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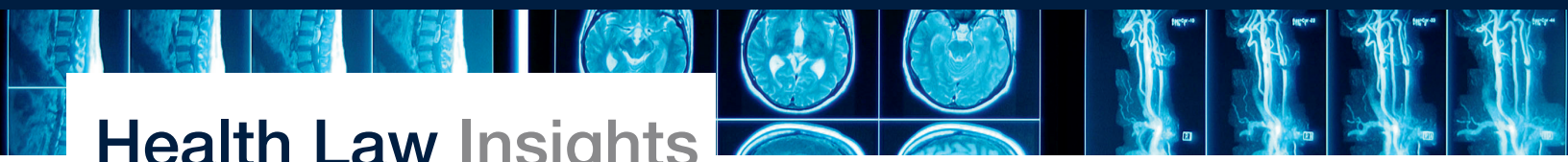

Health Law Insights

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NATIONAL

Providers' Obligation to Report Medicare Overpayments Clarified in New Rule

A final rule issued by the Centers for Medicare and Medicaid Services (CMS) on February 11 requires health care providers to report Medicare overpayments within 60 days of "identification" or risk liability for treble damages and crippling fines under the False Claims Act and Civil Monetary Penalties Laws. The rule implements an Affordable Care Act (ACA) requirement that practitioners, hospitals, and other Medicare participants identify and return reimbursement overpayments made in error or as a result of improper claim submissions within an abbreviated time period. The ACA and the final rule require that an overpayment be reported and returned by the later of 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable. Overpayments can result from errors on the part of Medicare contractors or providers and from receipt of payment for claims arising from violations of the Stark Law or Anti-Kickback Statute. The final rule clarifies that providers are obligated to exercise "reasonable diligence" by undertaking proactive compliance activities to monitor claims and by performing reactive investigations after receiving "credible information about a potential overpayment." The final rule further requires Medicare participants to "look back" six years to identify overpayments that may have been received during that extended time period. Pursuant to the rule, the 60-day clock does not begin to run until an overpayment is identified and quantified. An investigation to identify and quantify an overpayment must be completed within six months of receiving credible information about a potential overpayment.

New Core Clinical Quality Measures Released by Public, Private Collaborative

The Centers for Medicare and Medicaid Services (CMS) and America's Health Insurance Plans (AHIP) recently released, as part of a Core Quality Measures Collaborative, seven sets of clinical quality measures designed to be harmonized across commercial and government payors. The Collaborative's goal in developing the core quality measures was that they be meaningful to patients, consumers, and physicians, while reducing variability in measure selection, burden, and cost. The core measures were released in seven sets: Accountable Care Organizations, Patient Centered Medical Homes and Primary Care, Cardiology, Gastroenterology, HIV and Hepatitis C, Medical Oncology, Obstetrics and Gynecology, and Orthopedics. CMS intends to implement the new core measures in connection with various existing Medicare quality programs while eliminating redundant measures falling outside the core measures in future rulemaking. Additional information on the new quality measures can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html.

Opioid Abuse Gets the Attention of US Senate and Centers for Disease Control

Responding to the opioid prescription drug abuse and heroin epidemics that have swept the nation, the U.S. Senate on March 10 passed the Comprehensive Addiction and Recovery Act (CARA) of 2016 (S. 524) by a vote of 94-1. The bipartisan legislation authorizes grants for states to address the opioid and heroin crises, directs the Department of Health and Human Services (HHS) to develop an interagency task force charged with developing best practices for pain management, and calls for the creation of a program to curtail the overprescribing of opioids to Medicare beneficiaries by preventing those beneficiaries from shopping multiple physicians and pharmacies in search of large quantities of opioids. The bill, which requires House approval before becoming law, is seen as a start in dealing with the opioid problem. The Senate Health, Education, Labor and Pensions Committee will turn to additional legislation aimed at addressing the opioid epidemic later this month.

Meanwhile, on March 15, the Centers for Disease Control and Prevention (CDC) responded to a sharp increase in opioid-related deaths by releasing new guidelines recommending that physicians reconsider treating patients suffering from chronic pain with opioids. Noting that the incidence of opioid-related deaths has quadrupled since 1999 and that 2014 had more opioid-related deaths than any year on record, the CDC encouraged providers to initially seek alternative courses of treatment, such as exercise or anti-inflammatory drugs, and advised that if patients must be prescribed opioids, it should be in low doses and in conjunction with alternative therapies.

Rise in Drug Prices Being Eyed by Congress and Regulators

Recent headlines surrounding the aggressive pricing strategies employed by pharmaceutical companies such as Turing Pharmaceuticals, which increased the price of a drug to treat parasitic infections by 5000%, have drawn the attention of both legislators and regulators. While Turing provides the most notorious example of skyrocketing prices, the company is symptomatic of a larger trend in prescription drug price increases. A recent study by Bloomberg Business cited by a March 13 article in the Washington Post found that prices for 60 medications had more than doubled since December 2014 and, in the case of 20 of those medications, had more than quadrupled. The Post noted that these widespread increases have thrown hospital finances into disarray.

While the CEO of Turing went to Capitol Hill to testify before Congress last month, it appears the more immediate action may come from the National Institutes of Health (NIH). NIH Director Francis Collins testified at a House appropriations subcommittee hearing on March 16 that NIH, which funds drug development, would be open to exercising its "march-in rights" rights under the Bayh-Dole Act. The "march-in rights" permit an agency to intervene and ignore exclusivity rights on a patent, and issue patent licenses on its own when "reasonable terms are not being met" on drug pricing and the agency has intellectual property rights on the drug.

HEALTH INFORMATION TECHNOLOGY

Bipartisan Health Information Technology Improvement Bill Passes Senate Committee

On February 9, the Senate Committee on Health, Education, Labor and Pensions unanimously passed the Improving Health Information Technology Act (S. 2511). The goal of the bill, as described by Committee Chairman Lamar Alexander (R-TN), "is to make our country's electronic health record system something that helps patients rather than something that doctors and hospitals dread so much that patients are not helped . . . ." Among other provisions, the legislation would permit nonphysicians, such as nurses, to document on behalf of physicians; confer upon the Department of Health and Human Services Office of Inspector General the authority to investigate and establish deterrents to information-blocking practices that interfere with the sharing of electronic health information; and ask the Governmental Accountability Office to review mechanisms for securely matching patient records to the correct patient. The bill would also create a rating system permitting users to share feedback regarding health information products and helping providers select the best technology for their practices and facilities.

Lawmakers Seek Guidance from HHS on Mobile Health Apps

Responding to concerns of health care providers regarding the interplay between new health information technologies and privacy laws, a bipartisan group of lawmakers sent a letter to HHS on March 10 requesting clarification of the impact of privacy laws on mobile health applications. The lawmakers noted commitments made by HHS in 2014 with respect to clarifying standards for HIPAA compliance, cloud storage of health data, and regular engagement with technology companies, and expressed frustration regarding the lack of progress by the agency.

The HHS Office for Civil Rights (OCR), which is charged with monitoring the protection and security of health information, did provide some guidance in February of this year. OCR noted that app developers with direct provider relationships are deemed business associates subject to HIPAA rules because they contract for patient management services. On the other hand, app developers whose products are selected by consumers directly, and are not recommended for purchase by providers, likely would not be subject to HIPAA business associate obligations.

The lawmakers noted in their letter, though, that the "lack of clarity around HIPAA applicability in a mobile environment prevents many patients from benefiting from" technology and that many physicians "are

reluctant to receive information from their patients electronically without clear regulatory guidance." The letter further stated that "HHS has failed to provide even the simplest guidance to explain whether physicians and patients can text each other." This situation appears to be a prime example of technologies outpacing the agencies charged with regulating them.

MEDTECH and Regulations in the Medical Software Industry

Counsel for the CDS Coalition on March 10 reiterated its request for more clarity on regulations governing the industry. Clinical decision support (CDS) software is a classification of technologies ranging from software that communicates with implanted devices to tools that help providers with prescription decisions and automated alerts. The most recent request came in response to the Senate Health, Education, Labor and Pensions Committee's support of the Medical Electronic Data Technology Enhancement for Consumers' Health (MEDTECH) Act at a committee hearing on March 9. The MEDTECH legislation would strip the FDA of its authority to monitor certain technologies, including CDS software and electronic health records. While CDS software is generally considered low risk and does not require pre-approval from the FDA before going to market, the CDS Coalition counsel noted that the agency has been promising to develop CDS software guidance since 2011 and the lack of any progress since then has led to the delay and abandonment of many projects.

The majority of the CDS software affected by MEDTECH is low risk since CDS software primarily provides doctors with tools for sorting and finding relevant information in patient records. However, MEDTECH would not exempt CDS software that is capable of permitting doctors to confirm the software's recommendation. While the MEDTECH Act appears to ease the regulatory burden on some CDS software, the CDS Coalition notes that the lack of a clear and consistent regulatory framework has generated innovation-stifling uncertainty among developers and investors.

PEER REVIEW / CREDENTIALING

New York Court Holds Peer Review Statements Privileged under HCQIA, Dismisses Defamation Action

The New York Supreme Court, Appellate Division, held on January 13 that the Health Care Quality Improvement Act (HCQIA) precluded an aggrieved physician from maintaining a defamation action concerning statements made during a peer review meeting. Defendant Mercy Medical Center (MMC) received numerous complaints from other physicians and staff regarding the plaintiff physician's behavior, including allegations that the plaintiff raised his voice in the ICU, made rude and inappropriate remarks in front of patients, intimidated nurses, and made improper entries in patient charts. Consistent with MMC's medical staff bylaws, the medical director and staff chair requested that the medical staff executive committee take corrective action against the plaintiff, and referred the matter to the credentials committee. The medical director and other witnesses testified about the plaintiff's improper behavior during a subsequent meeting of the credentials committee. The committee unanimously recommended that the plaintiff's clinical privileges and medical staff membership be suspended. The medical executive committee later recommended the termination of the plaintiff's privileges, as authorized under the bylaws. The plaintiff failed to request a hearing to review that recommendation but instead instituted a defamation lawsuit against MMC, the medical director, and the staff chair. The Appellate Division held in Colantonio v. Mercy Med. Ctr. that although the statements made during the credentials committee meeting weren't absolutely privileged under the federal HCQIA insofar as the meeting was not quasi-judicial in nature, the statements were still protected from disclosure under HCQIA's qualified privilege. HCQIA's qualified privilege permits disclosure when a plaintiff produces evidence that the statements made by the witnesses were false and that the witnesses had knowledge that their statements were false. Because the plaintiff failed to meet this burden, the documents were shielded from production.

Privileges for Documentation Referenced by Peer Review Committees Not Absolute, According to West Virginia Court

In a ruling that has potential implications for state peer review privilege statutes across the country, West Virginia's highest court held on February 9 that a document is not shielded from disclosure solely by nature of its utilization by a peer review committee. Rather, a document must be created solely or exclusively by or solely for the use of the committee to trigger the protection of West Virginia's peer review privilege. The court in State ex rel Wheeling Hosp., Inc. v. Wilson observed that "merely because a review organization uses, in its deliberative process, records kept by a medical facility in the ordinary course of business does not mean that all such facility records are then sequestered from the grasp of discovery . . . ." Though the documents in the case at hand were protected from discovery by a medical malpractice plaintiff because they were created for the review committee, the court found that documents originating from other sources may be discoverable if requested from the original source.

Vermont Federal Court Denies Discovery of Joint Commission Documents in Wrongful Death Action

A federal court in Vermont held on January 25 that the state's peer review statute shielded from discovery documents relating to review by The Joint Commission (TJC) of a patient's suicide at a mental health facility. The plaintiff moved to compel production of records between the facility, TJC, and an HMO in a wrongful death action against the facility. The Vermont peer review statute identifies four kinds of entities that qualify as peer review committees privy to the law's protection, including a committee of a hospital or other health care provider. The law provides that the "proceedings, reports, and records" of such peer review committees are "confidential and privileged." The court acknowledged that TJC did not technically fall within any of the protected categories under the law but nevertheless held that the materials were shielded by the statute. The court noted that other Vermont courts had previously found that TJC constitutes a "peer review committee" under the statute, focusing on the type of work it does, which is "clearly peer review in nature." The court also rejected the plaintiff's argument that the documents were discoverable because they were not created during a formal review process, but rather reflected "conversations and documents arising in the course of ordinary business operations." The court found that the documents were consistent with the formal peer review processes contemplated by the statute and that they were very different from a mere "conversation between staff about 'quality control,'" which, presumably, would not be protected. The court also held that none of the records were "original source" documents merely reviewed by TJC.

NEW JERSEY

Law Restricting New Ownership of Ambulatory Surgery Centers

Governor Christie signed into law on January 16, 2016, a bill requiring certain surgical practices and ambulatory care facilities licensed in New Jersey to be owned by hospitals or medical schools located in the state.

New Jersey Bill Tracker

Medication Management Coverage

S-1175, a bill requiring the coverage of medication therapy management services under Medicaid and NJ FamilyCare, was reported favorably out of the Senate Health, Human Services and Senior Citizens Committee, with amendments, on February 29, 2016. The bill was referred to the Senate Budget and Appropriations Committee for further consideration.

Ambulatory Care Facilities

S-1710, a bill allowing ambulatory care facilities, including federally qualified health centers, to provide integrated primary health care services, including behavioral health care services, under a single license, was reported out of the Senate Health, Human Services and Senior Citizens Committee, with amendments, on February 29, 2016. Authorized treatment services under the bill would include, but would not be limited to, assessment and evaluation; referral, linkage, and follow-up; individual, group, and family therapy; psychiatric evaluation; medication services; and medication monitoring. The bill will now be considered by the full Senate.

Hepatitis C Testing

On February 29, 2016, the Senate Health, Human Services and Senior Citizens Committee favorably reported S-1279 out of committee, with amendments. The bill, as amended, requires hospitals and health care professionals who are not employed by nursing homes or other long-term care facilities to offer hepatitis C testing to individuals born between 1945 and 1965. It also 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 will be considered by the full Senate.

Behavioral Health Reimbursement

S-1730, a bill increasing Medicaid reimbursement rates for certain evidence-based behavioral health services under the state Medicaid program, was reported favorably out of the Senate Health, Human Services and Senior Citizens Committee, with amendments, on February 29, 2016. Under the bill, reimbursement rates could be no less than the market rate for the service, provided that the service meets certain criteria. The bill has been referred to the Senate Budget and Appropriations Committee for its consideration.

Ambulatory Surgical Centers

A-3101, a bill authorizing surgical practices registered with the Department of Health to convert to an ambulatory surgery facility, combine with an existing ambulatory care facility to expand the services offered through that facility, or allow a nonprofit hospital or an entity owned in part by a nonprofit hospital to acquire a joint ownership interest in the facility, was reported out of the Assembly Health and Senior Services Committee on February 22, 2016. The bill additionally permits two or more licensed ambulatory surgical facilities to combine. The bill will now be considered by the full Assembly.

Laboratory Supervision

S-976, a bill revising the requirements concerning supervision of bio-analytical laboratories to require that the laboratories be under the overall management and direction of either a licensed physician or a licensed bio-analytical laboratory director who is accessible to the laboratory to provide on-site, telephone, or electronic consultation as needed, was reported favorably out of the Assembly Health and Senior Services Committee on February 22, 2016. The bill was previously passed by the Senate and awaits a vote in the Assembly before being sent to the governor.

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