



Health Law Diagnosis

Monitoring the Pulse of Health Care and Life Sciences

January 2023

The Robinson+Cole Health Law Group is committed to examining and reporting on issues important to the health care and life sciences industries. Below are excerpts from our [Health Law Diagnosis](#) blog, where we post on fraud and abuse, government enforcement, Medicare and Medicaid, reimbursement, hospitals and health systems, pharmaceuticals, medical devices, and other areas of interest. For more updates on news and developments for the health care and life sciences industries, we invite you to [subscribe](#).

[New York Governor Vetoes Act Prohibiting Establishment and Expansion of For-Profit Hospices](#)

On December 23, 2022, New York Governor Kathy Hochul vetoed [Assembly Bill Number A8472](#) “An Act To Amend The Public Health Law, In Relation To The Establishment, Incorporation, Construction, Or Increase In Capacity Of For-Profit Hospice” (the Act). The Act was intended to prohibit the approval, incorporation, or construction of for-profit hospices and would have also prevented any existing for-profit hospices from increasing capacity. The Act would have gone into effect immediately had it not been vetoed. [Read more](#)

[No More Reasonable Diligence? CMS Proposes to Change Standard for Identifying Medicare Overpayments to Align with False Claims Act](#)

On December 27, 2022, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule ([Proposed Rule](#)), which proposes certain policy and technical changes to Medicare regulations, including a notable change to the current standard under the “60-Day Rule” for identifying a Medicare overpayment. Specifically, CMS indicated that it is proposing to (i) “adopt by reference” the federal False Claims Act’s (FCA) definitions of “knowing” and “knowingly” as governing when an overpayment is identified, and (ii) eliminate the “reasonable diligence” standard that has been in place, but subject to challenges, for a number of years. [Read more](#)

[OIG Issues Reports Reviewing Laboratory Billing Practices and Noting Increased Spending by Medicare Part B on Laboratory Tests](#)

As the year comes to a close, the government has signaled a specific focus on clinical laboratories for 2023. On December 6, 2022, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) issued a [Report](#) entitled, “Labs With Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny” (Report). The Report discusses why the study pertaining to the billing of additional tests alongside COVID-19 testing was conducted, how it was conducted, and what the key takeaways of the study are. This was followed by OIG’s issuance in mid-December of a [Data Brief](#) reviewing Medicare Part B spending on lab tests entitled, “Medicare Part B Spending on Lab Tests Increased in 2021, Driven by Higher Volume of COVID-19 Tests, Genetic Tests and Chemistry Tests” (Data Brief). [Read more](#)

[Timing is Everything: The Antitrust Division and OIG Sign Cross-Agency Agreement as Government Investigations Are Expected to Surge](#)

On December 9, 2022, the U.S. Department of Justice, Antitrust Division and the U.S. Department of Health and Human Services, Office of the Inspector General (OIG) (collectively, the Agencies) formalized their long-standing partnership to fight anti-competitive conduct in health care markets by signing a memorandum of understanding (MOU) to enhance cross-agency collaboration. Although the Agencies have conducted parallel investigations in the past, the timing of the MOU indicates that health care industries will receive increased scrutiny from both in 2023. Companies can proactively mitigate this risk with thorough compliance training that explains what constitutes misconduct and the grave civil and criminal penalties that can ensue. [Read more](#)

[Key Changes to the Medicare Shared Savings Program](#)

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) issued [changes](#) to the Medicare Shared Savings Program to advance CMS' broader strategy of growth, alignment, and equity. To improve the overall operations of the Shared Savings Program, CMS is finalizing changes that, among other things, will impact payment and Accountable Care Organization (ACO) beneficiary assignment, update quality reporting and performance requirements, and reduce the administrative burden for ACOs.

[Read more](#)

[California Governor Signs Bill Further Increasing Oversight of Hospice Agencies](#)

Last fall, California Governor Gavin Newsom signed [Assembly Bill No. 2673](#) (the Bill), which amends various sections of the California Health and Safety Code relating to hospice agencies. Among other things, the Bill prohibits hospice agency license transfers; adds requirements for hospice agency license applicants; increases oversight authority by the California State Department of Public Health (the Department); and updates the moratorium on new hospice agency licenses. [Read more](#)

If you have any questions, please contact any member of Robinson+Cole's [Health Law Group](#).

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