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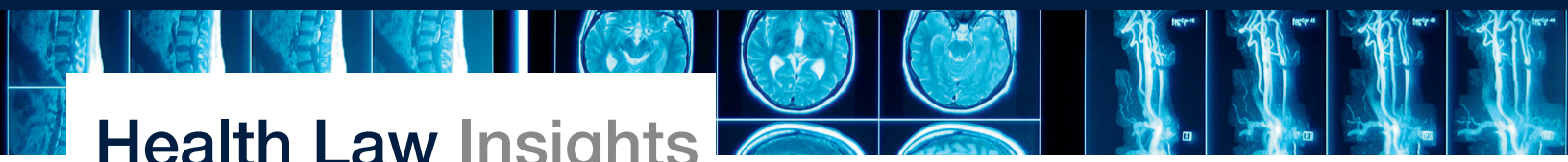

Health Law Insights

ISSUE | 8

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NATIONAL

New Payment Model for Part B Drugs Proposed

The Centers for Medicare and Medicaid Services published on March 11 a proposed rule (81 Fed. Reg. 13230) to experiment with an alternative payment model for Medicare Part B prescription drugs. Currently, physicians and hospitals receive a Part B drug reimbursement in the amount of the average sales price, plus 6%. The proposed payment model would reduce the add-on payment to 2.5% and pay a flat fee of $16.80 per drug per day. CMS would update the flat fee at the beginning of each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period.

CMS anticipates that the payment adjustment, which would cover the cost of nearly all drugs reimbursed under Part B, will result in savings through creating incentives for change in prescribers' behavior. The new model is envisioned by CMS as a solution to perverse incentives existing within the current Medicare Part B payment methodology, which can result in penalties "for selecting lower-cost drugs, even when these drugs are as good or better for patients based on the evidence."

Under the proposed rule, CMS would explore the efficacy of a variety of value-based pricing strategies currently used by commercial health plans, pharmacy benefit managers and hospitals within the Medicare Part B context, including:

- Discounting or eliminating patient cost-sharing.
- Feedback on prescribing patterns and online decision support tools for providers.
- Indications-based pricing.
- Reference pricing (i.e., a standard payment rate for a group of therapeutically similar drugs).
- Risk-sharing agreements between CMS and drug manufacturers based on outcomes.

All practitioners and entities furnishing and billing for Part B drugs would be required to participate in the model, which would run for five years. CMS would assess beginning in late 2016 whether the new model resulted in improved quality and value.

CMS is accepting comments on the proposed rule through May 9, 2016.

Home Care Agency's Effort to Circumvent Statutory Exhaustion Requirement Thwarted

The U.S. District Court for the Eastern District of Missouri on February 24 rejected a home health care provider's efforts to avail itself of a constitutional exception to the requirement to exhaust administrative remedies with respect to appeals of Medicare denials. The litigation resulted from the decision of a Medicare contractor to reopen 30 therapy claims submitted by Plaintiff and demand repayment of $1,397,353. Plaintiff exhausted the first two levels of administrative appeal and initiated the third level. However, Plaintiff filed suit in federal district court prior to the administrative hearing. While the court observed that the Eighth Circuit has recognized a constitutional exception to the exhaustion requirement, the court held that Plaintiff did not qualify for the exception, which applies only where the litigant "(1) raises a colorable constitutional claim

collateral to his substantive claim of entitlement; (2) shows that irreparable harm would result from exhaustion; and (3) shows that the purposes of exhaustion would not be served by requiring further administrative procedures." The court determined that Plaintiff sought "review of the Medicare contractor's determination that it overbilled the program, [and that such] relief [was] 'inextricably intertwined' with [Plaintiff's] claims for benefits." Accordingly, the claims were not collateral to Plaintiff's substantive claim of entitlement. Moreover, the court found that Plaintiff failed to demonstrate irreparable harm, as the "Medicare statute itself provides an escalation remedy designed to provide either an expeditious resolution of claims or access to judicial review in a timely manner." *Triple A Home Care Agency, Inc. v. Burwell*, No. 4:15CV668 (E.D. Mo. Feb. 24, 2016).

Stolen Laptops Result in Hefty HIPAA Settlements

The Department of Health and Human Resources Office of Civil Rights (OCR) announced on March 17 a settlement in which the nonprofit Feinstein Institute for Medical Research agreed to pay $3.9 million and to institute a Corrective Action Plan in resolution of alleged HIPAA violations resulting from the September 2012 theft of an unencrypted laptop from an employee's car. The laptop contained the electronic protected health information (ePHI) of approximately 13,000 individuals, including names, birth dates, addresses, Social Security numbers, diagnoses, laboratory results and other medical information. Following an investigation, OCR concluded that the research institute had violated numerous HIPAA Privacy and Security Rule provisions. Among the violations cited were impermissible disclosure of ePHI; failure to conduct an adequate risk analysis of potential risk and vulnerabilities of all ePHI held by the institute; failure to implement policies and procedures for granting access to ePHI by its employees; failure to implement physical safeguards for the stolen laptop to restrict access to unauthorized users; failure to implement procedures that govern movement of ePHI-containing media into, out of and throughout the facility; and failure to either encrypt ePHI or implement an equivalent alternative measure.

Also, OCR on March 17 announced a $1.55 million settlement with North Memorial Health Care of Minnesota stemming from the theft of an unencrypted but password-protected laptop from the locked car of one of its contractors. The laptop contained the ePHI of 6,697 North Memorial patients. OCR noted that the contractor, which had access to North Memorial's ePHI database, did not enter into a Business Associate Agreement with North Memorial as required under the HIPAA Privacy and Security Rules. OCR further concluded that North Memorial failed to conduct an accurate and thorough risk analysis that incorporated all of North Memorial's information technology equipment.

Phase 2 HIPAA Audits Underway

In March, federal regulators took the long-anticipated step of launching a new round of HIPAA audits to test the compliance of covered entities—health plans, health care clearinghouses and health care providers who electronically transmit any health information—and the business associates that handle the health care information on behalf of covered entities. The Office of Civil Rights (OCR) at the Department of Health and Human Services (HHS) has begun the process of collecting contact information for covered entities and business associates of various types for inclusion in the pool of potential audited entities. OCR is charged with enforcing HIPAA's Privacy and Security Rules.

OCR has stated that every covered entity and business associate is eligible for an audit, and HHS notes on its website that "for this phase of the audit program, OCR is identifying pools of covered entities and business associates that represent a wide range of health care providers, health plans, health care clearinghouses and business associates." Following the collection of contact information, OCR will send questionnaires to covered entities and their business associates, and the data collected from these questionnaires will be used to create a pool of potential auditees. OCR will randomly select auditees from the audit pool and those auditees will be notified of their participation.

The first set of audits will be desk audits of covered entities, and the second set will be desk audits of business associates. Both of these audit sets, which will be completed by December 2016, will examine specific requirements of the Privacy, Security, or Breach Notification Rules. Auditees will be given 10 days to submit the requested documentation to a secure online portal that OCR has set up. The third set of audits will be on-site audits that will examine a broader scope of requirements than the desk audits. Some desk auditees may be subject to on-site audits. The on-site audits will be conducted over three to five days at each site.

Following the audits, OCR will send draft findings to the auditees. The auditees will have 10 business days to review the draft findings and provide written comments to the auditor. The auditor will complete a final audit report for each entity within 30 business days after the auditee's response. OCR will share a copy of the final report with the audited entity. The auditors will not be looking to state specific privacy and security rules and will limit their review to the Privacy, Security and Breach Notification Rules under HIPAA.

HHS has stated that OCR will use the audit reports to determine what types of technical assistance should be developed, identify what types of corrective action would be most helpful and, by analyzing the information received from the audits, will develop tools and guidance to assist the industry in compliance self-evaluation and in preventing breaches. However, if an audit reveals a serious compliance issue, OCR may begin a compliance review to investigate the matter further.

MedPAC Annual Report Recommends Part B Cuts for 340B Hospitals, Reforming SNF, Home Health Payments

MedPAC's annual report published March 15 calls for far-reaching payment reforms with the potential to impact a variety of health providers. Notably, MedPAC proposes the reduction of Part B drug payments to eligible safety net hospitals participating in the 340B drug program under which hospitals obtain drugs from wholesalers at greatly discounted prices while continuing to receive standard Part B reimbursement rates from Medicare. The surplus reimbursement may, in turn, be utilized by eligible hospitals to improve access to care. MedPAC's proposal would reduce the Part B payment rates by 10% of the average sales price and allocate the resulting savings to the Medicare-funded uncompensated care pool. On March 15, 340B Health, an industry group representing safety net hospitals, expressed its strong opposition to the proposal, stating: "What MedPAC proposes is a radical restructuring of the 340B drug pricing program. It is a solution in search of a problem—and one that would negatively impact many safety net hospitals and their communities. Now is not the time to consider fundamental changes to the program, especially as 340B hospitals struggle to meet the needs of their low-income and underserved populations in an era of rapidly increasing drug costs."

Additionally, the MedPAC report urges Congress to freeze Skilled Nursing Facility (SNF) payments for 2017 and 2018, and to revise the prospective payment system for SNFs and home health to promote payment accuracy. MedPAC further recommends the elimination commencing in 2018 of the use of therapy as a payment factor in the home health prospective payment system.

STATE

BME Revokes Physician License for Unlawful Prescribing Practices

On April 7, the New Jersey Board of Medical Examiners (BME) announced that it had revoked the medical license of a Passaic County physician for a minimum of three years following an investigation that revealed he had prescribed painkillers to patients without having examined them. Dr. Mohamed Kawam Jabakji of Prospect Park, who initially had his license suspended in April 2015, was found to have prescribed oxycodone, Percocet and codeine to six patients without having assessed their medical condition. According to a Star Ledger article on the incident, Jabakji must pay a $110,000 civil penalty to the state in addition to a $57,702 fine to reimburse the investigative and legal costs associated with the state's investigation. While Jabakji may apply for reinstatement of his medical license after three years, the Star Ledger noted that his prescription privileges have been permanently revoked. Alluding to the state's prescription drug epidemic in an announcement regarding BME's revocation action, the acting attorney general noted, "It is appalling that a member of the medical profession would help fuel New Jersey's prescription drug abuse epidemic by prescribing highly addictive pain pills indiscriminately."

Minimum Wage Debate to Impact Health Care

As the minimum wage debate rages in the New Jersey legislature and in the state's media outlets, the issue could have a significant impact on a vital cog in the state's health care delivery system. While the issue typically brings to mind fast food workers and retail employees, the proposed raise to $15 an hour would have a serious impact on the state's home health care agencies. According to the state's Department of Labor, the minimum wage in New Jersey is currently $8.38 an hour. In an industry where the bottom line is tied so closely to reimbursements from private insurers and government programs such as Medicare and Medicaid, a small raise can have a major impact on the finances of industry actors, and a raise such as the one currently being proposed could have serious consequences for the home health care industry in the state.

A recent article in the Courier Post noted the potential pitfalls and opportunities for home health agencies facing the prospect of a minimum wage hike to $15 per hour. Noting that the chairman of the Partnership for Medicaid Home-Based Care said that the increase of "the states' minimum wage to $15 an hour could simultaneously be the best and worst thing to happen to the home health care industry," the article goes on to quote the president of the New Jersey Association of Health Plans, who noted that a raise of the minimum wage to $15 per hour would "trigger both a need for a Medicaid MCO to review rates paid to its provider partners and for the state to review the rates paid to MCOs to ensure continued access to quality care." While the raise could be a daunting proposition for many home health care providers, it nonetheless provides an opportunity to discuss a raise in Medicaid reimbursement rates, which the article notes range from $13.80 to $15.50 an hour. However, without a raise in reimbursement commensurate with the wage increase, industry insiders fear a future with fewer hours with home health aides and higher out-of-pocket costs for patients.

State Legislators Drop Bills to Address Horizon's OMNIA Plan

Responding to a backlash against Horizon Blue Cross Blue Shield of New Jersey's multi-tiered OMNIA plans, New Jersey state legislators reviewed and approved a series of four bills during the first week of April. The bills, which were approved by the Assembly Regulatory Oversight Committee, would force insurers to reveal how physicians and hospitals are placed into tiered networks. One of the bills would require state regulators to ensure that those hospitals serving low-income populations are included in the networks, which provide consumers with the opportunity to pay less if they use providers in tier 1, the preferred tier.

The Star Ledger notes that OMNIA, under which the insurer created a tier 1 of 32 hospitals where co-payments and deductibles were lower than the remaining tier 2 hospitals, generated outrage from those hospitals relegated to tier 2. Due to Horizon's role as the largest insurer in the state, covering 3.8 million people, a hospital executive from a tier 2 hospital was quoted by the paper as saying that tier 2 facilities would cease to exist in three to five years because they would be forced to merge or close as a result of the lost business that is anticipated from the OMNIA tiered structure. Seventeen hospitals have filed an appeal seeking to overturn the State Department of Banking and Insurance's decision to approve the OMNIA plans last September. The overriding concern with the program noted by Assemblyman Reed Gusciora, who sponsored the legislation, is Horizon's ability to pick "winners and losers" in the hospital marketplace. Meanwhile, some business owners have extolled the virtues of the program, with one quoted in the Star Ledger as saying of OMNIA, "I could not be more pleased with the results. Our employees are offered remarkably low co-pays when they go to the doctor and no co-insurance." The future of the OMNIA structure, and the decision by Horizon as to which providers will be included in which tiers, will have a significant impact on health care in New Jersey in the years to come.

New Jersey State Senate President Demands Insurers and Hospitals Disclose Profits

State Senate President Steven Sweeney ordered in a letter dated March 11 that New Jersey hospitals report the amount of "pure profit" they earn, echoing a similar demand made to insurance companies days earlier. In connection with his purported focus on controlling health care costs, Sweeney directed that hospitals and insurance companies disclose 10 years' worth of "balance sheets and net profit" for their New Jersey operations. Sweeney indicated in his letter that the Senate is "engaged in this process to examine whether our existing statutory framework is fostering an environment which produces high-quality care at a fair cost to New Jersey consumers."

Sweeney announced his demand during a committee hearing on legislation that would more strictly regulate tiered network insurance plans, such as Horizon Blue Cross Blue Shield's OMNIA plans, which offer consumers significant discounts if they elect to use a limited subset of "tier 1" hospitals and doctors.

Sweeney has vowed to oppose any legislation that restricts the availability of such tiered insurance products, which he regards as "positive alternatives to high-deductible plans for consumers."

New Jersey Bill Tracker

Hepatitis C Testing

S1279, a bill requiring hospitals and health care professionals not employed by nursing homes or other long-term care facilities to offer hepatitis C testing to individuals born between 1945 and 1965, was passed overwhelmingly by the Senate on March 14, 2016, by a vote of 36-2. The bill further requires nursing homes

and other long-term care facilities, as well as the health care professionals employed thereby, to offer to arrange for the provision of hepatitis C testing to individuals born between 1945 and 1965, either by setting up a screening test appointment with an appropriate health care professional or general hospital, or by arranging for a mobile laboratory or other laboratory site to provide the screening test. The bill was received by the Assembly, where it will be considered by the Assembly Health and Senior Services Committee.

Substance Abuse Treatment

S294, a bill requiring the health care professional or first responder who administers an opioid antidote to a person experiencing a drug overdose to provide that person with information concerning substance abuse treatment programs and resources, was reported favorably from the Senate Health, Human Services and Senior Citizens Committee on March 7, 2016. If the person is admitted to a health care facility or receives treatment in the emergency department of a health care facility, the bill would obligate the health care professional with primary responsibility for the person's care to provide the information at any time after treatment for the drug overdose is complete but prior to the person's discharge from the facility. This health care professional also would be required to document the provision of the information in the person's medical record and would be permitted to develop a substance abuse treatment plan for the person. The bill will proceed to the full Senate for a vote.

Alzheimer's Notation in Medical Records

S377, a bill requiring the inclusion of Alzheimer's-related diagnoses in medical records at the initiation of care, was reported favorably from the Senate Health, Human Services and Senior Citizens Committee on March 7, 2016. The bill obligates hospitals to require health care professionals, at the time of taking a medical history or performing a physical examination of a patient admitted to an emergency room or the hospital, to include a notation in the patient's medical record indicating, if applicable, that the patient has Alzheimer's disease and related disorders. The bill is intended to facilitate better care for patients and to help prevent elopement from hospitals. The bill will proceed to the full Senate for a vote.

Tiered Health Insurance Networks Task Force

A888, a bill establishing the New Jersey Task Force on Tiered Health Insurance Networks, was passed by the Assembly on April 7, 2016, by a unanimous vote of 73-0. According to a statement published by the Assembly Regulatory Oversight and Reform and Federal Relations Committee, "[t]he purpose of the task force is to study the recent trend toward tiered health insurance networks; identify the impact of tiered health insurance networks on consumers, hospitals, providers and the health care delivery system; and make recommendations for legislation and strategies to create more effective and efficient policies regarding tiered health insurance networks in the state and to ensure that tiered networks operate in the public interest." Among other responsibilities, the task force would assess the effects of tiered networks on hospitals, particularly "safety net" hospitals; examine how the process of creating tiered provider networks can be made more transparent, fair and equitable; evaluate the role of the Department of Health in assessing the effect tiered networks might have on the financial security of hospitals, particularly safety net hospitals; and confirm that network adequacy regulations are sufficient to ensure that tiered networks do not discriminate against community providers and hospitals that provide treatment to underserved or high-risk populations. The bill will proceed to the Senate, where it faces an uncertain fate. Senate President Stephen Sweeney has voiced strong support for tiered plans, vowing to oppose any bill that "threatens consumer choice."

CONTRIBUTORS

Justin C. Linder // Special Counsel
973.639.7988
jlinder@mcmarter.com

Dennis D. Barrett // Associate
973.639.7941
dbarrett@mccarter.com

HEALTH CARE TEAM MEMBERS

Dennis D. Barrett // Associate
973.639.7941
dbarrett@mccarter.com

Richard L. Green // Partner
860.275.6757
rgreen@mccarter.com

Justin C. Linder // Special Counsel
973.639.7988
jlinder@mcmarter.com

Richard J. Myslinski // Associate
973.849.4084
rmyslinski@mccarter.com

Geoffrey N. Rosamond // Partner
973.639.8461
grosamond@mccarter.com

Gerard G. Brew // Partner
973.639.6976
gbrew@mccarter.com

Daniel J. Kelly // Partner
617.449.6526
dkelly@mccarter.com

Christopher S. Mayer // Partner
973.848.5393
cmayer@mccarter.com

Richard T. Nolan, Jr. // Partner
973.639.2096
rnolan@mccarter.com

Beth Yingling // Partner
973.639.7911
byingling@mccarter.com

Mark A. Daniele // Partner
973.639.2090
mdaniele@mccarter.com

Scott A. Kobler // Partner
973.639.2019
skobler@mccarter.com

Robert A. Mintz // Partner
973.639.7916
rmintz@mccarter.com

Debra M. Perry // Partner
973.639.2083
dperry@mccarter.com