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DOJ, NY AG REACH SETTLEMENT WITH HOSPITALS IN LANDMARK 60-DAY RULE CASE

On August 24, 2016, the U.S. attorney for the [Southern District of New York](#) and the New York [State attorney general](#) announced a \$2.95 million settlement (Settlement) in *U.S. ex rel. Kane v. Continuum Health Partners, Inc., et al.*, the first publicly unsealed federal False Claims Act (FCA) case against a health care provider for allegedly violating the 60-Day Rule.

The 60-Day Rule—enacted in 2010 as part of the Affordable Care Act—requires a health care provider that receives an overpayment to report and return the overpayment by the later of (1) 60 days after the provider identifies the overpayment or (2) the date any corresponding cost report is due. An “overpayment” includes any Medicare or Medicaid funds received that the provider is not entitled to retain after an applicable reconciliation. Failure to report and return an overpayment within the 60-Day Rule’s time frame subjects a provider to liability under the FCA, including treble damages and civil penalties.

This case arose due to a software glitch that caused three Continuum hospitals (now part of Mount Sinai Health System) to balance bill New York’s Medicaid program as a secondary payor for certain managed care claims, in violation of Medicaid billing rules. After investigating the software error, the relator in this case (formerly a Continuum employee) e-mailed Continuum’s management a spreadsheet containing 890 claims, 444 of which had been impermissibly submitted to, and reimbursed by, New York’s Medicaid program in the amount of \$844,730.69. The relator subsequently filed a whistle-blower suit under the FCA and the New York State False Claims Act after his employment was terminated, and the suit was publicly unsealed in 2014 upon the intervention of the Department of Justice and the States of New York and New Jersey.

The Settlement comes over a year after U.S. District Judge Edgardo Ramos rejected the defendants’ motion to dismiss the case (see our previous analysis [here](#)) in a decision and order that turned on the court’s interpretation of when an overpayment is “identified” for purposes of the 60-Day Rule. The court held that the overpayment had been identified for purposes of the 60-Day Rule when the defendants were put on notice of the potential overpayments by the relator via the e-mailed spreadsheet, not when the exact amount of the overpayment was conclusively determined, as the defendants had argued. Following that decision, the parties entered into negotiations that produced the Settlement.

In pertinent part, the Settlement obligates the defendants to pay \$1,180,000 to the federal government and \$1,770,000 to the State of New York. The Settlement also follows the Centers for Medicare and Medicaid Services’ (CMS) February 2016 final rule interpreting application of the 60-Day Rule to overpayments under Medicare Part A and Part B (see further analysis [here](#)). Given CMS’s emphasis in that final rule on the providers’ obligation to undertake proactive and reactive compliance efforts to identify and return overpayments in a timely manner, and the significant monetary settlement in this case, hospitals and other health care providers may wish to review and update compliance programs as necessary.

MASSACHUSETTS ALLOWS MEDICAL ASSISTANTS TO ADMINISTER VACCINATIONS

Massachusetts Governor Charlie Baker recently signed legislation that expands the permissible scope of practice of certified medical assistants in Massachusetts to permit such individuals to administer vaccines. House Bill No. 3895, entitled “An Act increasing access to immunizations” (HB 3895), takes effect on November 8, 2016, and permits a licensed primary care provider to delegate to a certified medical assistant the ability to administer an immunization to a patient.

Under HB 3895, a “certified medical assistant” is an individual who meets the following requirements:

1. Is a graduate of a post-secondary medical assisting education program accredited by the Committee on Allied Health Education and Accreditation of the American Medical Association, or its successor, the Accrediting Bureau of Health Education Schools, or its successor or such other certificate program as DPH approves;
2. Is employed in the medical practice of a licensed primary care provider; and
3. Performs basic administrative, clerical, and clinical duties upon the specific authorization and under the direct supervision of a licensed primary care provider.

“Direct supervision” is defined as “oversight of a certified medical assistant exercised by a primary care provider who is present in the facility and immediately available to furnish assistance and direction throughout the course of the performance of a delegated procedure but is not required to be present in the room when the procedure is being performed.”

HB 3895 defines a “licensed primary care provider” as a “a health care professional qualified to provide general medical care for common health care problems who: (1) supervises, coordinates, prescribes, or otherwise provides or proposes health care services; (2) initiates referrals for specialist care; and (3) maintains continuity of care within the scope of practice.”

Robinson+Cole’s [Health Law Group](#) has experience counseling health care providers on compliance with the 60-Day Rule and on establishing scopes of practice for medical assistants in accordance with applicable laws. We will continue to monitor and provide updates on health care enforcement activities and legislative changes. Please contact any member of the Health Law Group listed below if you have any questions about the False Claims Act, the 60-Day Rule, the practice scope of medical assistants, or any other health care compliance issue.

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