Schenck Price
SCHENCK PRICE SMITH & KING, LLP
www.spsk.com

HEALTH LAW DISPATCH

October 2018

President Signs Bills Banning Pharmacy "Gag Clauses"

By Meghan V. Hoppe, Esq.

On October 10, 2018, President Donald Trump signed into law two bills that will allow pharmacists to inform patients that they can purchase prescriptions for less money, putting an end to so-called pharmacy "gag clauses."

The Patient Right to Know Drug Prices Act (S. 2554) and the Know the Lowest Price Act (S. 2553) both prohibit insurers and pharmacy benefit managers from including "gag clauses" in contracts with pharmacies. These types of "gag clauses" restrict pharmacists from informing patients that their medication would cost less by paying for it out-of-pocket rather than using their insurance plans.

The legislation was introduced in response to prescription drug overpayments known as "clawbacks." A "clawback" occurs when a patient remits a copayment that is actually more expensive than the retail cost of the medication (i.e., the price without insurance). The insurance company claws back, and ultimately pockets, the difference in cost. Patients rarely realize the price differential because of the "gag clauses" barring the pharmacy from telling patients there is a cheaper payment method. Under the new legislation, pharmacists will be allowed, though not required, to tell patients about lower cost alternatives for prescriptions.

In addition, the Patient Right to Know Drug Prices Act requires drug manufacturers to report to the Federal Trade Commission any "pay-for-delay" agreements that could postpone biosimilars from entering the market. This requirement modifies the Medicare, Prescription Drug, Improvement, and Modernization Act, which since 2004 has required drug manufacturers to similarly file agreements reached regarding generic drugs. However, unlike generics, a biosimilar drug only needs to be highly similar, not equivalent, to the existing medication. A "pay-for-delay" agreement is a type of settlement under which a brand name drug manufacturer will pay another manufacturer to delay marketing its cheaper version of a drug in order to prevent patent lawsuits. These arrangements can effectively be used by brand name drug manufacturers to stifle competition from lower-cost medications.

The new legislation promotes greater disclosure in drug pricing and highlights the administration's continued efforts to lower drug prices. President Trump and Health and Human Services Secretary Alex Azar both emphasized that the administration will continue its efforts to lower drug prices in the coming months.

For more information, *contact Meghan V. Hoppe, Esq. at mvh@spsk.com or 973-540-7351*.

OIG Raises Concerns About Medicare Advantage Organizations' Denials of Services and Payments

By Brian M. Foley, Esq.

The U.S. Department of Health and Human Services, Office of Inspector General ("OIG") recently conducted an audit of Medicare Advantage Organizations' ("MAOs") rates of denials, appeals and appeal outcomes. The OIG issued its findings and recommendations in a scathing final report on September 16, 2018, entitled "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns

About Service and Payment Denials". Significantly, the OIG found that when beneficiaries and providers appeal denials of authorization for service and/or denials of payment, the MAOs overturned seventy-five percent (75%) of their own denials (on the first level of appeal). These resulted in the overturning of hundreds of thousands of denials each year. Independent reviewers at higher levels of the appeals process overturned even more denials in favor of the beneficiaries and providers, raising the overturn rate for appealed cases to approximately ninety percent (90%).

The OIG said a central concern about the capitated payment model used in Medicare Advantage is the potential incentive for the MAOs to inappropriately deny access to services (deny authorizations of services) and/or deny payment in attempts to increase their profits. Under the capitated payment model, beneficiaries are enrolled in a managed care plan (also known as an MAO), and Medicare pays the MAO a risk-adjusted payment each month. In exchange for the monthly payment, the MAO agrees to authorize and pay for all medically necessary care for the beneficiary. The more the MAO denies services and/or payments, the greater the profit will be for the MAO.

The OIG's audit showed high rates of denials were overturned, demonstrating that the MAOs were inappropriately denying services to beneficiaries at an alarming number. It stated that "the high overturn rates of appealed denials and [previous] widespread and persistent CMS (Centers for Medicare & Medicaid Services) audit findings about inappropriate denials, raise concerns that some Medicare Advantage beneficiaries and providers were denied services and payments that should have been provided." The findings were especially concerning because beneficiaries and providers rarely used the appeals process designed to ensure access to care and payment, appealing only one percent (1%) of denials. The OIG said:

> MAOs that inappropriately deny the authorization of services for beneficiaries, or payments to healthcare providers who care for beneficiaries may not only contribute to physical or financial harm, but they also misuse Medicare Program dollars that CMS pays for beneficiary healthcare. Because Medicare Advantage covers so many beneficiaries (more than 20 million in 2018), even low rates of inappropriately denied services or payment can create significant problems for many Medicare beneficiaries and their providers.

As a result of the audit, the OIG recommended that CMS: (1) enhance its oversight of MAO contracts including those with extremely high overturn rates and/or low appeal rates, and take corrective action as appropriate; (2) address persistent problems related to inappropriate denials and insufficient denials letters in Medicare Advantage; and (3) provide beneficiaries with clear, easily accessible information about serious violations by MAOs. CMS concurred with all three recommendations.

The OIG audit and its report condemning the actions of the MAOs sends a very alarming message. Many MAOs are wrongfully denying services to beneficiaries and wrongfully denying payments to healthcare providers, to increase the MAOs' profits. The high rate of overturned appeals tells the beneficiaries and healthcare providers that they must appeal such denials, and fight for their rights to obtain the services beneficiaries need and the payments the providers are entitled to receive.

For more information, contact Brian M. Foley, Esq. at bmf@spsk.com or 973-540-7326.

Anthem Agrees to $16 Million Settlement Following Record Data Breach

By Deborah A. Cmielewski, Esq.

In the largest ever settlement involving an entity subject to HIPAA, Anthem, Inc. ("Anthem") has agreed to pay $16 million to the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") and to enter into a rigorous Corrective Action Plan ("CAP") arising from its failure to comply with the HIPAA Security Rule.

OCR began a compliance review of Anthem in February of 2015 following an announcement on its website and media reports that the health insurer had been the victim of a "sophisticated external cyber attack." In March of 2015, Anthem formally notified OCR of the breach of records arising from the attack and pertaining to nearly 79 million individuals. Through its investigation, OCR identified a number of significant deficiencies, including the failure of Anthem to (i) conduct an accurate and thorough risk analysis; (ii) regularly review information system activity; (iii) detect and respond to the security incident leading to the breach; (iv) control access rights; and (v) prevent unauthorized access to the electronic protected health information ("ePHI") of the records at issue. As a business associate under HIPAA, Anthem is required to adhere to the Security Rule, which includes these crucial elements.

In addition to the imposition of a $16 million fine, Anthem has agreed to a rigorous CAP with strict time frames for compliance. It also agreed to perform a risk analysis of the potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI and to provide a Statement of Work ("SOW") relating to the risk analysis for OCR's review and approval within 90 days of the effective date of the settlement agreement. The CAP also included provisions for OCR to work with Anthem to correct any deficiencies in the SOW identified by OCR and for the parties to meet and confer until such time as OCR approves the SOW. The CAP included similar provisions for OCR to work with Anthem to ensure that the risk analysis is performed in accordance with the SOW and the applicable HIPAA Rules. Anthem has also committed to revise certain policies and procedures, distribute them to its workforce and submit regular reports to OCR for a specific compliance period.

The Anthem resolution, which surpasses the previous high of $5.55 million dollars that OCR has collected in a single settlement, underscores the need for all covered entities and business associates to review and update their compliance plans on a regular basis. Failure to do so can result in catastrophic consequences.

For more information, contact Deborah A. Cmielewski, Esq. at dac@spsk.com or 973-540-7327.

FDA Provides Guidance on the Imposition of Civil Monetary Penalties for Failure to Comply with ClinicalTrials.gov Requirements

By Daniel O. Carroll, Esq.

In September, the U.S. Food and Drug Administration ("FDA") released draft guidance explaining how it will identify non-compliance with the ClinicalTrials.gov submission and certification requirements and how civil monetary penalties will be assessed. See FDA Draft Guidance, Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank (September 2018). Pursuant to 402(j) of the Public Health Service Act ("PHSA"), 42 U.S.C. §282(j), a "responsible party" is required to submit registration and results information to the ClinicalTrials.gov data bank for certain "applicable clinical trials." The Food and Drug Administration Amendments Act of 2007, which amended the Federal Food, Drug, and Cosmetic Act and its implementing regulations, clarified and expanded the requirements for clinical trial registration and results information submission and detailed certain prohibited acts in connection with such requirements. See 21 U.S.C. §331(jj); 42 C.F.R. Part 11.

Generally, the FDA intends to identify violations of the requirements relating to the ClinicalTrials.gov data bank through evidence collected during inspections conducted as part of the FDA's Bioresearch Monitoring Program or through complaints received by the FDA. The FDA's enforcement will be focused on the following: (i) responsible parties who have failed to register higher risk applicable clinical trials or applicable clinical trials of public health importance; (ii) responsible parties with a pattern of noncompliance with the reporting and certification requirements under Section 402(j) of the PSHA; and (iii) applicable clinical trials for which noncompliance with Section 402(j) of the PSHA exists in conjunction with potential violations of other clinical trial regulations.

The FDA's enforcement procedure will commence with the issuance of a Preliminary Notice of Noncompliance Letter upon the FDA's discovery of potential non-compliance,

followed by a 30-day period to correct such violations. Thereafter, if the FDA determines that a violation or non-compliance with Section 402(j) of the PHSA exists, then it will issue a Notice of Noncompliance. If a responsible party does not remedy noncompliance within 30 days after receiving a Notice of Noncompliance, the FDA will generally seek civil money penalties. If the FDA seeks civil monetary penalties, the responsible party has the opportunity to either: (i) pay the penalty prescribed by the FDA or (ii) file an Answer, contesting the allegations either in part or in whole, within 30 days of date of service. See 21 C.F.R. §17.9.

Responsible parties subject to the ClinicalTrials.gov submission and certification requirements should take note and consider the FDA's guidance as an indication of forthcoming increased enforcement efforts. The draft guidance is currently open for public comment until November 20, 2018.

For more information, contact Daniel O. Carroll, Esq. at doc@spsk.com or 973-631-7842.

Third Circuit Permits Unrelated Whistleblower's Swapping False Claims Lawsuit to Survive

By Divya Srivastav-Seth, Esq.

The Third Circuit Court of Appeals recently allowed a whistleblower of an alleged illicit nursing home "swapping" scheme to pursue his claim under the False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), despite the fact that the whistleblower had never worked for or conducted business with, the defendants and based his claim largely on publicly available knowledge. See United States v. Omnicare, Inc., 903 F.3d 78 (3d Cir. 2018). Under the FCA, a successful whistleblower can realize as much as 30% of the government's award. However, the FCA has a public disclosure bar that only allows whistleblowers to pursue their claims if they bring to light fraud based on facts that are not publicly available. In the instant case, the whistleblower was not associated with the defendants, relied on inferences and studies he made of the industry and its business practices, and deduced from publicly available sources that a prohibited transaction had occurred. The district court ruled that the public disclosure bar operated to require dismissal of the claim, but the appellate court revived the claim on the basis that the whistleblower had obtained certain private knowledge that connected the defendants to the alleged scheme.

The whistleblower claimed that the defendants, institutional pharmacies, had discounted prices for nursing home Medicare Part A patients in exchange for referrals to Medicaid and Medicare Part D patients and had violated the FCA because they had falsely certified their compliance with the Anti-kickback Statute when they submitted their claims for reimbursement. Nursing homes are reimbursed by Medicare Part A on a fixed per diem rate, which must cover all services, including the cost of prescription drugs. The associated financial risk of higher costs may be mitigated by the discounted rates offered by a supplier. On the other hand, Medicaid and Medicare Part D reimbursement for prescription drugs are paid to the pharmacies directly by the governmental programs involved and the nursing home has significantly less at stake. The exchange of discounts in one market for referrals to the other better paying market is known as "swapping."

The U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") has previously recognized this practice and stated that "swapping" is considered illegal remuneration under the Federal Anti-kickback Statute, as it constitutes a prohibited inducement for the furnishing of an item or service for which payment may be made in whole or in part under a federal health program. See 42 U.S.C. § 1320a-7b(b).

The district court dismissed the whistleblower's lawsuit because the public disclosure bar under the FCA requires dismissal of an FCA action if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed, unless the person bringing the action is the original source. See 31 U.S.C. § 3730(e)(4)(A). The district court stated that the whistleblower had

relied on the OIG opinions and guidance and SEC 10-K filings to make his case and had admitted in testimony that the swapping scheme could readily be deduced from such information.

On appeal, the whistleblower argued that the publicly available information was insufficient for an actual inference of fraud to be made and pointed to his own privately obtained knowledge of certain discounted rates in non-public contracts as the crux of the claim. The appeals court accepted the whistleblower's argument and noted that even if the whistleblower had testified that this information was publicly available, the court had an obligation to conduct its own examination of the publicly available documents to ascertain if an actual claim of fraud could be made. The court found that despite the OIG opinions and the defendant's publicly available financial information, the actual connection to fraud derived from the whistleblower's private knowledge of the amounts of the discounted rates and its connection to the profits realized by defendant. On this basis, the appeals court allowed the FCA claim to survive.

The FCA's public disclosure bar prevents parasitic whistleblowers from filing lawsuits based on knowledge that is generally known in order to obtain the large sums often awarded in FCA actions due to the inclusion of treble damages and penalties. In the past, whistleblowers have been employees or associates of the supposed defendants who were made privy to certain facts by virtue of their association. The recent ruling encourages whistleblowers to file these lawsuits even if they are not involved with the defendants as long as they can demonstrate that there is sufficient privately obtained knowledge to support the claim.

For more information, contact Divya Srivastav-Seth, Esq. at dss@spsk.com or 973-631-7855.