NH LEGAL UPDATE

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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.

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FEDERAL DEVELOPMENTS

OIG Issues Advisory Opinion Concluding that Provider Lookup Website's Inclusion of Per-Click Sponsored Provider Profiles Presents a Low Risk of Fraud and Abuse

On September 10, 2019, the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") issued Advisory Opinion No. 19-04, which addresses a technology company's proposal to make the following visible to Federal health care program beneficiaries: (i) its online healthcare directory for searching and booking medical appointments, where healthcare professionals pay, or would pay, per-click or per-booking fees to be listed in the directory; and (ii) sponsored advertisements on its online healthcare directory and third-party websites, where healthcare professionals pay, or would pay, per-impression or per-click fees for such sponsored advertisements. OIG concluded first that while the proposed arrangement does include the provision of remuneration to beneficiaries—in the form of the website's service—it would be unlikely to influence a beneficiary's decision to receive services from a particular provider. Next, OIG stated that the proposed arrangement does implicate the Anti-Kickback Statute, but that it would present only a low risk of fraud and abuse because: 1) the per-click fees charged to providers would be set in advance, would not exceed fair market value, and would not vary with the volume or value of Federal health program business generated by the website for a particular provider; 2) the website is not a provider or supplier, so its relationship with beneficiaries is not one that raises particular concerns of undue influence; 3) the website's services would not be directed only at Federal health care program beneficiaries; 4) the website's services are not related to specific items or services beneficiaries may obtain from providers; and 5) the website would not provide anything of value to beneficiaries to induce them to use the website or select a particular provider, other than the value of the website's service itself.

Advisory Opinion No. 19-04 is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-04.pdf.

OIG Issues Advisory Opinion Approving of FQHC's Proposal to Purchase Real Estate from Excluded Person

On September 11, the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") issued Advisory Opinion No. 19-05, which addresses the requesting Federally-Qualified Health Center's ("FQHC") proposed purchase of real estate from a limited liability company owned, in part, by an excluded individual. In its request for an advisory opinion, the FQHC certified that the purchase price would be based on a fair market appraisal of the real estate, that the FQHC would not seek reimbursement in any way from any Federal health care program for the cost of the real estate, and that the FQHC would not use Federal funds received from the Health Resources and Services Administration to purchase the real estate. Based on these certifications, OIG concluded it would not impose sanctions on the purchase of the real estate.

Advisory Opinion No. 19-05 is available at: https://oig.hhs.gov/fraud/docs/advisoryopinions/2019/AdvOpn19-05.pdf.

First Settlement with OCR under Right of Access Initiative

On September 9, the Office for Civil Rights ("OCR") announced its first enforcement action under its Right of Access Initiative, its promise to vigorously enforce the rights of patients to receive prompt access to their medical records without being overcharged. Bayfront Health St. Petersburg ("Bayfront"), located in St. Petersburg, Florida agreed to pay $85,000 and enter into a corrective action plan after the hospital failed to provide a mother timely access to records about her unborn child. After the mother complained to OCR, Bayfront finally provided the requested records nine months after the initial request. Bayfront's corrective action plan includes one year of monitoring by OCR.

To read OCR's press release on the settlement, see here: https://www.hhs.gov/about/news/2019/09/09/ocr-settles-first-case-hipaa-right-access-initiative.html

To read the Corrective Action Plan Resolution Agreement in full, visit here: https://www.hhs.gov/sites/default/files/bayfront-st-pete-ra-cap.pdf

OIG Says CMS Should Use Error Rate Testing Data to Identify High-Risk Home Health Agencies

On September 9, the Office of Inspector General ("OIG") issued a data brief stating that the Centers for Medicare & Medicaid Services ("CMS") should use Comprehensive Error Rate Testing ("CERT") data along with aspects of its Fraud Prevention System to reduce improper payments and the error rate for claims paid to home health agencies ("HHAs"). After a review of CERT data from fiscal years 2014 to 2017, OIG found that Medicare paid more than $4 billion to 87 high-risk HHAs. OIG said that 78% of the CERT-reviewed payments were improper, amounting to approximately $1 million in improper payments. Although CMS acknowledged that HHAs are a major source of improper payments, it did not agree with OIG's methodology for identifying high-risk HHAs.

The data brief may be found here: https://oig.hhs.gov/oas/reports/region5/51700035.asp

OIG Report Identifies Extremely High Incidence of Improper Billing for Emergency Ambulance Transports from Hospitals to SNFs

On September 16, the U.S. Department of Health and Human Services' Office of the Inspector General ("OIG") published a report titled "Medicare Incorrectly Paid Providers for Emergency Ambulance Transports from Hospitals to Skilled Nursing Facilities." The report found that 99% of claims reviewed for emergency ambulance transport from hospitals to skilled nursing facilities ("SNFs") were billed incorrectly, and that Medicare contractors paid approximately 86% of the incorrectly billed claims. OIG's review of claims for transportation to SNFs revealed that oversight from the Centers for Medicare & Medicaid Services was inadequate, resulting in an estimated $849,170 in incorrect payments from 2015 through 2017 and likely an additional $119,548 in improper payments in 2018. The report includes OIG's recommendation that CMS develop a fraud prevention model specific to this type of transport. CMS concurred with the recommendations.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region9/91803030.pdf.

U.S. District Court Rejects CMS' Expansion of Site-Neutral Payments to Grandfathered Provider-Based Departments

On September 17, the U.S. District Court for the District of Columbia struck down the Centers for Medicare & Medicaid Services' ("CMS") attempt to impose site-neutral payment rates on off-campus provider-based departments ("PDBs") that were specifically grandfathered under the applicable statute. The District Court's order was issued in *American Hospital Ass'n v. Azar*, No. 18-2841 (D.D.C.), in which the American Hospital Association and other plaintiffs filed suit challenging CMS' calendar year 2019 outpatient prospective payment system ("OPPS") final rule. Under the Balanced Budget Act of 2015, site-neutral payments were to be imposed for new off-campus PBDs after November 2, 2015, but would not apply to PBDs in existence at that time. Despite this clear distinction, CMS in its 2019 OPPS final rule expanded the site-neutral payment policy to evaluation and management services performed at grandfathered PBDs. The District Court rejected this action, holding that CMS' rule was contrary to the statutory mandate. The District Court declined to order a specific remedy, instead remanding the matter back to CMS for further proceedings.

The District Court's decision is available at: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2841-31.

Provider Organizations Demand Answers for CMS' Failure to Pay APM Participation Bonus for 2017

On September 17, nine organizations representing an array of providers sent a letter to Seema Verma, Administrator for the Centers for Medicare & Medicaid Services ("CMS") seeking an explanation for CMS' failure to pay the bonuses due to more than 90,000 clinicians as a result of their participation in Advanced Alternative Payment Models ("APMs"). The bonuses were authorized under the 2015 Medicare Access and CHIP Reauthorization Act ("MACRA") as an incentive to encourage providers to participate in risk-bearing payment models. No bonuses have been paid since the APMs began in 2017, however providers who participated in MACRA's Merit-Based Incentive Payment System ("MIPS") have been receiving bonuses since January for their participation in that program in 2017. The letter states that the reason for the delay in APM bonus payments is unclear, and requests that CMS expeditiously pay the bonuses that are currently due and commit to paying future bonuses by June 30th of each year that they become due.

The letter to Administrator Verma is available at: https://www.apg.org/wp-content/uploads/2019/09/091719-AAPM-Bonus-Letter.pdf.

A press release from America's Physician Groups—one of the signatories to the letter—is available at: https://www.apg.org/news/aapm/.

CMS Issues Final Rule for Discharge Planning

On September 30, the Centers for Medicare & Medicaid Services ("CMS") published its final rule revising discharge planning requirements for hospitals (including short-term acute care and long-term care, rehabilitation hospitals, psychiatric hospitals, childrens' hospitals, cancer hospitals, critical access hospitals, and home health agencies). The final rule also implements requirements to give patients and their families access to information to help them make informed decisions about post-acute care and goals of treatment and care preferences, in order to ultimately reduce the chances of rehospitalizations. A new discharge planning process under the final rule for critical access hospitals and home health agencies requires the discharge or transfer of a patient along with his or her necessary medical information to not only post-acute care service providers but also to outpatient service providers responsible for the patient's follow up or ancillary care. In a Fact Sheet on the final rule, CMS says that the rule empowers patients to make informed decisions as they are discharged from acute care to post-acute care.

The final rule as published in the Federal Register may be read here: https://www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals

A CMS Fact Sheet on the final rule is found here: https://www.cms.gov/newsroom/fact-sheets/cms-discharge-planning-rule-supports-interoperability-and-patient-preferences

CMS Issues Final Rule to Simplify Conditions of Participation

On September 30, the Centers for Medicare & Medicaid Services ("CMS") published a final rule advancing its Patients over Paperwork Initiative with a goal of increasing administrative efficiency as well as increasing transparency. The rule finalizes three different proposed rules into one, including: (1) *Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction ("Omnibus Burden reduction")*, published September 20, 2018; (2) *Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care*, published June 16, 2016; and (3) *Fire Safety Requirements for Certain Dialysis Facilities*, published November 4, 2016. As explained in a CMS Fact Sheet, the three rules address reforms to Medicare regulations that are considered obsolete, unnecessary, or excessively burdensome on providers and suppliers.

The final rule as published in the Federal Register may be read here: https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and

A CMS Fact Sheet on the final rule is found here: https://www.cms.gov/newsroom/fact-sheets/omnibus-burden-reduction-conditions-participation-final-rule-cms-3346-f

CMS Needs More Oversight of Manufacturer Price Reporting says OIG

On September 20, the Office of Inspector General ("OIG") issued a report calling for the Centers for Medicare & Medicaid Services ("CMS") to improve its oversight of manufacturer calculations of average sales prices ("AMPs") and best prices ("BPs"). Using a sample of drug manufacturers participating in the Medicaid Drug Rebate Program, OIG found that nearly two-thirds of reporting manufacturers wanted additional guidance from CMS on their use of "reasonable assumptions" when calculating AMPs and BPs. OIG determined that oral specialty drugs, value-based purchasing arrangements, bona fide service fees, and rebates to pharmacy benefits managers were areas that needed particular attention from CMS. Specifically, OIG recommends that CMS: (1) issue guidance related to value-based purchasing agreements; (2) assess the costs and benefits of implementing a targeted process to review certain assumptions; and (3) implement a system to share responses to manufacturer technical assistance inquiries. CMS agreed with all three recommendations.

The OIG report, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices*, may be accessed here: https://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf

FDA Warns of Potential Cybersecurity Risks for Connected Medical Devices, Hospital Networks

On October 1, the U.S. Food and Drug Administration ("FDA") issued a safety communication titled "URGENT/11 Cybersecurity Vulnerabilities in a Widely-Used Third-Party Software Component May Introduce Risks During Use of Certain Medical Devices." The communication provides information about eleven vulnerabilities that a security firm had identified as potentially allowing anyone to remotely take control of a medical device and change its function, cause denial of service, or cause information leaks or logical flaws. The FDA recommends that providers: advise patients who use medical devices that may be affected; remind patients who use medical devices to seek medical help right away if they think operation or function of their medical device changed unexpectedly; and work with device manufacturers to determine which medical devices in their facilities or in use by their patients could be affected by these vulnerabilities and develop risk mitigation plans.

The safety communication is available at: https://www.fda.gov/medical-devices/safety-communications/urgent11-cybersecurity-vulnerabilities-widely-used-third-party-software-component-may-introduce.

Trump Signs Executive Order to Protect and Improve Medicare, Oppose Single-Payer System

On October 3, President Trump signed an "Executive Order on Protecting and Improving Medicare for Our Nation's Seniors." The purpose of the executive order is to reaffirm the administration's commitment to the current Medicare system in the face of calls from some politicians to move to a "Medicare for All" or single-payer system. Such a system, according to President Trump, would eliminate the choices that are currently available to Medicare beneficiaries. The executive order contains several directives to the U.S. Department of Health & Human Services including to: provide more plan choices to seniors; improve access through network adequacy; enable providers to spend more time with patients; encourage innovation for patients; reward care through site neutrality; empower patients, caregivers, and health care providers; and reducing obstacles for improved patient care. Specific directives include: implementing a payment model that would allow beneficiaries to share more directly in the savings from the Medicare Advantage ("MA") program; modifying Medicare fee-for services ("FFS") payments to more closely reflect

MA prices, and inject market pricing into Medicare FFS reimbursement; and propose a regulation adjusting network adequacy requirements for MA plans.

The executive order is available at: https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/.

Major Changes Proposed to Stark Law and Anti-Kickback Statute

On October 9, the Department of Health and Human Services ("HHS") released proposed rules on both the Stark Self-Referral Prohibition ("Stark Law") and the Medicare Anti-Kickback Statute ("AKS"). The proposed regulations are issued by the Centers for Medicare & Medicaid Services ("CMS") and the Office of Inspector General ("OIG") and take into consideration comments responding to Requests for Information by the two agencies in the summer of 2018.

With respect to the AKS, the proposed rule contains both new safe harbors as well as changes to existing safe harbors. The OIG explained that its proposals are designed to allow for beneficial innovations in health care delivery; to avoid regulations that do not reflect the most current understanding of science, medicine, and technology; and to make safe harbor protections that can be used by a variety of different providers, regardless of type or size. Three of the new safe harbors relate to value-based enterprises ("VBEs") which are networks of individuals or entities that collaborate to achieve a value-based purpose. The three VBE safe harbors are: (1) care coordination arrangements; (2) value-based arrangements with substantial downside financial risk; and (3) value-based arrangements with full financial risk. Other new safe harbors include those for the provision of cybersecurity technology to potential referral sources and a codification of a statutory exclusion under the Balanced Budget Act of 2018 excluding incentive payments made to a beneficiary under an ACO Beneficiary Incentive Program.

Proposed changes to existing safe harbors include those made to the personal services and management safe harbor, which would protect payments made for certain outcomes, such as payments made from a hospital to a physician to improve infection rates and replacement of the current requirement that the aggregate payment be set forth in advance with the requirement that only the methodology be set in advance. Additional modifications under the proposed rule are made to the warranty safe harbor and the local transportation safe harbor.

Under the Stark Law, the proposed rule also focused on supporting VBEs with three new exceptions: (1) Full Financial Risk (applicable to VBEs in an arrangement where participants have assumed full financial risk for the cost of all patient care items and services covered by the applicable payor for each patient in a target area for a particular time period); (2) Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician (where remuneration is protected if a physician has meaningful downside risk for failure to achieve the value-based purpose of the VBEs; and (3) Value-Based Arrangements (that protects the arrangement regardless of the level of risk of the VBE or its participants).

Among other changes, the proposed Stark Law rule also proposes clarification to several definitions, including those for "designated health services," "physician," "referral," "remuneration," and "transaction."

Comments on both proposed rules are due December 31, 2019.

The proposed rule for the Anti-Kickback Statute as published in the *Federal Register* on October 17, 2019, may be found here: https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the

The proposed rule for the Stark Law as published in the *Federal Register* on October 17, 2019, may be found here: https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations

Final Rule for Home Health Prospective Payment System

On October 31, the Centers for Medicare & Medicaid Services ("CMS") issued its final rule with comment period on the Home Health Prospective Payment System ("HH PPS"), which includes an increase of 1.3% or $250 million in aggregate Medicare payments to home health agencies ("HHAs") in calendar year 2020, as well as a new permanent home infusion therapy benefit. The final rule implements the Patient-Driven Groupings Model ("PDGM") that relies on patient characteristics rather than volume of care. It also finalizes a 30-day payment amount for 2020 of $1,864.03 for HHAs that report certain quality data. Additionally, to reduce fraud, CMS is phasing out pre-payments for home health services so that they will be eliminated completely by 2021. Also under the final rule, therapist assistants will now be able to perform maintenance therapy under the Medicare home health benefit if permitted under state practice regulations.

With respect to home infusion drug therapy, home infusion drugs will be grouped into three payment categories, each with a unit of single payment. Payment will be made in accordance with specified infusion codes and units for such codes under the Physician Fee Schedule. CMS will also be paying more for the first home infusion visit to account for the cost of initiating the service.

The final rule with comment period is effective January 1, 2020. Comments are due no later than December 30, 2019.

The final rule as published in the *Federal Register* may be found here: https://www.federalregister.gov/documents/2019/11/08/2019-24026/medicare-and-medicaid-programs-cy-2020-home-health-prospective-payment-system-rate-update-home

A CMS Fact Sheet about the final rule may be read here: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-calendar-year-2020-payment-and-policy-changes-home-health-agencies-and-calendar-year

Approximately $1.9 Billion Expected for Value-Based Incentive Payments in 2020

On October 29, the Centers for Medicare & Medicaid Services ("CMS") announced that in Fiscal Year 2020, more hospitals will see positive payment adjustments than negative adjustments under the Value-Based Purchasing ("VBP") Program. In a Fact Sheet, CMS estimated that the amount for distribution under the VBP Program would be $1.9 billion. The VBP Program is designed to pay for quality rather than volume of care provided to patients, and makes adjustments to what Medicare pays to hospitals under the Inpatient Prospective Payment System based on four measurement domains: clinical outcomes; safety; person and community engagement; and efficiency and cost reduction.

The CMS Fact Sheet may be found here: https://www.cms.gov/newsroom/fact-sheets/cms-hospital-value-based-purchasing-program-results-fiscal-year-2020

OIG Reports that Medicare Overpaid $54.5 Million for Improperly Coded Post-Acute-Care Transfers

On November 1, the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") issued a report based on a review of $212 million in Medicare Part A payments for 18,647 inpatient claims with dates of services from January 1, 2016 through December 31, 2018. OIG found that Medicare overpaid acute-care hospitals $54.4 million for claims that were subject to the post-acute-care transfer policy. Pursuant to that policy, Medicare pays the full Medicare Severity Diagnosis-Related Group ("MS-DRG") payment to an acute care hospital when a patient is discharged home or to certain types of healthcare institutions. However, if the patient is transferred to post-acute care, Medicare only pays a per diem rate for each day of the patient's stay in the hospital. OIG's review found that hospitals were improperly coding discharges, which resulted in the full MS-DRG payment being made, rather than the correct per diem rate. The report states that a contributing factor was that some Medicare contractors did not receive notifications from the applicable edits that the discharge codes were improper. OIG recommended to the Centers for Medicare & Medicaid Services that it recover the identified overpayments, conduct a further audit of claims to identify additional overpayments, and ensure that all contractors are receiving edit updates so they can properly catch incorrect discharge coding. CMS concurred with the recommendations.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region9/91903007.pdf.

OIG Reports that Medicare Paid $337.5 Million More for Certain Orthotic Devices Than Other Payers

On November 4, the U.S. Department of Health & Human Services, Office of the Inspector General ("OIG") issued a report titled "Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made By Select Non-Medicare Payers." In a review of $2.8 billion in Medicare allowable amounts for 7.9 million orthotic devices billed under 161 Healthcare Common Procedure Coding System ("HCPCS") codes during calendar years 2012 through 2015, OIG found that Medicare and its beneficiaries paid $337.5 million more for orthotic devices than non-Medicare payers for the same HCPCS codes. Of this amount, OIG estimates that Medicare paid $270 million and beneficiaries paid $67.5 million. OIG identified that the Centers for Medicare & Medicaid Services ("CMS") currently has authority to adjust the allowable amounts for 95 of the 161 codes reviewed, and that the remaining codes would require statutory changes to adjust. OIG recommended that CMS take action to adjust the 95 codes and seek authority or statutory change to adjust the remaining codes, in order to ensure that Medicare allowable amounts are in alignment with payments made by non-Medicare payers. OIG reports that CMS concurs with the recommendations.

OIG's report is available at: https://oig.hhs.gov/oas/reports/region5/51700033.pdf.

Two Federal Courts Vacate Administration's Conscience Rule

On November 6, Judge Paul A. Engelmayer for the U.S. District Court for the Southern District of New York issued a decision vacating the U.S. Department of Health & Human Services' ("HHS") "Conscience Rule," which was aimed at protecting health care entities and individuals who refuse to provide or pay for medical services because of religious or moral beliefs. Under the rule, a provider's failure to comply with the protection could result in termination of federal funding.

In his 147-page decision, Judge Engelmayer laid out several reasons why he vacated the rule: HHS lacked statutory authority to promulgate the rule; the rule conflicted with EMTALA and Title VII's employer nondiscrimination rule; the rule was arbitrary and capricious and lacked an adequate explanation for the change in policy; and the possible termination of federal funding was an unconstitutional violation of separation of powers and the spending clause.

The day after Judge Engelmayer's decision, Judge Stanley Bastian of the U.S. District Court for the Eastern District of Washington also struck down the rule. As of publication, the government has not filed an appeal of either decision.

Judge Engelmayer's decision is available at: https://www.michigan.gov/documents/ag/NY_Conscience_Rule_-_Order_granting_Ps_MSJ_670928_7.pdf.

CMS Issues OPPS Final Rule, Pushes Ahead With Expansion of Site-Neutral Payments, 340B Cuts Despite Court Orders

On November 12, the Centers for Medicare & Medicaid Services ("CMS") published the CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule ("OPPS Final Rule"). In addition to updates to payment rates and the wage index, the OPPS Final Rule includes key provisions concerning site neutral payments and the 340B drug discount program.

Despite CMS' recent losses in federal court over its expansion of the site neutral payments policy to grandfathered Provider-Based Departments, CMS intends to press forward with the second year of its two-year expansion, arguing that it is not "appropriate at this time to make a change" and that "[t]he government has appeal rights, and is still evaluating the rulings and considering . . . whether to appeal the final judgment." CMS expects the expansion of the site-neutral payment policy to net $800 million in savings in 2020.

CMS is moving ahead with its plan to pay for Part B drugs purchased under the 340B program at the average sales price ("ASP") minus 22.5%, rather than the historic rate of ASP plus 6%. CMS acknowledged in the OPPS Final Rule that a federal court had ruled this year that the rate cuts were unlawful, and the case is currently on appeal to the court of appeals. CMS is seeking comments about potential alternative payment options depending on the outcome of the appeal.

The OPPS Final Rule increases OPPS and ASC payment rates by 2.6% in 2020. The OPPS Final Rule also sets the hospital Inpatient Prospective Payment System post-reclassified wage index for urban and rural areas as the OPPS wage index.

The OPPS Final Rule is available at: https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf.

CMS Publishes Physician Fee Schedule Final Rule

On November 15, the Centers for Medicare & Medicaid Services ("CMS") published the Final Rule for the calendar year 2020 Medicare Physician Fee Schedule, which includes numerous payment and other provisions, with a strong focus on reducing administrative burden.

Payment changes and updates include: aligning evaluation and management ("E/M") codes with the changes adopted by the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel, which results in retaining 5 levels of coding for established patients, reducing the number of levels to 4 for office/outpatient E/M visits for new patients, and revising the code definitions, among other changes; adding flexibility to the physician supervision requirements for physician assistants to clarify that physician supervision is a process in which a PA has a working relationship with one or more physicians to supervise the delivery of their health care services; changing documentation rules so that physicians and non-physician practitioners can review and verify, rather than redocument, notes made by other practitioners; adding three new allowable codes for telehealth for treatment of opioid use disorders; implementing rules for the new Part B benefit for opioid use disorder treatment; and refining the Medicare Shared Savings Program to better align the quality metrics with the Merit-based Incentive Payment System.

The Final Rule is available at: https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other.

CMS' Fact Sheet on the Final Rule is available at: https://www.cms.gov/newsroom/fact-sheets/finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar.

CMS Issues Proposed Rule Aimed at Curbing Abuse of Medicaid Supplemental Payments

On November 12, the Centers for Medicare & Medicaid Services ("CMS") announced a proposed rule aimed at addressing supplemental payments to Medicaid providers, which are additional payments states make to providers above base reimbursement levels for a particular service. According to CMS, supplemental payments have steadily increased from 9.4% of all other Medicaid payments in 2010 to 17.5% in 2017. The proposed rule would establish new reporting requirements for states to provide CMS with certain information on supplemental payments to Medicaid providers, and would establish requirements to ensure that state plan amendments proposing new supplemental payments are consistent with the proper and efficient operation of the state plan and with efficiency, economy, and quality of care. The proposed rule would also impose a three-year sunset on supplemental payment methodologies, requiring states to seek approval from CMS for further supplemental payments.

CMS is seeking comments to the proposed rule by January 17, 2020.

The proposed rule is available at: https://www.federalregister.gov/documents/2019/11/18/2019-24763/medicaid-program-medicaid-fiscal-accountability-regulation.

CMS' fact sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/fact-sheet-2019-medicaid-fiscal-accountability-regulation-mfar.

CMS Issues One Final and One Proposed Rule Aimed at Increasing Price Transparency

On November 15, the Centers for Medicare & Medicaid Services ("CMS") issued two rules—one proposed and one final—aimed at increasing pricing and cost transparency for beneficiaries. The proposed rule would require health plans to make available to beneficiaries real-time information about cost sharing and negotiated rates for in-network providers and allowable amounts for out-of-network providers. The final rule requires hospitals to post on their websites a machine-readable file listing all standard charges. The final rule defines "standard charges" to mean "gross charges, discounted cash prices, payer-specific negotiated charges, and de-identified minimum and maximum negotiated charges." The final rule empowers CMS to enforce this requirement through audits, corrective action plans, and civil monetary penalties of $300 per day.

Comments on the proposed rule will be due 60 days after the rule is published in the Federal Register.

The proposed rule on health plan cost transparency is available at: https://www.hhs.gov/sites/default/files/cms-9915-p.pdf.

A fact sheet on the proposed rule is available at: https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-proposed-rule-cms-9915-p.

The final rule requiring hospitals to post standard charges is available at: https://www.hhs.gov/sites/default/files/cms-1717-f2.pdf.

A fact sheet on the final rule is available at: https://www.cms.gov/newsroom/fact-sheets/cy-2020-hospital-outpatient-prospective-payment-system-opps-policy-changes-hospital-price.

OIG Identifies Overpayments for Chronic Care Management

On November 12, the Office of Inspector General ("OIG") released a report identifying $640,452 in overpayments for chronic care management ("CCM") services during 2015 and 2016. Out of that total, OIG found that $436,877 of those overpayments were due to providers or facilities billing for CCM services more than once for the same beneficiary for the same period. An additional circumstance resulting in overpayments occurred when the same physician billed for both CCM services and overlapping care management services for the same beneficiaries. OIG also identified 37,124 claims totaling $1.2 million in potential overpayments where a CCM services was billed by an outpatient facility, but a corresponding claim was not submitted by a physician. OIG is setting aside those claims for review and determination by CMS. OIG concluded that CMS does not have adequate controls in place to prevent and detect overpayments for CCM services. Specifically, it recommends that CMS recoup $640,452 from providers and instruct providers to refund $173,495 to beneficiaries; review the potential overpayments; and implement claim processing controls, including system edits. CMS agreed with all of OIG's recommendations.

OIG's report may be read in full here: https://oig.hhs.gov/oas/reports/region7/71705101.pdf

US Court in Louisiana says HHS Cannot Recoup without Holding ALJ Hearing

On November 5, the U.S. District Court for the Western District of Louisiana held that a physician is entitled to mandamus relief from the government's attempted recoupment of $4.3 million in claims after the government failed to provide a timely administrative law judge ("ALJ") hearing. Michael Dole, M.D., A Professional Medical Corporation ("APMC") was notified by a Medicare contractor ("MAC") that two overpayments were made, in the respective amounts of approximately $9,000 and $10,500. From the $10,500 overpayment, the MAC used statistical sampling and extrapolated a calculated amount of $4.3 million in overpayments to APMC. Although APMC sought hearings before the ALJ for the $4.3 million amount on July 28, 2017 and for the approximately $9,000 overpayment amount on August 18, 2017, it still had not received a hearing in over two years. Despite that, the government moved forward with recoupment and charged 10.25% in annual interest and withheld all of APMC's current Medicare reimbursements. In making its decision, the court said the government "is clearly shirking its statutorily required responsibility to hold a hearing before an ALJ and issue a decision within 90 days." It also found that the recoupment would force APMC to shut down, leaving patients without a pain management provider in a reasonable geographic area.

The decision in *Dole v. Azar*, No. 1:18-cv-1198 (W.D. La. Nov. 5, 2019) may be read here: https://www.leagle.com/decision/infdco20191112730

STATE DEVELOPMENTS

Health and Human Services Commissioner Will Not Seek Reappointment

On October 14, DHHS Commissioner Jeffrey Meyers announced that he will not seek reappointment to the position which he has held for nearly four years. The Governor nominated and the Executive Council approved the nomination of Kerrin Rounds, the current CFO of the Department, to serve as the interim Commissioner. The Governor also announced a selection committee to interview and recommend candidates to be the new Commissioner. The Selection Committee is comprised of:

- Donnalee Lozeau, Executive Director of Southern New Hampshire Services, Inc. and former Mayor of Nashua;
- Don Shumway, former Commissioner of NH DHHS and former President/CEO of Crotched Mountain Foundation;
- Kris McCracken, President/CEO, Amoskeag Health; and
- Nick Toumpas, former Commissioner of NH DHHS.

The Governor's announcement of the selection committee on November 12th was accompanied by a note indicating that anyone interested in being considered for the position must have emailed their resume by Friday, November 15th.

NH Commissioner of Insurance Orders Two Companies to Stop Selling Illegal Health Insurance

On October 30, the Commissioner of Insurance ordered Aliera Healthcare, Inc. and Trinity Healthcare, Inc. to immediately stop selling or renewing illegal health insurance in New Hampshire. The 1,400 New Hampshire residents currently holding these plans will need to find new health insurance options. Aliera administers and markets health coverage on behalf of Trinity Healthshare, which represents itself as a health care sharing ministry. In a statement by the Commissioner, he said that "[t]here are legitimate health care sharing ministries that offer coverage for their members, but Aliera and

Trinity are not one of them." The action taken by the Department came following dozens of complaints and concerns from consumers. Both Aliera and Trinity have 30 days from the date of the order to request a hearing.

Legislators File Bills to Lower Prescription Drug Costs

On October 16th, Senate Democrats filed four proposed initiatives intended to lower prescription drug costs. These initiatives include: changes in the law to allow the importation of low-cost drugs from Canada; an initiative to expand drug pricing transparency and establish a prescription drug affordability board; a bill to prohibit prescription price gouging; and a bill to address rebates paid to pharmacy benefit managers. In a separate announcement, two democratic legislators announced they were filing a bill that would set a price ceiling on the amount patients pay for insulin, noting the skyrocketing cost of the medication.

Open Enrollment Period for Health Insurance Marketplace Runs from November 1-December 15

The open enrollment period to purchase health insurance on the Marketplace runs from November 1, 2019 - December 15, 2019 for coverage beginning on January 1, 2020. There will be three insurance companies offering individual plans on the NH Marketplace for 2020: Anthem; Ambetter from NH Healthy Families; and Harvard Pilgrim Health Care.

2019 LEGISLATIVE SERVICE REQUESTS

HB 2020-2007 Title: relative to laboratory testing

HB 2020-2023 Title: relative to telemedicine and substance use disorder.

HB 2020-2028 Title: relative to noncompete agreements for certain mental health professionals.

HB 2020-2032 Title: relative to copayments for insulin.

HB 2020-2033 Title: requiring insurance coverage for epipens.

HB 2020-2097 Title: relative to regulation of interpreters for the deaf, deaf blind, and hard of hearing.

HB 2020-2145 Title: establishing a hospital merger advisory commission.

HB 2020-2159 Title: relative to HIV/AIDS prophylaxis treatment for minors without parental consent and allowing pharmacists to dispense a limited supply of pre-exposure prophylaxis for the human immunodeficiency virus.

HB 2020-2342 Title: relative to membership on the board of psychologists and the board of licensing for alcohol and other drug use professionals, and relative to insurance credentialing of out-of-state applicants for licensure as alcohol and drug counselors.

HB 2020-2490 Title: establishing the New Hampshire health policy commission.

HB 2020-2493 Title: relative to "In and Out Medical Assistance."

HB 2020-2516 Title: relative to reporting of health care associated infections.

HB 2020-2537 Title: requiring the insurance department to make a report regarding the impact of insurance coverage for pediatric autoimmune neuropsychiatric disorders.

HB 2020-2556 Title: relative to the Medicaid dental benefit working group.

HB 2020-2591 Title: relative to pharmacists-in-charge, the inspection and regulation of prescription drugs by the pharmacy board, and disciplinary actions by the pharmacy board.

HB 2020-2640 Title: relative to retroactive denials of previously paid claims.

HB 2020-2662 Title: relative to allied health professional temporary licensure.

SB 2020-2726 Title: relative to rebates paid to pharmacy benefits managers.

SB 2020-2727 Title: relative to transparency in prescription drug pricing and establishing a New Hampshire prescription drug affordability board.

SB 2020-2728 Title: prohibiting price gouging in the sale of prescription drugs.

SB 2020-2737 Title: relative to prohibiting persons licensed by the board of nursing and other persons from using titles or descriptions of services for the practice of medicine.

SB 2020-2752 Title: relative to certification requirements for speech pathologists.

SB 2020-2784 Title: relative to hearings of the New Hampshire board of nursing.

SB 2020-2846 Title: relative to the New Hampshire granite advantage health care trust fund.

SB 2020-2852 Title: relative to prior authorizations under group health insurance policies and managed care.

SB 2020-2868 Title: relative to prior authorization for prescription drug coverage.

SB 2020-2869 Title: relative to the scope of medical payments under a motor vehicle insurance policy.

SB 2020-2956 Title: relative to prescription medication for treatment or prevention of communicable disease.

SB 2020-2966 Title: relative to penalties for violations of privacy.

SB 2020-2975 Title: establishing an oversight committee on the office of professional licensure and certification.

SB 2020-3085 Title: relative to medication assisted treatment (MAT) by telemedicine and telehealth services.

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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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