services, under which it may substitute a lower reimbursement price for a drug under Part B whenever the average sales price ("ASP") of the drug exceeds average manufacturer price ("AMP") by 5 percent or more in the previous 2 quarters or in 3 of the previous 4 quarters.

OIG found that CMS substituted a lower reimbursement price for 13 drugs on the basis of 2015 data, saving Medicare and its beneficiaries $5.4 million over one year. OIG recommends further expansion of the price substitution policy, including substituting a lower price when the ASP exceeds the AMP by 5 percent or more in a single quarter, which OIG believes could save up to an additional $17 million over one year. CMS is currently opposed to further expansion of price substitution, but noted that its opinion could change based on future data.

OIG's report is available at: https://oig.hhs.gov/oei/reports/oei-03-17-00360.pdf

OIG Report Recommends Increased Tracking of Costs for Faulty Devices

On October 2, 2017, On October 2, 2017, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") published a report, *Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices*. The report was conducted following concerns raised by the Centers for Medicare & Medicaid Services ("CMS") that Medicare expenditures associated with recalled or prematurely failed medical devices were not being reliably tracked, despite stating its intention to do so almost a decade ago. After reviewing Medicare claims from 2005 through 2014 for replacements of selected cardiac devices, OIG determined that costs related to the

replacement of recalled or prematurely failed medical devices could not be identified and tracked using only claim data. OIG was able to utilize claim and other date through a labor-intensive audit process to estimate that services related to the replacement of the selected cardiac devices cost Medicare approximately $1.5 billion during the years reviewed, including $140 million in beneficiary copayment and deductible liabilities. OIG's main recommendation after conducting its review and making its cost estimates is for CMS to modify current claim forms to include spaces for more device-specific information that would allow CMS to more effectively identify and track costs related to recalled or prematurely-failed devices.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region1/11500504.pdf

GOP's Latest ACA Repeal Effort Fails for Lack of Votes

On September 13, 2017, Senate Republicans unveiled their latest effort to repeal and replace the Affordable Care Act, the so-called Graham-Cassidy bill, named after its main sponsors Sens. Lindsay Graham and Bill Cassidy. As with previous attempts, the latest bill makes various substantive changes to the current health care system, including repealing the individual and employer mandates, creating a market-based grant program to provide funding to states, and reshaping Medicaid by transforming it into a per capita cap model starting in 2020. The bill suffered a major setback on September 22 when Sen. John McCain announced that he would not support the bill in its current state. With Sens. Rand Paul and Susan Collins having previously stated their opposition to the bill, Sen. McCain's announcement all but destroyed any hope of passing a repeal and replace bill before the September 30 reconciliation deadline requiring only a simple majority. Following this latest setback, numerous lawmakers from both parties have called for the resumption of bipartisan talks to improve the current health care framework.

STATE DEVELOPMENTS

Commission Studying Medicaid Expansion Faces December 1, 2017 Deadline to Submit Report

The 15-member Commission to Evaluate the Effectiveness and Future of the Premium Assistance Program has until December 1, 2017 to make its report to the New Hampshire Legislature. The Premium Assistance Program is the mechanism through which 50,000 New Hampshire residents have obtained coverage under the New Hampshire Health Protection program also known as expanded Medicaid. Currently the program is set to expire on December 31, 2018. New Hampshire was one of 32 states which opted for the expanded Medicaid program but only one of 5 states that did not enroll its expansion population into the already existing traditional Medicaid program. Instead it opted to offer premium assistance to allow eligible individuals to purchase insurance in the marketplace offered on the exchange. The result has been a significant increase in premiums in the individual marketplace due, in part, to the increased cost of claims associated with the Medicaid expansion population. The Commission is considering a number of options including continuing the program in its current form, moving all or some of the expanded Medicaid population into the traditional Medicaid program and offering a re-insurance program to stabilize the market place. While the Commission members appear to be in favor of continuing the Medicaid expansion program in some form, the full legislature will be responsible for making the ultimate decision regarding its future.

2017 LEGISLATIVE UPDATES

2018-2004 HB **Title: relative to the New Hampshire health protection program.**

2018-2010 HB **Title: relative to the transparency and cost control of**

pharmaceutical drug prices.

2018-2032 HB **Title: relative to information regarding abortion.**

2018-2033 HB **Title: relative to regulation of assistant physicians.**

2018-2034 HB **Title: relative to maintenance of certification by physicians or applicants for a license to practice medicine in New Hampshire.**

2018-2116 HB **Title: prohibiting Medicaid from paying for sex reassignment surgery.**

2018-2147 HB **Title: establishing an office of inspector general.**

2018-2161 HB **Title: deleting the sunset provision on the law relative to the practices of pharmacy benefit managers.**

2018-2203 HB **Title: prohibiting release of certain information relative to users of therapeutic cannabis to federal agencies.**

2018-2204 HB **Title: establishing a commission to assess benefits and costs of a "health care for all" program for New Hampshire.**

2018-2205 HB **Title: relative to newborn screening for Krabbe Leukodystrophy.**

2018-2207 HB **Title: making hormonal contraceptives available directly from pharmacists by means of a collaborative pharmacy practice agreement.**

2018-2209 HB **Title: relative to notification procedures and certain sunset provisions of the New Hampshire health protection program.**

2018-2222 HB **Title: relative to the rights of conscience for medical professionals.**

2018-2233 HB **Title: establishing a New Hampshire single payor health care system.**

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

BIOS

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