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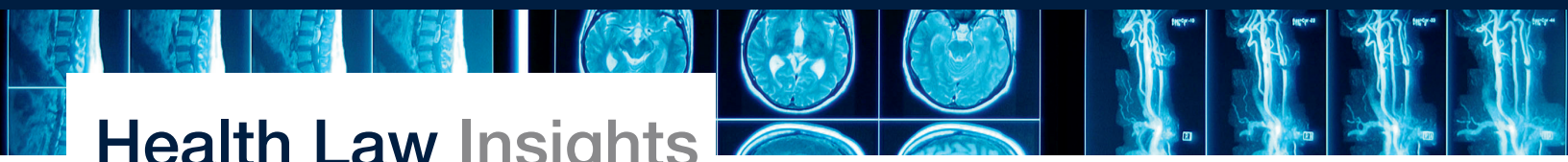

Health Law Insights

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NATIONAL

Medicare Proposes New Part B Payment System

The Center for Medicare and Medicaid Services (CMS) on April 27 proposed a new rule that would transform Medicare Part B reimbursement to practitioners into a two-track payment system commencing in 2019. Under the new system, called the Quality Payment Program, practitioners would have the option of electing to receive payment of a 5 percent annual bonus under an "advanced alternative payment model" (APM) or opt for payment under a Merit-Based Incentive Payment System (MIPS), which would subject them to payment increases or reductions based upon a quality performance score. The proposal is designed to replace the sustainable growth rate formula.

Strict requirements are anticipated to make it difficult for most practitioners to avail themselves of the APM option. Among other restrictions, Medicare Advantage participants would be ineligible for the 5 percent APM bonus.

Although the new payment system would not be effective until 2019, practitioners would be assessed for their MIPS performance scores over a two-year period commencing in 2017. Performance scores would, in turn, inform payment reductions and increases, beginning at 4 percent in 2019 and increasing to 9 percent in 2022. MIPS will replace the current crop of incentive payment programs, including the Electronic Health Records Meaningful Use Incentive Program, the Physician Quality Reporting System and the Value-Based Payment Modifier. The comment period for the proposed rule ends on June 27, 2016.

Providers Prepare for Potential Doubling of FCA Penalties

A regulation promulgated by a little-known federal agency has set the stage for a wide-ranging change to one of the federal government's most powerful penalties involving health care providers that are recipients of funds from federal health care programs. While the regulation involving the False Claims Act (FCA) was promulgated by an agency unrelated to health care, it has far-reaching effects and could have a significant impact on the penalties associated with health care enforcement actions in the future.

On May 2, the Railroad Retirement Board (RRB) became the first federal agency to adjust penalties for the FCA. The RRB raised the range of per-claim penalties from a minimum of $5,500 per claim and maximum of $11,000 per claim to a minimum of $10,781 per claim and a maximum of $21,563 per claim. The rise in penalties is a result of the Bipartisan Budget Act of 2015, which was signed into law on November 2, 2015, and which included a provision that required that civil monetary penalties must be raised by August 2016. The RRB was the first of the federal agencies impacted by the Bipartisan Budget Act to raise the associated fees under the FCA.

The changing penalties also raise a number of additional issues for providers and health care attorneys to consider. One commentator, writing in Law 360, notes, "The bigger penalties, which will be further adjusted for inflation on an annual basis, stir up some important issues. For one thing, they make it more likely that a company will be able to successfully challenge FCA penalties under the Eighth Amendment, which prohibits 'excessive fines.' The situation would most likely arise in a case involving a vast number of fraudulent billing claims but only a small amount of actual damages." While opening the door to Eighth Amendment challenges,

the increased penalties likely to impact FCA claims in the health care space should remind providers of the importance of proper billing practices and the serious financial implications associated with FCA penalties.

U.S. Supreme Court Hears Arguments in Pivotal Fraud Case

The Supreme Court on April 19 heard arguments in a case whose repercussions could reverberate throughout the health care industry by clarifying the level of regulatory compliance necessary to avoid violation of the federal False Claims Act (FCA). Alternatively, the Court can split 4-4, leaving a controversy central to FCA enforcement unresolved and subject to divergent standards applied by various Circuit Courts of Appeal. At issue in *Universal Health Servs., Inc. v. United States ex rel. Escobar* is the validity of the "implied false certification" theory of liability under the FCA. Under this theory, a submission of a claim that is factually accurate (that is, no factual falsity or false certification) may nevertheless be considered a false claim if the claim itself (or the manner in which the services underlying the claim were performed) breaches some governmental rule, regulation, standard, or contractual term on which payment is conditioned. Without limitation, noncompliance by a provider with one of the vast number of contractual provisions and/or state/federal statutes and regulatory provisions governing the rendering of a service, however minor, could result in a false claim and crippling sanctions. In *United Health*, the Justices are being asked to endorse or reject the implied certification theory and, in the event it accepts the theory, define its limitations.

The case under review involves allegations by a whistleblower that a provider fraudulently misrepresented that mental health treatment was provided to a patient by appropriately licensed and supervised staff, as required under state law. The trial court held that the violation of state law could not form a basis for FCA liability because that law was a Medicare condition of participation rather than a condition of payment. The First Circuit Court of Appeals reversed, finding that the state staffing regulations were conditions of payment. The controversy before the Court, as articulated in Universal Health's petition for certiorari, is whether a reimbursement claim could be legally false for purposes of the FCA if the provider failed to comply with a statute, regulation or contractual provision that did not expressly state that it was a condition of payment. While Justice Breyer suggested that materiality may be key to deciding whether a violation rises to the level of fraud, Chief Justice Roberts expressed concern over the materiality distinction, noting that "there are thousands of pages of regulations under Medicaid or Medicare programs."

Deputy Solicitor General Malcolm Stewart, appearing as amicus curiae in support of the whistleblower, asserted that a claim is false when that claimant is aware that he is not entitled legally to be paid. Stewart opined that "A person who knew himself to be in breach of a nonmaterial term and requested payment anyway wouldn't be making a false claim. But if the term that was being breached was material, the claim of legal entitlement would be false." When asked by Justice Kagan what would constitute immaterial terms, Stewart responded: "I don't know if there are any terms that are wholly immaterial, because if there were, they wouldn't be in the agreement or the regulations." Stewart acknowledged, however, that "there are certainly terms that would be immaterial to particular claims."

IRS Rejects 501(c)(3) Status for Non-Medicare ACO

In a recent Private Letter Ruling, the IRS found that a nonprofit entity organized to operate an Accountable Care Organization (ACO) independent of the Medicare Shared Savings Program (MSSP) did not qualify for 501(c)(3) status. Prior IRS guidance had previously confirmed that MSSP ACOs are 501(c)(3) eligible because they act to lessen governmental burdens.

The ACO that was the subject of the letter ruling was formed as a separate corporation by a tax-exempt health care system to create a clinically integrated network of providers, including physicians employed by the system, physicians not employed by the system but who were members of the medical staffs of affiliated hospitals and physicians practicing at unaffiliated hospitals. The IRS determined that the joint contracting arrangement proposed by the ACO to achieve lower health care costs and promote the tripartite goal of better care, lower cost and better health provided substantial private benefits to the participating physicians. Of particular concern to the IRS were the benefits conferred upon the physicians that were not employed by or on the medical staffs of hospitals affiliated with the nonprofit system.

In light of this guidance, Section 501(c)(3) tax-exempt providers that are already participating in non-MSSP, non-Medicaid ACOs should reassess the risks that the arrangement poses to their tax-exempt status.

Social Security Numbers to Be Removed From Medicare Cards

In an effort to reduce the potential for identity theft, CMS is taking steps to remove all patient Social Security numbers from Medicare identification cards by 2018. According to an informational bulletin that CMS released on May 5, the agency is acting pursuant to Section 501 of the Medicare Access and CHIP Reauthorization Act (MACRA). MACRA requires the removal of all Social Security numbers from Medicare identification cards. CMS is charged with replacing the existing system of Medicare Health Insurance Claim Numbers (HICNs) with Medicare Beneficiary Identifiers (MBIs) to reduce the risks of identity theft.

The process of shifting from HICNs to MBIs will begin in early 2018 when CMS will transfer 60 million beneficiaries, including so-called dual eligibles, those individuals that are eligible for both Medicare and Medicaid, to the MBIs. In order for states to comply with MACRA, state Medicaid agencies must evaluate their existing systems and identify those areas that require changes or modifications before CMS assigns MBIs and distributes new Medicare ID cards.

Dissemination of Celebrity Medical News Offers HIPAA Compliance Crash Course

While the sudden and shocking death of famed musician and cultural icon Prince on April 21 led to a deluge of media coverage surrounding the artist's life and legacy, it may also have led to significant HIPAA violations. In the days after Prince's death, celebrity gossip site TMZ was notifying readers that the artist's flight had to make an emergency landing just a week before his death due to what sources told the site was a prescription drug overdose. Those sources, if they are in fact medical professionals or hospital employees connected to the facility where Prince was treated, could be found to have violated Prince's rights under the HIPAA privacy rule.

he incident is reminiscent of media disclosures surrounding an accident last year involving professional football player Jason Pierre-Paul, who severely damaged his hand while attempting to set off fireworks last July 4th at his home in Florida. While much speculation surrounded the damage to the athlete's hand in the days following the widely publicized incident, not much was known until ESPN reporter Adam Schefter published Pierre-Paul's medical records. The reporter had been given the medical records by two hospital employees. Reports from this February indicate that the responsible employees have been terminated by the hospital and the hospital reached a settlement with the athlete for violation of his HIPAA rights. While some speculated about the liability of reporters disclosing such information, neither ESPN nor TMZ is a covered entity and thus neither party in its respective scenario is liable under HIPAA. The incidents do reveal the importance of training employees and staff regarding the serious nature of HIPAA violations and the importance of maintaining patient privacy.

STATE

NJ Appeals Court Finds Root Cause Analysis Absolutely Privileged

The Superior Court of New Jersey, Appellate Division, held in a May 4 decision that the Patient Safety Act establishes an 'absolute privilege' for documents that are required to be prepared by a health care facility for filing with the New Jersey Department of Health for incidents involving the injury or death of a patient. The three-judge panel, in its May 4 ruling in *Conn v. Rebustillo*, overruled a Sussex County Superior Court ruling by Judge Edward Gannon.

The Patient Safety Act (PSA), which was signed into law in 2004, was enacted to improve health outcomes through a review of medical errors. On its website, the Department of Health describes the Act by noting, "The statute was designed to improve patient safety in hospitals and other health care facilities by establishing a medical error reporting system. Rather than seeking to place blame, the system promotes comprehensive reporting of adverse patient events, systematic analysis of their causes, and creation of solutions that will improve health care quality and save lives."

In *Conn v. Rebustillo*, patient David Conn fell from his hospital bed, suffered an "intracerebral hemorrhage" and died while staying at Newton Medical Center. As a result of his death, Newton was required under the PSA to file a "root cause analysis" (RCA) with the DOH. Conn's wife, Patricia, filed a motion seeking to obtain a copy of the RCA, arguing that the report was not protected under the PSA because it did not fully comply with the Act. Judge Gannon, citing a 2004 decision that held discoverable the factual contents of a

peer review report that were prepared prior to the PSA's enactment, held the RCA to be discoverable

Writing on behalf of the three-judge panel, Appellate Division Judge Marianne Espinosa wrote that the state legislature "recognized that it was critical to encourage disclosure by creating a nonpunitive culture" focused on improving outcomes rather than placing blame. Judge Espinosa went on to note that while RCAs should conform to those standards established by DOH, "receipt of the documents by the department…is sufficient to trigger the absolute privilege as to all documents." While she did note that the PSA allows for certain parts of the RCA to be covered by the privilege while others were not, she stated that the "plain language of the statute does not condition the privilege upon the satisfaction of other criteria." The ruling has significant meaning for hospitals and medical staffs and should provide comfort to providers that their findings in an RCA that conforms with the PSA will be protected from disclosure in a wrongful death or tort action.

Cooper Hospital Loses Battle for Increased Medicare Reimbursement

A federal district court ruled on April 11 that Cooper Hospital was ineligible to receive additional Medicare Disproportionate Share Hospital (DSH) payments for the treatment of disadvantaged patients under the New Jersey Charity Care Program. Cooper argued that Medicaid-ineligible patients that who were nonetheless treated under the charity care program should have been included in computing the hospital's DSH payment, which provides increased payment to hospitals with a high Medicaid patient population. Cooper asserted that the decision of the Department of Health and Human Services (HHS) to exclude patients of the charity are program violated its due process rights because HHC permits other charity care programs to be included in the payment calculation under Section 1115 waivers. Rejecting Cooper's contention, the U.S. District Court for the District of Columbia ruled in *Cooper Hosp./Univ. Med. Ctr. v. Burwell* that there was a legitimate governmental purpose for distinguishing between Section 1115 waiver programs and other state charity care programs and including only Section 1115 program patients in DSH payment calculations because Section 1115 programs "promote the objectives of Medicaid."

New Jersey Bill Tracker

NonPrescription Access to Opium Antidotes

S295, a bill authorizing pharmacists to supply opioid antidotes such as naloxone without prescription, was reported favorably out of the Senate Health, Human Services and Senior Citizens Committee on May 2, 2016. The bill would expand public access to opioid antidotes under standardized protocols to be adopted by the Board of Pharmacy. The bill also would immunize pharmacists from civil, criminal or administrative penalties for dispensing opioid antidotes in accordance with the bill's requirements. S295 will proceed to the full Senate for consideration.

Homemaker-Home Health Aide Certification

S2036, a bill imposing deadlines on the New Jersey Board of Nursing with respect to determinations on certifications for home health aides, was reported favorably out of the Senate Health, Human Services and Senior Citizens Committee, with amendments, on May 2, 2016. The bill would require the Board to review and determine eligibility for conditional certification within 10 days of receipt of a completed application and to issue a final certification within 120 days from the date of issuance of the conditional certification. Current law requires the Board to issue a certification if an applicant meets statutory requirements but is silent with respect to conditional certification or deadline for a final determination. The bill moves on to the Senate Budget and Appropriations Committee for consideration.

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