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HEALTH LAW DISPATCH

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New State Law Caps Medicaid Reimbursements for Low Acuity Hospital Emergency Room Visits

By Divya Srivastav-Seth, Esq.

Pursuant to recently enacted law and effective November 1, 2018, P.L.2018, Chapter 51 (the "Act"), New Jersey hospitals providing services to patients enrolled in the New Jersey State Medicaid fee-for-service program must accept $140.00 as final payment for an emergency room ("ER") triage if the services provided are determined to be low acuity encounters. The Act defines "acuity" as the measurement of the intensity of nursing care required by a patient and requires the Commissioner of Human Services to publish a list of diagnostic codes that would be considered low acuity ER encounters for the purpose of applying this fee. Although the Act is likely to realize an increase in savings within the fund for the Medicaid fee-for-service program, these savings will be realized at the expense of hospitals, which are federally mandated under the Emergency Medical Treatment and Labor Act, 42 U.S. Code § 1395dd ("EMTALA") to provide the medical screening and treatment necessary to stabilize a patient who presents at the hospital ER, regardless of the patient's ability to pay. Accordingly, New Jersey hospitals will have to provide services required by the federal law but will be subject to the state-imposed cap if it is later determined to be a low acuity event.

EMTALA requires hospital-based ER providers to perform the emergency services necessary to screen, treat and stabilize a patient or risk civil penalties and/or Medicare de-certification. An EMTALA obligation is triggered for a hospital when an individual comes to the hospital's ER and a request is made by the individual or on the individual's behalf, or a prudent layperson observer would conclude from the individual's appearance or behavior a need for examination or treatment of a medical condition. The Center for Medicare and Medicaid Services ("CMS") interpretive guidelines for EMTALA provide that an appropriate screening exam of a possible emergency condition is not an isolated event but is rather an ongoing process required to reach, with reasonable clinical confidence, a determination whether the individual has an emergency medical condition or not. CMS describes an appropriate screening exam as depending on the individual's symptoms and ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures, such as (but not limited to) lumbar punctures, clinical laboratory tests, CT scans and/or other diagnostic tests and procedures. See CMS Manual System Department of Health & Human Services (DHHS) Pub. 100-07 State Operations Provider Certification Centers for Medicare & Medicaid Services (CMS) (Rev.60, 07-16-10), Appendix V-Interpretive Guidelines-Responsibilities of Medicare Participating Hospitals in Emergency Cases §489.24(a). Accordingly, even though federal law requires the hospital to perform a wide range of services if necessary to make a reasonable clinical determination about an emergency medical condition, state law would cap the reimbursement for those services if it is discovered to be a condition on the Commissioner's list of pre-determined low acuity conditions.

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OIG Issues a Favorable Advisory Opinion Regarding a Group Purchasing Organization Acting on Behalf of Affiliated Facilities

By Brian M. Foley, Esq.

On August 6, 2018, the Department of Health and Human Services, Office of Inspector General ("OIG") issued Advisory

Opinion No. 18-07, in which it approved of a proposed arrangement for a group purchasing organization ("GPO") to serve as a purchasing agent for certain affiliated health care facilities, even though they were related to the GPO.

The Federal Anti-Kickback Statute, 42 U.S.C. 1320a-7b ("AKS") makes it a criminal offense to offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services that are reimbursable by a Federal health care program. The safe harbor for GPOs excludes from the definition of "remuneration" fees paid by vendors to GPOs if certain conditions are met. One of the conditions of the safe harbor is that the GPO acts as the purchasing agent for a group of individuals or entities that are neither owned by the GPO, nor subsidiaries of a parent organization that also owns the GPO.

The requestor of the Advisory Opinion is a GPO that has provided hospital group purchasing services for over 20 years, with more than 100 member hospitals and other health care facilities. Consistent with the safe harbor, none of the GPO's current members are either owned by the GPO, or subsidiaries of a parent organization that owns the GPO. Due to a corporate restructure, the GPO has become a subsidiary of a parent organization that owns 31 hospitals. The GPO proposed to expand its membership to include the 31 hospitals owned by its parent organization. The OIG noted that the addition of the 31 hospitals would remove the GPO from safe harbor protection because the GPO and the 31 hospitals are all subsidiaries of the same parent organization. As such, the proposed arrangement would not be protected under the GPO safe harbor.

Arrangements that implicate the AKS but do not satisfy the conditions of a safe harbor may be reviewed by the OIG on a case-by-case basis, to determine their potential to increase the risk of fraud and abuse. The OIG engaged in such a review of the proposed arrangement and decided that although the proposed arrangement could potentially generate remuneration under the AKS, and would not qualify for safe harbor protection, it would not impose administrative sanctions because the addition of the affiliated facilities to the GPO would not materially increase the risk of fraud and abuse under the AKS. The OIG cited the following reasons in support of its favorable opinion. First, the requestor already exists as a GPO that satisfies the GPO safe harbor and currently serves over 100 unaffiliated facilities. Second, the new, affiliated facilities would only constitute approximately 35 percent of the total membership and approximately 20 percent of the sales volume, and all members would be subject to the same GPO contract terms and conditions. In other words, the GPO would continue to operate as the purchasing agent for a group of entities, the majority of which are unrelated to it. Third, the parent organization is an independent public company that owns many hospitals and other health care organizations, each of which is a separate legal entity. The OIG concluded that although the proposed arrangement cannot receive GPO safe harbor protection due to the ownership structure by the parent organization, based on the totality of the facts and circumstances the arrangement would present an acceptably low risk of fraud and abuse under the AKS.

Through Advisory Opinion No. 18-07, the OIG has again demonstrated flexibility in its interpretation and enforcement of the AKS to approve a sensible arrangement with a low risk of fraud and abuse, despite not satisfying the conditions of the safe harbor.

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HHS Secretary Announces Changes Coming to HIPAA and 42 CFR Part 2

By Deborah A. Cmielewski, Esq.

The Secretary of the United States Department of Health & Human Services ("HHS"), Alex Azar, has announced that the HHS will implement plans to update health privacy regulations to further the coordination of care among providers. The proposed changes will include, among other items, modifications to the Health Insurance Portability and Accountability Act ("HIPAA") and the regulations governing alcohol and substance use disorders, 42 CFR Part 2.

During a recent address to the Heritage Foundation in Washington, D.C., Secretary Azar discussed the importance of transforming the health care system in America into

one that pays for value through better coordination of care among providers. Secretary Azar stressed the importance of removing barriers to information sharing and encouraging the use of electronic health technology to coordinate care. HHS has recognized that the decades-old regulatory schemes interfere with the advancement of such care coordination. Varying interpretations of HIPAA and 42 CFR Part 2 continue to exist, which affect value-based arrangements and interfere with the ability of communities and facilities to work together in the delivery of effective care. Secretary of Azar pointed out that coordination of care is an essential component of combating the opioid crisis in America, which remains a top priority for the Trump Administration.

To that end, HHS is beginning a comprehensive review of regulations that interfere with the ability of providers to share information and to deliver coordinated care. In the upcoming months, HHS Deputy Secretary Eric Hargan will release requests for information. Interested stakeholders will have the ability to submit comments to the HHS, which will be used to draft modifications to the privacy regulations.

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Government's Close Scrutiny of Patient Assistance Programs Continues

By Daniel O. Carroll, Esq.

The health care industry and the government have long acknowledged that properly structured and administered charitable patient assistance programs ("PAPs") provide important and needed assistance to patients with limited financial resources who cannot otherwise afford certain medical products. Since PAPs are supported through donations from medical product manufacturers ("Manufacturer Donors") and the financial assistance usually comes in the form of free or discounted products or copayment assistance, the government has recognized the potential risks of fraud and abuse and its scrutiny concerning properly structured and utilized PAPs appears to be on the increase.

The U.S. Department of Health and Human Services, Office of Inspector General ("OIG") has expressly approved independent charitable PAPs that assist patient beneficiaries with health care expenses. However, merely using a charity and relying on its charitable purpose will not shield a PAP and its Manufacturer Donors from government scrutiny and enforcement for fraud and abuse violations. The OIG has authored written guidance regarding the proper structure and administration PAPs for the health care industry, which is insightful but continues to evolve. See Dept. of Health and Human Services, Office of Inspector General, Publication of OIG Special Advisory Bulletin Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), as supplemented by, Dept. of Health and Human Services, Office of Inspector General, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistant Programs, 79 Fed. Reg. 31120 (May 30, 2014); OIG Advisory Opinion No. 06-04 (April 20, 2006), as modified by, Notice of Modification of OIG Advisory Opinion No. 06-04 (Dec. 23, 2015), and rescinded by, Final Notice of Rescission of OIG Advisory Opinion No. 06-04 (Nov. 28, 2017); OIG Advisory Opinion No. 06-13 (Sept. 18, 2006), as first modified by, Modification of OIG Advisory Opinion No. 06-13 (June 21, 2013), and subsequently modified by, Modification of OIG Advisory Opinion No. 06-13 (Dec. 9, 2015) and OIG Advisory Opinion No. 09-04 (May 11, 2009).

As warned by the OIG, donations to PAPs can run afoul of the fraud and abuse laws and OIG guidance if they are made to induce the PAP to recommend or arrange for the purchase of the Manufacturer Donor's product. Similarly, financial assistance from PAPs can violate fraud and abuse laws if they are made to influence a patient to purchase (or a patient's physician to prescribe) the Manufacturer Donor's product.

The OIG's guidance stresses fundamental considerations to properly structure and use PAPs. the importance of ensuring that (i) the PAP is truly independent of any Manufacturer Donor and severs any link between donations and patient beneficiary's choice of product, (ii) the financial need of the patient beneficiary is verified, and (iii) any such Manufacturer Donor does not receive data from the PAP allowing it to correlate the amount and frequency of donation to the number of subsidized prescriptions for their products.

Additionally, the disease funds of a PAP cannot be defined in a manner to inappropriately steer patient beneficiaries to the products of a particular Manufacturer Donor.

In addition to the OIG's evolving guidance, enforcement efforts of the U.S. Department of Justice ("DOJ") with respect to improperly structured or utilized PAPs have increased as evidenced by numerous recent settlements with Manufacturer Donors supporting PAPs. See, e.g., Aegerion Pharmaceuticals, Inc. Settlement (Sept. 22, 2017); United Therapeutics Corporation Settlement (Dec. 20, 2017), Jazz Pharmaceuticals Plc Proposed Settlement (April, 2018), Pfizer Inc. Settlement (May 24, 2018) and Lundbeck LLC Proposed Settlement (June 6, 2018). Each of these settlements (or proposed settlements) provides further insight into the government's concern with ensuring the independence of PAPs from the commercial business decisions of Manufacturer Donors and prohibiting the steering of patients to particular Manufacturer Donors.

It is essential to properly structure and utilize PAPs to provide important and needed assistance to patients with limited financial resources who cannot otherwise afford certain drugs. Now, with increasing scrutiny and enforcement efforts of government agencies, Manufacturer Donors must be proactive in assessing compliance risks and issues related to their interactions with and support of PAPs.

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Attempt by Borough to Retroactively Deny Hospital's Property Tax Exemption Denied

By Farah N. Ansari, Esq.

In a recent New Jersey Tax Court case, Meridian Hospitals Corporation, as successor to Riverview Medical Center ("RMC"), was granted summary judgment dismissing a suit brought by the Borough of Red Bank (the "Borough") which sought to impose omitted assessments for tax years 2014 and 2015. See Borough of Red Bank v. RMC — Meridian Health, 2018 N.J. Tax LEXIS 12 (N.J. Tax 2018). In tax years 2014 and 2015, RMC used the subject property as a hospital (the "Property") and the Property was listed as exempt from taxation in the Borough's tax rolls.

After the 2015 decision in AHS Hosp. Corp. v. Town of Morristown, 28 N.J. Tax 456 (N.J. Tax 2015), the Borough tried to revoke RMC's previously granted tax exemption for the Property by relying on the Morristown case as support. In Morristown, the court found that the hospital commingled its activities with for-profit entities and as a result, the town was justified in revoking the hospital's property tax exemption with respect to particular parcels of hospital property. Without offering any evidence as support, the Borough alleged that RMC was not entitled to exemption for the same reasons. It appeared that the complaint was filed as a means to use discovery to reveal that the Property was being used for "profit-making purposes."

The Borough attempted to use omitted assessment law as a procedural basis to tax the Property for tax years 2014 and 2015. The Court found that under the controlling statute, N.J.S.A. 54:4-63.26, under these facts, there must be a "change in use" of property for a property tax exemption to end, after which tax would be imposed on a pro-rata basis. The Court granted summary judgment because the Borough failed to produce any evidence that demonstrated that there was a "change in use" of the Property.

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Regional Medicare Fraud Strike Force to Target Opioid Abuse in NJ

By Meghan V. Hoppe, Esq.

In an August 13, 2018 press release, the U.S. Justice Department's Criminal Division announced the formation of the Newark/Philadelphia Regional Medicare Fraud Strike Force ("Regional Strike Force"). The Regional Strike Force will investigate and prosecute cases involving fraud, waste and abuse in federal health care programs, as well as target cases involving illegal prescribing and distribution of opioids and other dangerous narcotics in New Jersey. See Press Release, U.S. Attorney's Office, District of New Jersey, Assistant Attorney General Benczkowski Announces

Newark/Philadelphia Regional Medicare Fraud Strike Force (Aug. 13, 2018).

The Justice Department noted the state's abundance of health care and pharmaceutical operations as a potential breeding ground for prescription drug fraud and the opioid addiction epidemic. "New Jersey is home to some of the best health care facilities and most successful pharmaceutical companies in the country," U.S. Attorney Craig Carpenito said. "Unfortunately, that also means that we offer substantial targets for those who would try to defraud the health care system or try to profit from the misery of people battling addiction to opioids." Id.

The addition of the Regional Strike Force marks an expansion of interagency Medicare Fraud Strike Forces targeting health care fraud and abuse. There are 10 other Strike Forces operated in large cities across the United States. Each Strike Force combines the resources and expertise of the Justice Department's Criminal Division, U.S. Attorney's Offices, the FBI, U.S. Department of Health and Human Services Office of the Inspector General and U.S. Drug Enforcement Administration.

The Strike Forces "constitute one of our most important and effective means for containing" the threat of health care fraud and opioid abuse, Assistant Attorney General Brian A. Benczkowski said. Id. Since March 2007, the Strike Forces have led to charges for over 3,700 defendants who collectively falsely billed the Medicare program for more than $14 billion.

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RECENT HEALTH LAW LEGAL ALERTS

New Jersey Supreme Court Affirms Judgment in Case Involving an Offer of Judgment and a High-Low Agreement