THREE KEY THINGS IN HEALTH CARE

HUNTON ANDREWS KURTH

September 22, 2020

- **Research on multipliers used in FCA settlements highlights need to evaluate most appropriate mechanism for self-disclosures.**
  - In a forthcoming law review article, Professor Jacob Elberg of Seton Hall University School of Law analyzes damage multipliers under recent Civil Settlement Agreements (CSAs) for False Claims Act (FCA) cases to highlight both a lack of uniformity in resolving FCA cases across different components of the Department of Justice (DOJ) and an absence of evidence that compliant behaviors are rewarded by DOJ. Some of the more striking findings from Elberg's analysis are:
    - The average multiplier was 1.78; 49% of cases used a 2.0 multiplier and only 12% had multipliers above 2.0.
    - The average multiplier for CSAs involving non-qui tam cases (including voluntary self-disclosures) was only 6% lower than the multiplier for qui tam cases.
    - There were several instances where voluntary self-disclosures were settled at multipliers higher than the overall average of 1.78.
    - 18% of the CSAs had multipliers of 1.0 (two of these were settlements that our health care team was able to secure on behalf of clients).
  - These findings illustrate the need for more coherent and consistent DOJ policy on providing cooperation credit that incentivizes voluntary self-disclosures, as Professor Elberg points out; however, they also highlight the need for providers to give appropriate consideration to the best mechanism and strategy for resolving potential overpayment issues through self-disclosures.
    - An important factor is the extent to which a disclosing party believes there is a need to obtain a formal settlement agreement (which would not occur in a self-disclosure refund to the MAC) and whether that agreement needs to include a release of potential claims under the FCA by the government.
    - Depending on the circumstances, it may not be necessary to pursue a resolution through DOJ. Even in resolutions involving DOJ, obtaining an FCA release (and paying the additional multiplier typically required to secure such a release) may not be warranted if the disclosing party has not engaged in culpable activity.
  - Different mechanisms for resolving a potential overpayment issue that should be considered, depending on the background facts and nature of the issue, include:
    - CMS Stark Self-Disclosure Protocol – only available to address potential overpayments arising out of Stark Law violations; CMS has not provided specific methodologies for calculating penalty amounts but these cases have consistently been settled for a small percentage of the total Medicare reimbursement arising out of prohibited referrals (i.e., a damages multiplier of less than 1.0).
    - OIG Self-Disclosure Protocol – only available to address potential overpayments arising out of the Civil Monetary Penalties Law (including

violations of the Anti-Kickback Statute); OIG has indicated that they generally apply a minimum damages multiplier of 1.5.

- Self-Disclosure to DOJ through local U.S. Attorney's Office – available to address all varieties of overpayment issues; DOJ has not provided any clear policy on settlement multipliers as illustrated by Professor Elberg's article, though an FCA release often requires a damages multiplier of 2.0 or more.
- Self-Disclosure Refund to local Medicare Administrative Contractor – available to address all varieties of overpayment issues; involves refund of actual overpayments received but there is no settlement agreement providing a formal release and may result in a referral to DOJ/OIG depending on the nature and scope of the overpayment issue.

- **Key Takeaway:** The lack of consistent DOJ policy to incentivize self-disclosures with reduced multipliers illustrated by Professor Elberg's research serves to highlight the importance, and potential financial impacts, in evaluating the most appropriate and effective strategy to resolve potential overpayments through self-disclosures.

- **The U.S. Department of Labor (the "DOL") tackles employee leave benefits under the Families First Coronavirus Response Act ("FFCRA") in a recent revised temporary rule, leaving employers scrambling to adapt quickly to remain in compliance with DOL regulations.**
  - On September 16, 2020, the DOL published its temporary rule, "Paid Leave under the Families First Coronavirus Response Act," (the "Temporary Rule"), promulgating revisions and clarifications to the initial temporary rule published on April 6, 2020 (and subsequently corrected on April 10, 2020) (the "Initial Rule"), and implementing the paid sick leave and expanded family and medical leave provisions of the FFCRA. The revised Temporary Rule comes on the heels of a U.S. District Court for the Southern District of New York decision that invalidated key provisions of the Initial Rule. *State of New York v. U.S. Dept. of Labor, et al.*, Civil Action No. 20-CV-3020 (JPO) (S.D.N.Y. Aug. 3, 2020). Among those provisions invalidated by the District Court decision, was the Initial Rule's definition of a "health care provider."
  - Under the FFCRA, certain employers may elect to exclude health care providers from some or all forms of leave benefits, giving the definition of "health care provider" great significance. Under the Initial Rule, the DOL provided what the District Court characterized as a "vastly overbroad" definition that included "employees whose roles bear *no nexus whatsoever* to the provision of healthcare services, except the identity of their employers, and who are not even arguably necessary or relevant to the healthcare system's vitality." (emphasis in original). *Id*. at *19. The District Court stated that the definition of health care provider may not hinge "entirely on the identity of the *employer* . . . rather than the skills, roles, duties, or capabilities of a class of employees." (emphasis in original). *Id*. at *18-19.
  - In the Temporary Rule, the DOL provides a narrower definition of "health care provider" that includes only employees who: (1) satisfy the definition of that term under the Family and Medical Leave Act ("FMLA"); or (2) "are employed to provide diagnostic services, preventive services, treatment services, or other services that are integrated with and necessary to the provision of patient care and, if not provided, would adversely impact patient care."

© 2020 Hunton Andrews Kurth LLP

- The Temporary Rule further identifies specific employees who may be excluded from FFCRA leave benefits, including but not limited to, nurses, nurse assistants, medical technicians and others directly providing diagnostic, preventive, treatment or other integrated services, and provides descriptions of what services constitute diagnostic, preventive, treatment and other integrated services.
- **Key Takeaway**: The Temporary Rule is jam-packed with information that employers will need to analyze carefully. In terms of the revised definition of health care provider, employers are left to determine which of their employees are now eligible for FFCRA leave benefits under the Temporary Rule, which may differ, perhaps significantly, from the employees such employers classified as eligible for FFCRA leave benefits under the Initial Rule.

- **Following several high profile settlements for potential violations of the HIPAA Security Rule, the U.S. Department of Health and Human Services Office of Civil Rights ("OCR") announced five new settlements under its HIPAA Right of Access Initiative, reinforcing that an individual's right of access to their protected health information ("PHI") is an essential component of HIPAA compliance.**
  - OCR first announced its HIPAA Right of Access Initiative in 2019, "promising to vigorously enforce the rights of patients to get access to their medical records promptly, without being overcharged, and in the readily producible format of their choice."
  - As a general matter, the HIPAA Privacy Rule gives an individual a right of access to their PHI. Covered entities may require requests for access to be in writing and may charge a reasonable, cost-based fee for access, but under the Privacy Rule must respond to requests within 30 days of receipt. If the covered entity grants the request, it generally must provide access to the PHI in the requested form and format, to the extent readily producible. Specific regulatory requirements are set forth in 45 C.F.R. §164.524.
  - While historically the vast majority of OCR's HIPAA enforcement actions addressed failures to comply with HIPAA Security Rule and Privacy Rule provisions designed to protect against impermissible disclosures of PHI, the Right of Access Initiative reflects OCR's focus on, and willingness to pursue enforcement against, covered entities that fail to provide access to PHI as required by the Privacy Rule.
  - OCR announced its first enforcement action and settlement under its Right of Access Initiative in September 2019 against Bayfront Health St. Petersburg. Several months later, in December 2019, it announced its second enforcement action and settlement, this time against Korunda Medical, LLC. In each instance, the enforcement action and settlement resulted from investigations prompted by complaints lodged with OCR.
  - Last week, OCR announced an additional five enforcement and settlement actions under its Right of Access Initiative, bringing the current total to seven. Again, each investigation resulting in the enforcement action and settlement was based on a complaint received by OCR. Total dollar amounts of the settlements range from $3,500 to $70,000 and include corrective actions plans with one to two years of monitoring.

- Importantly, in three of the recent enforcement actions – one involving Housing Works, Inc. and the others involving King MD and Wise Psychiatry, PC – OCR initially responded to complaints for failure to provide access to PHI by giving technical assistance to the covered entity and closing out the complaints. Only when the covered entity continued to fail to provide the required access and OCR received subsequent complaints did it seek enforcement and settlement for potential violations of the Privacy Rule.
- **Key Takeaway:** Covered entities should review their policies and procedures for responding to requests for access to PHI to ensure compliance with the HIPAA Privacy Rule requirements. In the event a covered entity receives an offer for technical assistance from OCR, it should undertake to provide access to PHI consistent with the technical assistance and recognize that failure to do so is likely to materially increase the likelihood of an OCR enforcement action.

Contacts

Mark S. Hedberg
mhedberg@HuntonAK.com

James M. Pinna
jpinna@HuntonAK.com

Holly E. Cerasano
hcerasano@HuntonAK.com

Matthew D. Jenkins
mjenkins@HuntonAK.com

Elizabeth A. Breen
ebreen@HuntonAK.com

© 2020 Hunton Andrews Kurth LLP. Attorney advertising materials. These materials have been prepared for informational purposes only and are not legal advice. This information is not intended to create an attorney-client or similar relationship. Please do not send us confidential information. Past successes cannot be an assurance of future success. Whether you need legal services and which lawyer you select are important decisions that should not be based solely upon these materials.