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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 UPDATES

Affordable Care Act Implementation

2017 ACA Marketplace Premiums Rise by 25%

On October 24, the U.S. Department of Health and Human Services (HHS) announced that premiums for Affordable Care Act (ACA) marketplace plans will increase by an average of 25% in 2017 in states using the HealthCare.Gov marketplace platform. The median increase in the second-lowest cost silver plan will be 16% in 2017, but when premium data from 4 of the 12 states not using the HealthCare.Gov platform (California, Connecticut, Massachusetts, and Minnesota) are factored in, that increase rises to 22%. New Hampshire is expected to see the smallest rate hike with an average 2% increase as compared to the 25% average increase in other states. The agency noted that many states seeing premium increases had 2016 plan premiums that were well below the national average. In making its announcement, HHS underscored that tax credits protect consumers from rate increases.

There are 167 issuers participating in the Marketplace in HealthCare.gov states in 2017, with 15 new plan issuers entering and 83 issuers leaving. HHS reports that reduced issuer participation in large part reflects multi-state withdrawals by a few large insurers; in particular, withdrawals by United Health and Aetna account for 26 and 17 issuer exits, respectively. Open enrollment for 2017 plans began on November 1.

3 Federal Agencies Jointly Issue ACA Final Rule

On October 31, the U.S. Departments of Health and Human Services (DHHS), Treasury, and Labor issued a final rule that imposes new limits on short-term plans that the agencies say could interfere with the Affordable Care Act (ACA) marketplace risk pool. The final rule says that short-term plans designed to fill coverage gaps on the marketplace are not subject to the same consumer protections under the ACA, which include discrimination based on pre-existing conditions and the coverage of essential health benefits. These plans are intended to cover less than 12 months, however some consumers are using these plans as their primary form of health coverage. The agencies contend that these plans could be targeting healthier individuals for primary (longer than 12 month) coverage, which would adversely affect the ACA marketplace risk pool. The final rule reduces the coverage time for these short-term plans to three months and prohibits their subsequent renewal. The rule also requires these insurers to inform their beneficiaries that their plans are not compliant with the ACA and do not prevent them from owing tax penalties for failing to maintain minimum essential coverage. The rule will be effective on January 1, 2017, with enforcement being delayed on products sold before April 1, 2017 that extends their coverage thru December 31, 2017 in order to accommodate state regulators who already have approved some 12-month short-term plans for the market.

The final rule can be found here:

https://www.gpo.gov/fdsys/pkg/FR-2016-10-31/pdf/2016-26162.pdf

CMS Awards $25 Million for ACA Consumer Protection Oversight

On October 31, the Centers for Medicare and Medicaid Services (CMS) awarded $25.2 million to 22 states and the District of Columbia for enforcing and overseeing issuer compliance with Affordable Care Act (ACA) consumer protections. States may use the money to fund planning and implementing of selected Federal market reforms and consumer protection attributes in the areas of essential health benefits, preventive services, parity in mental health and substance abuse disorder benefits, appeal processes, and reducing the cost of coverage. The agency said 16 states will receive a total of $3.5 million for overseeing compliance with essential health benefits requirements; 19 states will receive $5.3 million for overseeing preventative health services; 10 states will receive $1.4 million to oversee medical loss ratio compliance; 11 states will receive $2.1 million for appeals process oversight; and 20 states will receive $9.3 million for overseeing parity in mental health and substance use disorder benefits. The rest of the money will be used to fund activities that are applicable to consumer protections across all of the selected markets. Among the states receiving funds, New Hampshire will receive $1,120,164.00 for use in the areas of essential benefits, preventive health services, and parity in coverage for mental health and substance abuse disorder coverage. [See additional information in the State update on page 11.]

CDC Reports that Uninsured Rate is Down 8.9% in First Half of 2016

In an October report, the Centers for Disease Control and Prevention (CDC) found that the uninsured rate dropped by 8.9% in the first half of 2016. The report was based on January-June 2016 insurance data from the 2016 National Health Interview Survey, which indicated that 20.2 million individuals gained insurance coverage since the Affordable Care Act (ACA) was enacted in 2010. Notable takeaways from the report included the fact that adults aged 25-34 were almost twice as likely to be uninsured than adults aged 45-64; the fact that low socio-economic status directly correlated with lack of insurance; and the fact that Medicaid expansion states had higher rates of insurance than those states that have not expanded Medicaid.

Other Federal Developments

ONC Issues Health IT Certification Program Final Rule

On October 14, the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) issued a final rule that enhances the Health Information Technology (IT) Certification Program's oversight and developer accountability. The final rule gives the ONC the ability to directly review certified health IT in the event there is a reasonable that: (1) the IT presents a serious risk to public health or safety; or (2) the review of IT could present practical challenges to an ONC-Authorized Certification Body (ONC-ACB), such as the unavailability of information received for a review, or a review that exceeds the capacity of an ONC-ACB's resources. The rule gives ONC the authority to provide direction to and impose corrective action plans on health IT developers, as well as suspend and terminate certifications. The rule also establishes a process for ONC to authorize and oversee accredited testing laboratories (ONC-ATLs) to align with ONC's existing oversight of ONC-ACBs, and facilitates ONC's ability to quickly, directly, and precisely address testing and performance issues.

The final rule is available here:
http://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations

CMS Issues New Medicare Physician Payment Program Final Rule

On October 14, the Centers for Medicare and Medicaid Services (CMS) issued a final rule implementing the Medicare Access and Chip Reauthorization Act of 2015 (MACRA), which replaced the sustainable growth rate formula physician payment model with the Quality Payment Program (QPP). The QPP consists of two tracks: (1) the Merit-based Incentive Payment System (MIPS) – a fee-for-performance model that adjusts payment for services with performance and quality outcome modifiers – and (2) the Advanced Alternative Payment Models (APMs) – models that reward physicians for the quality, rather than quantity of services. The official start of the QPP is January 1, 2017, however CMS has emphasized that after receiving over 4,000 comments during the comment period, the first year will be focused on encouraging participation and educating participating clinicians.

CMS has previously explained that the 2017 performance year will be strictly transitional in its nature and scope, allowing physicians to participate in one of four participation tracks—three different tracks that offer varying flexibilities in reporting data to MIPS and one track that offers participation in Advanced APMs. In the transition year, CMS has adjusted the MIPS performance threshold so that any physician scoring 70 or higher in their performance evaluations will be eligible for the exceptional performance adjustment. CMS envisions 2018 to be another transitional year in order to slowly ramp-up the program standards and performance thresholds. CMS expects between 592,000 and 642,000 providers will be required to participate in MIPS in the transitional year, and estimates that MIPS payment adjustments will be approximately equally distributed between positive and negative MIPS payment adjustments, which will ensure budget neutrality.

CMS expects that between 70,000 and120,000 physicians in 2017 and between 125,000 and 250,000 physicians in 2018 will qualify as Advanced APM participants who do not participate in MIPS but will see a 5% incentive payment bonus from 2019 to 2024. CMS estimates these providers will receive between $333 million and $571 million in 2019.

In 2017, many small, independent practices will be excluded from the new requirements. In an effort to provide education and maximizing participation, $100 million in technical assistance will be available to certain small practitioners, with priority given to practices located in rural areas and medically underserved areas.

In addition to announcing the final rule, CMS has established a website intended to help educate physicians on the QPP: https://qpp.cms.gov/

You can find the final rule in full here: https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm

OIG Issues Advisory Opinion on Subsidized Transportation Between Clinic and Hospital

On October 11, the U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) issued Advisory Opinion 16-10, an opinion concerning a healthcare district's desire to subsidize transportation between its clinic and hospital locations for patients in financial need. The healthcare district is a public agency that owns a hospital and two clinics, one clinic in a different local healthcare district and the other in a medically underserved area. All three locations owned by the organization reside within a DHHS Primary Care Health Professional Shortage Area. The two healthcare districts want to establish a jointly-funded transportation education and subsidization program to help patients, including Federal healthcare program beneficiaries, obtain transportation from the clinic in one

district to the hospital in another district and vice versa. Under the proposed arrangement, a jointly funded transportation coordinator would be available to educate patients of transportation services, and the districts would split the cost for subsidizing the transportation costs for needy patients.

OIG found that two possible streams of remuneration were at issue in the arrangement: (1) remuneration between the two districts and (2) remuneration from the districts to the patients. OIG found that remuneration would certainly occur between the two districts under the arrangement because of the joint funding of the transportation coordinator position and subsidies to needy patients. OIG also found that the second district could be considered a referral source for the first district that operates the clinic. Nonetheless, OIG found that there was little risk of fraud and abuse because both districts were public agencies tasked with providing healthcare directly and with providing assistance in operating facilities or services. In that manner, OIG found that the arrangement fell under the purview of the districts' missions. OIG also found that the educational role of the transportation coordinator did not constitute remuneration. OIG then went on to explain that the subsidies to needy patients would be considered remuneration under the Federal Anti-Kickback Statute and the beneficiary inducements Civil Monetary Penalty, but still found the arrangement to pose a low risk of fraud and abuse. It cited the public nature of the districts, and also noted that the subsidies were incredibly meager, ranging from $0.50 to $2.50 per trip, but would be helping patients in financial need. OIG also noted that the proposal would not be advertised and would only be offered to patients in financial need.

The full advisory opinion can be found here:

https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-10.pdf

OCR Offers HIPAA Cloud Computing Guidance

In guidance issued on October 6, the U.S. Department of Health and Human Services Office for Civil Rights (OCR) clarified that when an entity enlists the services of a cloud services provider (CSP) to create, receive, maintain, or transmit electronic protected health information (EPHI), the CSP is considered a business associate and must comply with the privacy, security, and breach notification requirements of the Health Insurance Portability and Accountability Act (HIPAA). OCR confirmed that CSPs are still considered business associates under HIPAA even if they only store encrypted EPHI without possessing the encryption keys. Furthermore, CSPs are typically ineligible for the conduit exception to HIPAA, as they typically store EPHI rather than just transmit it. OCR also noted that CSPs are not liable for compliance failures that are solely attributable to the actions or inactions of their customers, even though they may still be storing the relevant EPHI. Furthermore, the guidance notes that CSPs that receive and maintain de-identified information in accordance with HIPAA are not considered business associates under the law.

You can access the guidance on the OCR website here:

http://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html

FDA Posts Software as Medical Devices Draft Guidance

On October 10, the International Medical Device Regulators Forum (IMDRF) issued draft guidance concerning conducting clinical evaluations of software as medical devices. The Food and Drug Administration (FDA) posted the guidance in a notice in the Federal Register. The FDA has asked for comments on the draft to be turned in no later than December 13, and is seeking comments on a number of

specific issues, including whether the guidance adequately addresses the relevant clinical evaluation methods and processes for software as medical devices to generate clinical evidence, and whether there are other appropriate methods for generating clinical evaluation evidence that are relevant for software as medical devices beyond those described in the guidance.

You can access the draft guidance here:

https://www.gpo.gov/fdsys/pkg/FR-2016-10-14/pdf/2016-24805.pdf

CMS Issues 2017 Medicare Advantage and Part D Plan Star Ratings

On October 12, the Centers for Medicare and Medicaid Services (CMS) published the 2017 star ratings for Medicare Advantage (MA) and Part D Drug Plans on its Medicare Plan Finder website. About 47% of MA plans with prescription drug coverage (MA-PD) and roughly 49% of Part D plans received four stars or higher. CMS noted that more than 90% of MA-PD enrollees were enrolled in plans with 3.5 stars or higher, and about 41% of Part D enrollees were enrolled in plans rated four stars or higher. The ratings are based on measures in five broad categories: Outcomes; Intermediate Outcomes; Patient Experience; Access; and Process. Outcomes and Intermediate Outcomes continue to be weighted three times as much as Process measures, and Patient Experience and Access measures are weighted 1.5 times as much as Process measures.

You can access the star ratings at the following link:

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.html

Kentucky Supreme Court Rules on PSQIA Privilege

In a September 22 decision, the Kentucky Supreme Court held that patient information collected in a provider's internal patient safety evaluation system (PSES) that is also information required in order to comply with state requirements is not considered patient safety work product, and therefore not privileged, under the Patient Safety and Quality Improvement Act (PSQIA). The finding in *Baptist Health Richmond, Inc. v. Clouse,* 2015-SC-000657-MR (Ky. Sept. 22, 2016) arose from the medical malpractice plaintiff's discovery request for various reports pertaining to his deceased wife. Baptist Health argued that such documentation was privileged under the PSQIA, rendering it undiscoverable.

The Kentucky Supreme Court reviewed precedent in *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014) and also considered new guidance on the PSQIA released by the U.S. Department of Health and Human Services (DHHS) during the time the appeal was pending. The court quoted the DHHS guidance stating that the PSQIA "does not permit providers to use the privilege and confidentiality protections for [patient safety work product] to shield records required by external record keeping or reporting requirements." (*Baptist Health* at 4). The court vacated the trial court's order for Baptist Health Richmond, Inc. to produce the documents and remanded the case with instructions to the court to conduct an *in camera* review to separate the information contained in state-mandated reports for production.

CMS Announces Physician Burden Reduction Pilot Program

On October 13, the Centers for Medicare and Medicaid Services (CMS) announced the launch of an 18-month pilot program that is designed to reduce the medical record review burden for certain physicians practicing in specific Advanced Alternative Payment Models (APMs). The following Advanced APMs will be

included in the pilot: Next Generation ACOs, Medicare Shared Savings Program Track 2 and 3 participants, Pioneer ACOs, and Oncology Care Model 2-sided Track participants. CMS chose these Advanced APMs because they have participating providers who share financial risk with the Medicare program. Phase 1 of the program will concern post-payment reviews from January 1, 2017 to June 1, 2018. During that phase, Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), and the Supplemental Medical Review Contractor will be directed by CMS to consider as a low-priority post-payment medical record reviews for participating providers. In Phase 2, running from April 1, 2017 to June 1, 2018, certain providers will have their pre-payment medical record reviews considered as a low priority by MACs. CMS said that claims from durable medical equipment suppliers, home health agencies, and other providers are excluded from the pilot.

OIG Estimates 82% Error Rate in Payments for Chiropractic Services

In an October report, the U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) estimated that 82% of Medicare Part B payments for chiropractic services were unallowable. The report, *Hundreds of Millions in Medicare Payments for Chiropractic Services Did Not Comply with Medicare Requirements*, focused on 2013 data from which OIG estimated that $358.8 million of a total $438.1 million rendered for chiropractic services by Medicare were overpayments. OIG sampled a total of 105 services with claims using the Acute Treatment (AT) modifier, finding that documentation by chiropractors for 94 services did not support medical necessity under the program. OIG observed that for 37 of those 94 services, the initial treatment date and the date of service were more than 90 days apart, indicating that the service might have been maintenance therapy rather than acute treatment. OIG recommended that CMS determine a reasonable number of necessary chiropractic services relating to spinal subluxation and implement a system to review services in excess of the number. OIG also recommended that CMS re-examine its chiropractor education efforts in regards to Medicare coverage and billing.

St. Joseph Health Enters Into $2 Million HIPAA Settlement

On October 18, the U.S. Department of Health and Human Services (DHHS) Office for Civil Rights (OCR) announced that it had reached a $2.14 million settlement of potential Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule violations with St. Joseph Health (SJH). SJH is a large health system with hospitals, clinics, and physician organizations throughout California, New Mexico, and Texas, that reported to OCR in February 2012 that it discovered that specific files used for the meaningful use program were accessible on the internet via common search browsers from February 1, 2011 to February 13, 2012. The files contained personal health information (PHI). OCR found that SJH had purchased a server to store the files that had a file sharing application embedded into it, leaving the PHI of 31,800 individuals accessible to the public via internet search. OCR noted that SJH had hired contractors to assess vulnerabilities and risk, but due to the patchwork nature of the contracts, such action did not effectuate or constitute the HIPAA-required, organization-wide risk analysis. It also found that SJH failed to conduct an evaluation in response to the environmental and operational changes presented by implementation of the new server. In addition to the monetary settlement, SJH agreed to follow the corrective action plan provided by OCR.

Cigna to End Opioid Addiction Medication Preauthorization

On October 21, the New York Attorney General announced that Cigna had agreed to end its preauthorization policy regarding medication-assisted treatment (MAT) for opioid addiction. The intention of the policy shift is to decrease the amount of time patients in critical need of treatment have to wait to receive it.

According to the Centers for Disease Control (CDC), drug overdoses related to opioid abuses have increased dramatically over the past decade, including over 2,000 drug overdose deaths in New York and over 10,000 overdose deaths nationally in 2014. The CDC considers MAT a proven, effective treatment for individuals with an opioid use disorder. One research study showed that for half the patients treated with buprenorphine/naloxone for addiction to opioid pain relievers, they were abstinent from the drugs 18 months after starting MAT, and after three and a half years 61% of the patients reported abstinence.

OCR & FTC Issue Consumer Health Information Sharing Guidance

In October 21 guidance issued by the U.S. Department of Health and Human Services Office of Civil Rights (OCR) and the Federal Trade Commission (FTC), the agencies remind covered entities and business associates that the Health Insurance Portability and Accountability Act (HIPAA) is not the only law to consider when sharing consumer health information. The guidance highlights the FTC Act as another law that applies to the sharing of consumer health information. The agencies emphasize that the FTC Act requires that the information provided to patients when obtaining authorization to disclose health information must not be deceptive or misleading.

CMS Releases Information on Hospital Value-Based Purchasing Program for FY 2017

On November 1, the Centers for Medicare and Medicaid Services (CMS) published a fact sheet with information about the Hospital Value-Based Purchasing (VBP) Program's projected operations in FY 2017. The VBP Program adjusts what Medicare pays hospitals under the Inpatient Prospective Payment System (IPPS) based on the quality of care they provide to patients. For FY 2017, the applicable percent reduction, the portion of Medicare payments available to fund the program's value-based incentive payments, will increase from 1.75 to 2 percent of the base operating Medicare Severity Diagnosis-Related Group (MS-DRG) payment amounts for all participating hospitals. CMS estimates that the total amount available for value-based incentive payments for FY 2017 discharges will be approximately $1.8 billion.

CMS estimates that for FY 2017, more hospitals will have an increase in their base operating MS-DRG payments than will have a decrease. In total, over 1,600 hospitals will have a positive payment adjustment. About half of hospitals will see a small change in their base operating MS-DRG payments (between -0.5 and 0.5 percent). After taking into account the statutorily mandated 2 percent withhold, the highest performing hospital in FY 2017 will receive a net increase in payments of slightly more than 4 percent, and the lowest performing hospital will incur a net reduction of 1.83 percent.

You can view CMS' fact sheet on this issue at the following link:

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-01.html

CMS Finalizes Hospital Outpatient Prospective Payment and ASC Changes for 2017

On November 1, the Centers for Medicare and Medicaid Services (CMS) published the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule. For CY 2017, CMS is increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.65 percent. Based on this update, CMS estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2017 will be approximately $773 million. CMS is also increasing payment rates under the ASC payment system by 1.9 percent for ASCs that meet the quality reporting requirements

under the ASC Quality Reporting Program. CMS estimates that total payments to ASCs for CY 2017 will be approximately $4,478 million, an increase of approximately $177 million compared to estimated CY 2016 Medicare payments. The rule also finalizes certain changes of the Hospital Outpatient and ASC Quality Reporting Programs.

An unpublished version of the final rule can be found at the following link, and is scheduled for publication in the *Federal Register* on November 14.

https://www.federalregister.gov/documents/2016/11/14/2016-26515/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment

CMS Announces Final Payment Changes for Medicare Home Health Agencies for 2017

On October 31, the Centers for Medicare and Medicaid Services (CMS) announced final changes to the Medicare home health prospective payment system (HH PPS) for calendar year (CY) 2017. In the final rule, CMS estimates that Medicare payments to home health agencies in CY 2017 would be reduced by 0.7 percent, or $130 million based on the finalized policies. The rule decreases the standardized 60-day episode payment rate for CY 2017 by $80.95. The overall impact due to the rebasing adjustments is estimated to be a 2.3 percent decrease in HH PPS payments for CY 2017.

CMS also finalized its proposal to implement the Home Health Value-Based Purchasing (HHVBP) Model for all Medicare-certified home health agencies (HHAs) that provide services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington. For HHAs in these nine states, payment adjustments will be based on each HHA's total performance score on a set of measures for all patients serviced by the HHA, or determined by claims data, plus three new measures where points are achieved for reporting data.

You can view the final rule at the following link:

https://www.federalregister.gov/documents/2016/11/03/2016-26290/medicare-and-medicaid-programs-cy-2017-home-health-prospective-payment-system-rate-update-home

CMS Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System

On October 28, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that updates payment policies and rates under the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services furnished to beneficiaries on or after January 1, 2017. The updated ESRD PPS rate is $231.55. The final rule also made changes to the ESRD Quality Incentive Program (QIP), including payment years 2019 and 2020, under which payment incentives are applied to dialysis facilities to improve the quality of care that they provide.

You can view the final rule at the following link:

https://www.federalregister.gov/documents/2016/11/04/2016-26152/medicare-program-end-stage-renal-disease-prospective-payment-system-coverage-and-payment-for-renal

CMS Finalizes 2017 Physician Fee Schedule Rule

On November 2, the Centers for Medicare & Medicaid Services (CMS) issued the 2017 Physician

Fee Schedule (PFS) final rule, which updates payment policies and rates for services furnished on or after January 1, 2017. Focusing on the importance of primary care, the PFS rule finalizes a number of policies to improve payment for chronic care management, behavioral health, and cognitive impairment.

In order to improve payment accuracy, the PFS rule finalizes a number of coding changes, including revaluating certain existing Current Procedural Terminology (CPT) codes (as required by the Affordable Care Act) and making separate payments for certain existing codes that had previously been bundled into the evaluation and management codes. CMS reported in a fact sheet that the changes will result in 0.32% in net expenditures reductions. CMS also explained that taking into account all adjustments the 2017 PFS conversion factor is $35.89, a $0.09 increase from the 2016 PFS conversion factor.

The PFS rule also adds codes to the list of services eligible to be furnished via telehealth, including end-stage renal disease-related services for dialysis, advance care planning services, and critical care consultations. Regarding Medicare Advantage (MA) (Part C) provider and supplier enrollment, the final rule requires screening and enrollment in Medicare for health care providers and suppliers to contract with an MA organization to provide items and services to beneficiaries enrolled in MA Health Plans. CMS also stated it will make MA bid pricing and medical loss ratio data sets publicly available.

The PFS rule also finalized several policies regarding the Shared Saving Program regulations, including updating Accountable Care Organizations (ACO) quality reporting requirements, modifying the assignment algorithm for assigning beneficiaries to an ACO, and establishing beneficiary protection policies related to the use of the Skilled Nursing Facility 3-day waiver.

An unpublished version of the final rule can be found at the following link, and is scheduled for publication in the *Federal Register* on November 15.

https://www.federalregister.gov/documents/2016/11/15/2016-26668/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

OIG Issues Advisory Opinion

On November 3, the U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) issued Advisory Opinion 16-11 concerning the use of a preferred hospital network as part of Medicare Supplemental Health Insurance (Medigap) policies. As it has opined in the past, the OIG said the proposed arrangement would not trigger Federal sanctions under the civil monetary penalty provisions or exclusion authority provisions of the Social Security Act. The proposed arrangement involves an insurance company ("Requestor") who proposes to enter into a contractual arrangement with a preferred hospital organization (PHO). The PHO would contract with hospitals (the "Network Hospitals") and the Network Hospitals would provide discounts of up to 100% on Medicare Part A inpatient deductibles for the Medigap plan policyholders that would normally be covered by the Requestor. Each time the Requestor receives the discount from the network hospitals, it would pay the PHO an administrative fee. The Requestor stated it would share the savings with their policyholders via $100 premium credits. The OIG gave five reasons why the arrangement presented a low risk of fraud and abuse under the Anti-Kickback Statute, including (1) that the discounts and premium credits would not increase per-services Medicare payments; (2) that the arrangement would not likely increase utilization because the discounts would be effectively invisible to policyholders; (3) that the arrangement would not unfairly affect hospital competition as all Medicare certified hospitals are eligible for participation in the PHO; (4) that it would be unlikely to affect medical judgment because the policyholders' physicians and surgeons would receive no remuneration; and (5) that it would

operate transparently so that policyholders would know they had the freedom to choose hospitals without incurring additional out-of-pocket expenses.

You can access the full advisory opinion here:

https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-11.pdf

CMS Further Delays Part D Enrollment Requirements

On October 31, the Centers for Medicare and Medicaid Services (CMS) delayed the full enforcement of the provider Medicare enrollment requirement for practitioners who write Part D-covered prescriptions to January 1, 2019. The agency had previously delayed enforcement of the prescriber enrollment requirement to February 1, 2017. Citing concerns about beneficiary access to needed care, the agency decided to delay the implementation of the policy yet again. Instead, CMS will be implementing a phased approach to enforcing the requirement leading up to the January 1, 2019 full enforcement date. Beginning in the second quarter of 2017, the prescriber enrollment requirement will be enforced for prescriptions written by individuals who are currently excluded by the Department of Health and Human Services Office of Inspector General, who are revoked by the Medicare program, or who are non-enrolled prescribers with a felony conviction within the last ten years. CMS will also ease the enrollment application process, including allowing prescribers to review, update, electronically sign, and submit a pre-populated enrollment application online. Additionally, CMS will begin targeted, prioritized risk-based outreach and education, including direct mailings and coordination with Part D plans to enroll prescribers of Schedule II drugs or high volumes of Part D drugs. In the third quarter of 2017, CMS will be sending mail-outs to all prescribers not enrolled in the program. Despite delaying enforcement of the prescriber enrollment requirement, CMS encouraged all prescribers who prescribe Part D drugs to enroll in the Medicare program if not yet enrolled.

U.S. Court of Appeals Rules Against Hospitals in DSH Dispute

On October 27, the First Circuit Court held that the U.S. Department of Health and Human Services (DHHS) Secretary properly determined that eight Maine hospitals had received substantial disproportionate share hospital (DHS) overpayments. The core issue in the DSH dispute was whether or not the hospitals should have included patient days for Medicare Part A and Medicaid dual eligible patients, but not supplemental security income (SSI) days, known as “non-SSI type 6” days. The Secretary maintained that the hospitals should not have included the non-SSI type 6 days in their cost reports for calculating DSH claims. The hospitals argued that they included the non-SSI days based on 1997 settlement agreements requiring them to include the non-SSI type 6 days in certain DSH payment calculations and that the statutory scheme allowed for the inclusion of Medicare or Medicaid eligible patients in DSH calculations regardless of their SSI entitlements. They also argued that excluding certain low-income patients from the DSH calculation undermines the purpose of the DSH payments. The First Circuit rejected the hospitals’ arguments and found that the statutory language is unambiguous and that the Secretary’s construction of the statute was permissible.

You can read the full text of the First Circuit’s opinion here:

http://media.ca1.uscourts.gov/pdf.opinions/15-2408P-01A.pdf

STATE DEVELOPMENTS

Omnicare to Pay New Hampshire over $700K

On October 18, Attorney General Joseph Foster announced that New Hampshire will receive $703,242 from Omnicare as part of a $28.1M settlement to resolve allegations made by the federal government and several other states. Omnicare, Inc., a recently purchased subsidiary of CVS Health Corporation, reached an agreement to resolve allegations that it violated the anti-kickback statute by conspiring with Abbott Laboratories to increase the overall use of Depakote, a drug used to treat seizure disorders and bipolar disease. It was alleged that Omnicare knowingly solicited and received illegal remuneration from Abbott in exchange for engaging in certain programs, grants and providing other financial support.

State Approves Funds to Support Substance Misuse Recovery

On October 26, the Governor and Executive Council approved $600,000 in contracts to provide substance misuse recovery services. Citing the need to get resources to the local community as quickly as possible, the Governor commended the Executive Council for its unanimous bipartisan effort. Most of the funds will go to Hope for New Hampshire Recovery and Navigating Recovery of the Lakes Region to provide peer recovery support services in the Claremont, Concord, Manchester and Winnipesaukee regions. In addition, a contract for $260,000 in federal funds was unanimously approved to provide education and prevention services to at-risk youth through local school districts.

2017 Open Enrollment for Health Insurance Marketplace Started November 1

Open enrollment for the New Hampshire federally facilitated Health Insurance Marketplace started November 1, 2016 and will continue through January 31, 2017. For coverage to be effective starting January 1, the deadline for enrollment is December 15, 2016. Residents of New Hampshire have four health insurance companies to choose from including Anthem, Ambetter (NH Healthy Families), Harvard Pilgrim Health Care and Minuteman Health. There are five levels of coverage in the individual and small group market including bronze, silver, gold, platinum and catastrophic. Plans in each level pay for different portions of the health care cost. Individuals who qualify for cost-sharing assistance must choose a silver plan to obtain such assistance. Maine Community Health Options will no longer be offering a plan in New Hampshire in 2017 and those enrolled with that insurer will need to choose another plan or they will be automatically be assigned one.

Federal Grant of $1.1M to New Hampshire to Support Mental Health and Substance Abuse Parity

On October 31, CMS announced its grant of $1.1M to the New Hampshire Department of Insurance (the "Department") to address issues related to coverage parity for mental health and substance use disorders. Using grant funds, the Department will create template tools to evaluate prescription drugs within benefit plans to identify provisions that do not meet the requirements of non-discrimination for prescription drugs and associated CMS-identified health conditions. Similarly, the Department will create templates to evaluate preventative health services and to evaluate parity within benefit plans including the non-quantitative requirements of the Mental Health Parity and Addiction Equity Act. The Department will use its payer claims database to compare the use of mental health and substance use disorder benefits under regulated plans and will develop targeted education and outreach programs based on historical patterns of care and will gather information necessary to evaluate the adequacy of member access to services.

NH Supreme Court Rules Board of Psychologists May Need a Court Order to Obtain Patient Records

In a decision issued on September 20, the NH Supreme Court held that when conducting an investigation of a licensee, the Board of Psychologists ("Board") may need to obtain a court order to compel the production of patient records. In the case of *N.C. v. NH Board of Psychologists v. Alethea E. Young, PH.D (N.H. Sept. 20, 2016)*, the Board issued a subpoena for patient records after receiving a complaint from the father of the patient regarding the actions of the psychologist ("Young") in the course of providing treatment. The subpoena was issued in accordance with RSA 329-B:22 which allows the Board, upon a finding of just cause, to subpoena records when conducting an investigation. Young objected on the basis the records were subject to the patient-psychologist privilege citing RSA 329-B:26 which provides that the disclosure of privileged communications cannot be compelled without a court order. In reaching its decision, the court held that both RSA 329-B:22 and B:26 can be read together without conflict. Accordingly, the court held that the Board may issue a subpoena for psychological records provided it has just cause, but when a privilege-based objection is raised, the Board must seek a court order to compel compliance with the subpoena.

2016 Legislative Updates

NH Legislators Begin Submitting Bills for the 2017 Session

Legislative Service Requests filed thus far for the upcoming legislative session include the following:

2017-0007: relative to involuntary administration of medication to inmates with mental illnesses.
2017-0027: repealing the prospective repeal of the New Hampshire health protection program.
2017-0071: permitting qualifying patients to cultivate cannabis for their own therapeutic use.
2017-0115: adding opioid addiction to qualifying medical conditions under therapeutic use of cannabis.
2017-0116: adding fibromyalgia to qualifying medical conditions under therapeutic use of cannabis.
2017-0117: adding post-traumatic stress disorder to qualifying medical conditions under therapeutic use of cannabis.
2017-0118: relative to the definition of "qualifying medical condition" for the therapeutic use of marijuana.
2017-123: relative to hypodermic syringes and needles containing residual amounts of controlled drugs and authorizing the operation of syringe exchange programs in New Hampshire.
2017-124: establishing a controlled substances scientific review board.

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BIOS

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