BRACH EICHLER LLC

Health Law UPDATE

September 2018

In This Issue:

TCPA Class Action Against CVS Dismissed

Insys Agrees to Pay Over $150 Million to Settle *Qui Tam* Whistleblower Lawsuits

HHS Releases Report Recommending Actions for CMS to Ensure Hospices Provide Quality Care

State Update

Brach Eichler in the News

FEDERAL UPDATE

CMS Proposed Rulemaking Addresses Changes to Medicare Fee Schedule and Quality Payment Program

On July 27, 2018, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule to address changes to the Medicare physician fee schedule (PFS) for 2019 and other Medicare Part B payment policies to ensure that payments are updated to reflect changes in medical practice and the relative value of services.

The proposed rulemaking was prompted, in part, by the Bipartisan Budget Act of 2018 (Act), which requires CMS to establish payments under the PFS based on relative value units (RVUs) that account for the resources used in furnishing a service. The Act requires that RVUs be established for work, practice expenses, and malpractice expenses. In addition, the Act requires that CMS establish annual payment amounts for all physician services paid under the PFS.

The proposed rule discusses:

- Communication technology-based services;
- Valuation of new, revised, and mis-valued codes;
- Streamlining of evaluation and management (E/M) payments;
- Therapy services;
- Clinical laboratory fee schedule;
- Ambulance fee schedule;
- Appropriate use criteria for advanced diagnostic imaging services;
- Physician self-referral law; and
- Issuing a request for information on price transparency to improve beneficiary access to charge information.

This significant proposal also includes policies for Year 3 of the Quality Payment Program (QPP). CMS seeks to continue to identify low-value or low-priority process measures, which will be recommended for removal. According to the agency, the focus is on increasing meaningful quality outcomes for patients and streamlining reporting for clinicians with the goal of improving quality measures over time.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com

CMS Proposes Overhaul of Medicare ACO Program

The Centers for Medicare & Medicaid Services (CMS) has issued a proposed rule that would overhaul the Medicare Shared Savings Program under which the vast majority of Medicare's Accountable Care Organizations (ACOs) operate. CMS developed the redesigned program, which CMS refers to as "Pathways to Success," based on a comprehensive analysis of ACO performance to date that indicated that under the Shared Savings Program, Medicare spending by CMS and taxpayers has increased because a great majority of ACOs only participate in shared savings but have not taken on any risk for increases in costs. "Pathways to Success" is designed to advance the goals of accountability, competition, engagement, integrity, and quality. CMS projects that the new program will account for a savings of $2.2 billion over ten years.

Under the new program, the amount of time an ACO is permitted to stay in the program without taking on risk would be reduced from six years to two years. The new program would also require ACOs to provide more information to patients to allow them to make decisions about their care, and permit certain ACOs that have taken on risk to provide incentive payments to patients for taking steps that promote good health. CMS has also proposed rewarding ACOs that take on more risk by providing them with more flexibility in modalities of care. The new rule would also provide measures for patients to control their medical data. In addition, the new rule would streamline the measures that ACOs are required to report under the Meaningful Use Program to reduce burden and ensure that all measures have a meaningful impact on patient care. CMS would also institute measures to ensure that ACO spending targets accurately reflect spending levels and growth rates in their local market, and authorize CMS to terminate ACOs with poor financial performance.

In order to implement the newly designed ACO system, CMS has proposed to cancel the application cycle during 2018 for new ACO agreement periods that would start on January 1, 2019, and instead offer an application cycle for a one-time new agreement period start date of July 1, 2019. CMS would resume the usual annual application cycle for the performance year starting on January 1, 2020 and subsequent years. In order to provide ACOs time to review new policies, make business and investment decisions, and complete and submit a Shared Savings Program application for a performance year beginning July 1, 2019, existing ACOs with a participation agreement ending on December 31, 2018 would have an opportunity to extend their current agreement period through June 30, 2019.

For more information, contact:

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com

TCPA Class Action Against CVS Dismissed

On August 14, 2018, a federal judge in New Jersey dismissed a putative class action in *Bailey v. CVS Pharmacy, Inc.*, 2018 WL 3866701 (D.N.J. Aug. 14, 2018) in which the plaintiff alleged that CVS violated the Telephone Consumer Protection Act (TCPA) with unsolicited telemarketing when it included the words “Flu Shots Available” in text messages to customers notifying them that their prescriptions were ready for pickup. The patients had signed up for the CVS Ready Text Program but claimed they never consented to receive information by text about flu shots or anything other than their prescription order status.

The TCPA was passed by Congress to protect individual consumers from receiving intrusive and unwanted calls. This applies to text messages as well. The law exempts emergency calls, calls made with the prior express consent of the called party, and calls that fall under the Healthcare Exemption. The Healthcare Exemption provides that calls or text messages do not require prior written consent if the call delivers a “health care” message made by, or on behalf of, a “covered entity” or “business associate” as defined by the HIPAA Privacy Rule. Courts have applied a three-prong standard to determine if the Healthcare Exemption applies: 1) the call or message involves an “inarguably health-related” product or service, 2) “an established health care treatment relationship” exists between the provider and the recipient, and 3) the call or message deals with “the individual health care needs” of the recipient.

The court found that the “Flu Shots Available” message was a health care message exempted from the TCPA. As a pharmacy and therefore a health care provider, CVS was a covered entity. The message was a health care message under the three-prong standard because a flu shot is health-related, the text messages were limited only to CVS customers who had enrolled in the CVS Ready Text Program, and the messages were sent in the course of notifying patients about their prescription order. The court also found that the patients had in fact expressly consented to receiving the flu shot message by providing their phone numbers for the prescription order alerts. So long as the message “closely relates” to the circumstances under which the phone number was given, as it did here, the message falls within the scope of the express consent.

For more information, contact:

Lani M. Dornfeld | 973.403.3136 | ldornfeld@bracheichler.com
Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

Insys Agrees in Principle to Pay Over $150 Million to Settle *Qui Tam* Whistleblower Lawsuits Over Opioid Kickback Scheme and Related Commercial Practices

On August 7, 2018, the United States Department of Justice (DOJ) and pharmaceutical manufacturer Insys Therapeutics, Inc. (Insys) agreed in principle to settle multiple lawsuits initially brought by several *qui tam* whistleblowers (Relators) over Insys’ alleged state and federal False Claims Act violations. The whistleblower lawsuits, first brought by an Insys employee back in 2013, generally allege that Insys paid illegal kickbacks to prescribers to induce them to prescribe Subsys, a sublingual spray form of the highly addictive and powerful opioid fentanyl. Additionally, the Relators alleged that Insys employees were trained and encouraged to misrepresent patients’ diagnoses to insurers in order to obtain prior authorization and coverage for the drug despite the fact that Subsys is only approved by the Food and Drug Administration (FDA) to treat opioid-tolerant cancer patients suffering from breakthrough pain subject to a special Risk Evaluation and Mitigation Strategy program for drugs such as Subsys.

The settlement-in-principle comes on the heels of the DOJ’s April 2018 intervention in five different *qui tam* actions filed across the country and consolidated within the United States District Court for the Central District of California (the Court). In the DOJ’s subsequent press release on the intervention, United States Attorney Nicola T. Hanna explained that “[o]ur intervention in these cases is just one part of the Justice Department’s multi-pronged efforts to combat the opioid crisis. The illegal marketing activities alleged in the government’s case helped fuel the crisis by improperly introducing opioids into the market. We are committed to hold accountable corporations and individuals who use kickbacks, off-label promotions and other illegal activities to sell lethal and highly addictive narcotics. Our goal is to bring about an end to the tragic epidemic that is harming untold numbers of people across the United States.”

Under the disclosed terms of the proposed settlement, Insys agreed to pay over $150 million in civil monetary penalties over the span of five years, with additional potential contingency payments of up to $75 million if certain conditions are not met. In its August 9th status report to the Court, the DOJ explained that while the settlement-in-principle is “subject to further governmental and other approvals, the tentative agreement resolves material terms that have been the subject of ongoing settlement negotiations.” For its part, Insys’ current president and CEO Saeed Motahari commented in a press release that the proposed settlement is “a very important step for our company to move forward and continue our transformative efforts to foster a compliant and ethical culture and to execute against our well-differentiated product pipeline, which we believe can bring value to patients globally.”

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Andrew J.D. Russo | 973.403.3135 | arusso@bracheichler.com

HHS Releases Report Recommending Actions for CMS to Ensure Hospices Provide Quality Care and Necessary Services to Medicare Beneficiaries

The Office of Inspector General, U.S. Department of Health and Human Services (OIG) released a report on July 31, 2018 which details the various vulnerabilities it observed in the Medicare hospice program which negatively impact the quality of care and the program’s overall integrity. Specifically, the OIG found that “hospices do not always provide needed services to beneficiaries and sometimes provide poor quality care. In some cases, hospices were not able to manage effectively symptoms or medications, leaving beneficiaries in unnecessary pain for many days.” The OIG also found that hospices do not always provide critical information to beneficiaries and their families in order for them to make informed decisions as to the beneficiaries’ care. In other cases, the OIG observed that hospices are engaging in fraudulent, wasteful, or abusive billing practices which cost Medicare “hundreds of millions of dollars.” Finally, the OIG opined that “the current payment system creates incentives for hospices to minimize their services and seek beneficiaries who have uncomplicated needs.” Ultimately, as to this latter issue, the OIG posited that a fee-for-service payment scheme under which hospices are simply paid for every day a beneficiary is in its care, regardless of the quantity or quality of that care, is inadequate and urged the Centers for Medicare & Medicaid Services (CMS) to seek the

appropriate statutory authority to establish remedies for hospices who perform poorly in providing quality care to beneficiaries.

The report outlined 16 specific actions that the OIG recommended CMS should take to rectify the issues it observed with the Medicare hospice program. In response, CMS only concurred with six of the OIG's recommendations, did not concur with nine of the recommendations, and neither concurred nor rejected the recommendation to seek statutory authority to promulgate and enforce quality measures for hospices, adding that CMS would "consider this recommendation when developing requests for the President's budget." After reviewing CMS' comments to the report, the OIG consolidated two of its recommendations, and continues to recommend the following actions: "CMS should strengthen the survey process—its primary tool to promote compliance—to better ensure that hospices provide beneficiaries with needed services and quality care. CMS should also seek statutory authority to establish additional remedies for hospices with poor performance. Also, CMS should develop and disseminate additional information on hospices, including complaint investigations, to help beneficiaries and their families and caregivers make informed choices about hospice care. CMS should educate beneficiaries and their families and caregivers about the hospice benefit, working with its partners to make available consumer-friendly information. CMS should promote physician involvement and accountability to ensure that beneficiaries get appropriate care. To reduce inappropriate billing, CMS should strengthen oversight of hospices. This includes analyzing claims data to identify hospices that engage in practices that raise concerns. Lastly, CMS should take steps to tie payments to beneficiary care needs and quality of care to ensure that services rendered adequately serve beneficiaries' needs, seeking statutory authority if necessary."

For more information, contact:

Lani M. Dornfeld | 973.403.3136 | ldornfeld@bracheichler.com
Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com
Andrew J.D. Russo | 973.403.3135 | arusso@bracheichler.com

STATE UPDATE

New Jersey Attorney General Issues Guidance Regarding Municipal Prosecutors Discretion in Prosecuting Marijuana-Related Offenses

New Jersey Attorney General Gurbir Grewal released a memorandum dated August 29, 2018 addressing how municipal prosecutors should exercise their discretion in cases involving marijuana-related offenses. The memorandum states that "municipal prosecutors and/or their subordinates may not adopt a policy or practice of marijuana decriminalization in which they categorically will not pursue convictions for statutory offenses related to marijuana." According to the memorandum, the adoption of such a practice would be an abuse of discretion. Regarding the use of prosecutorial discretion, the memorandum further clarifies that marijuana-related cases should not be treated differently than any other case by the prosecutor.

When exercising prosecutorial discretion, the prosecutor is to base their discretion on "the particular facts and applicable law, and consistent with their ethical obligations to the State, the defendant, and the courts." To the extent permitted by law, when determining whether to seek a dismissal or amend the charges, municipal prosecutors should consider the impact of adverse results of a conviction based on the specific circumstances of the case at hand. Regarding the memorandum, New Jersey Attorney General Gurbir Grewal stated that "the guidance that I am issuing today confirms that municipal prosecutors can responsibly exercise discretion to deal with minor marijuana possession offenses in a progressive, equitable manner, while respecting the rule of law, including the authority of the Legislature and the Courts."

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

Newark/Philadelphia Medicare Fraud Strike Force Formed

Assistant Attorney General Brian A. Benczkowski of the Justice Department's Criminal Division announced the formation of the Newark/Philadelphia Regional Medicare Fraud Strike Force to combat the opioid epidemic. The Regional Strike Force will be made up of prosecutors and data analysts within the Health Care Fraud Unit in the Criminal Division's Fraud Section, prosecutors with the U.S. Attorney's Offices for the District of New Jersey and Eastern District of Pennsylvania, and special agents with the FBI, U.S. Department of Health and Human Services Office of the Inspector General and U.S. Drug Enforcement Administration. The Strike Force will focus on prosecuting cases involving fraud, waste, and abuse, and cases involving illegal prescribing and distribution of opioids and other narcotics.

Assistant Attorney General Benczkowski stated that "according to the CDC, in 2016, more than 40 percent of all U.S. opioid overdose deaths involved a prescription opioid." The Strike Force operations already in existence are successful in combating health care fraud and its role in feeding the opioid epidemic. Since the inception of the Strike Force operations in March 2007, prosecutors in the ten Medicare Fraud Strike Force locations have charged over 3,700 defendants who falsely billed the Medicare program for over $14 billion. Assistant Attorney General Benczkowski further stated that the Medicare Fraud Strike Force is a measure that will contain this threat to the American people and will allow the Department of Justice to handle more of these cases.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

New Jersey Legislative Update

Amendments to Meal Limits Proposed For New Jersey Rules Limiting Compensation from Pharmaceutical Manufacturers—On August 6, 2018, the New Jersey Attorney General officially proposed modifications to the meal limitations set forth in the recently enacted regulations limiting gifts and payments from prescription drug and biologics manufacturers to prescribers. The regulations, which became effective on January 16, 2018, imposed a limitation of $15 on the amount of a modest meal that could be provided at an educational event or promotional activity hosted by a pharmaceutical manufacturer. Due to concerns expressed by manufacturers and prescribers that the $15 limitation is unrealistic in New Jersey, the Attorney General proposed to amend the limitation. The proposed modifications to the meal limits were originally announced in a letter to the four professional boards regulating New Jersey prescribers dated May 14, 2018, in which the Attorney General provided that he will forbear from prosecuting matters during the rule-making process if a prescriber's conduct is in compliance with the proposed amendments.

Under the Attorney General's proposed modifications, the definition of "modest meal" would allow $15 for breakfast and lunch and $30 for dinner in calendar year 2018. This sum would be tied to a consumer price index, allowing for dollar increases in subsequent years. In addition, standard charges for delivery, service, facility rental, and taxes would not be included in the fair market value of a modest meal. Furthermore, the dollar limits for meals associated with educational events, even if supported by a pharmaceutical manufacturer, would not be applicable, so long as the presentations are conducive to the educational purpose and include information concerning disease states and treatment approaches. Meals provided by a pharmaceutical manufacturer to prescribers through promotional activities would remain subject to the meal limitations.

Maternity Care Report Card Law Enacted—On August 10, 2018, Bill A2366 was signed into law by Governor Phil Murphy requiring the New Jersey Department of Health to gather and compile information necessary to develop a New Jersey Report Card of Hospital Maternity Care. The report card will be designed to inform members of the public about maternity care provided by each general hospital licensed in New Jersey and will be made available on the website of the Department of Health, with annual updates. For each hospital, the report card is to include the number of vaginal deliveries performed, the number of cesarean deliveries performed, and the rates of certain complications based on the type of delivery.

BME Proposes Amendments to CME Requirements for Opioid Education—On September 4, 2018, the New Jersey State Board of Medical Examiners proposed new regulations to require physicians and physician assistants to complete one continuing education credit in each biennial renewal period in topics concerning prescription opioid drugs, including responsible prescribing practices; alternatives to opioids for managing and treating pain; and the risks and signs of opioid abuse, addiction, and diversion. The regulations are intended to implement a New Jersey law which requires physicians and physician assistants to complete one credit of continuing education in topics concerning prescription opioid drugs every biennial renewal period. Written comments on the proposed regulations are due by November 3, 2018.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com

Brach Eichler In The News

Managing Member and Health Law Chair **John D. Fanburg** and Health Law Member **Mark Manigan** presented at "Everything a One-Room Center Needs to Know to Become Licensed," an event hosted by the New Jersey Association of Ambulatory Surgery Centers on September 12.

Health Law Member **Carol Grelecki** spoke on a panel, "Healthcare – Will It Be the Next Meltdown Like Retail?," at the New York Institute of Credit on September 13.

To view a full listing of recent news items and to read the articles mentioned above, please visit http://bit.ly/2tYYFha.

Attorney Advertising: This publication is designed to provide Brach Eichler, LLC clients and contacts with information they can use to more effectively manage their businesses. The contents of this publication are for informational purposes only. Neither this publication nor the lawyers who authored it are rendering legal or other professional advice or opinions on specific facts or matters. Brach Eichler, LLC assumes no liability in connection with the use of this publication.

Health Care Practice Group | 101 Eisenhower Parkway, Roseland, NJ 07068 | 973.228.5700

Members

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Lani M. Dornfeld, HLU Editor | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Debra C. Lienhardt | 973.364.5203 | dlienhardt@bracheichler.com
Mark Manigan | 973.403.3132 | mmanigan@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Counsel

Lauren D. Goldberg | 973.364.5228 | lgoldberg@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Randall H. Lee | 973.364.5205 | rlee@bracheichler.com
Richard B. Robins | 973.403.3147 | rrobins@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Associates

Colleen Buontempo | 973.364.5210 | cbuontempo@bracheichler.com
Lindsay P. Cambron | 973.364.5232 | lcambron@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Andrew J.D. Russo | 973.403.3135 | arusso@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com

Stay Connected!

*Follow us on **LinkedIn**: www.linkedin.com/company/brach-eichler-llc and **Twitter**: http://twitter.com/BrachEichler*

You have the option of receiving your **Health Law Updates** *via e-mail if you prefer, or you may continue to receive them in hard copy. If you would like to receive them electronically, please provide your e-mail address to akatz@bracheichler.com. Thank you.*