



# FEDERAL HEALTHCARE LAW UPDATE

## CMS Issues Guidance for Expiration of COVID-19 Public Health Emergency

The Centers for Medicare and Medicaid Services (CMS) recently issued [guidance](#) addressing the status of certain temporary rules and waivers that were instituted as a result of the COVID-19 Public Health Emergency (PHE), which is set to expire on May 11, 2023. The guidance includes a long list of rule waivers and modifications that were put in place by CMS during the PHE that will either terminate when the PHE finally expires or that will continue for either a limited or indefinite duration.

Among the rules addressed by the new guidance, cost sharing for COVID-19 tests will continue to be waived for fee-for-service Medicare beneficiaries, while Medicare Advantage plans may institute cost sharing at their discretion. Also, state Medicaid programs will be required to cover COVID-19 vaccinations, testing, and treatment without cost-sharing through September 30, 2024. In addition, certain flexibilities that CMS instituted during the PHE to provide Medicare beneficiaries with broader access to telehealth services will continue through December 31, 2024.

With the expiration of the PHE, all Medicare providers and suppliers will be required to comply with emergency preparedness rules that were waived during the PHE. CMS will also reinstate rules regarding pre-admission hospitalization and wellness requirements for patients requiring care at skilled nursing facilities, and rules relating to preadmission screenings, transfers, and discharge for residents of long-term care facilities. CMS will also change COVID-19 reporting obligations, education requirements, vaccination requirements, and testing requirements for both long term care, inpatient, and outpatient facilities.

CMS is also terminating some of the flexibilities that were instituted for certain types of acute and continuing care providers. Ambulatory Surgical Centers (ASC) and Licensed Independent Freestanding Emergency

Departments (IFED) that elected to temporarily enroll in Medicare as a hospital according to emergency rules that were promulgated during the PHE will be required to either revert to ASC or IFED status or apply to Medicare to become fully Medicare certified as a hospital. ASCs will once again be required to periodically review medical staff privileges and the scope of procedures performed in the ASC. Also, certain emergency waivers that modified the supervision requirements for certified nurse anesthetists at hospitals, critical care facilities, and ASCs will end when the PHE expires.

*For more information, contact:*

Isabelle Bibet-Kalinyak | 973.403.3131 | [ibibetkalinyak@bracheichler.com](mailto:ibibetkalinyak@bracheichler.com)

Caroline J. Patterson | 973.403.3141 | [cpatterson@bracheichler.com](mailto:cpatterson@bracheichler.com)

Joseph M. Gorrell | 973.403.3112 | [jgorrell@bracheichler.com](mailto:jgorrell@bracheichler.com)

## OIG Approves Providing Gift Cards to Promote Patient Compliance for Colon Cancer Screening Test

On March 24, 2023, the Department of Health and Human Services Office of Inspector General (OIG) issued [Advisory Opinion 23-03](#) allowing a proposed arrangement where a manufacturer of a colorectal cancer screening test and its processing laboratory issues prepaid Visa or Mastercard gift cards to federal healthcare program beneficiaries. These gift cards would encourage patients to return their test kits for processing and increase the detection of possible colorectal cancer. The OIG determined that, while the proposed arrangement may implicate the prohibition against beneficiary inducements under the federal Civil Monetary Penalties Law (CMP) and the federal Anti-Kickback Statute (AKS), the OIG would not impose sanctions.

Typically, the beneficiary's physician prescribes the colorectal screening test, the manufacturer mails the test kit to the beneficiary's home, and the beneficiary collects the stool sample and returns the test kit for



processing. Under the proposed arrangement, if the test kit is not received within a certain period of time, the laboratory will send a final reminder indicating that, if the laboratory receives the sample promptly, the laboratory will send the beneficiary a Visa or Mastercard gift card of up to \$75. First, the OIG determined that the gift card would not violate the CMP because “remuneration” under that law excludes incentives to beneficiaries that promote the delivery of preventive care. Second, the OIG found that the gift card presented a minimal risk of fraud and abuse under the AKS because it is unlikely to lead to overutilization of services, encourages patient compliance, and includes additional safeguards. The safeguards include: advising beneficiaries that the gift card may not be used for items or services provided by the laboratory, each beneficiary would be limited to one gift card in a 36-month period, and there would be no advertisement of the arrangement to prescribers or beneficiaries.

This opinion is consistent with other advisory opinions relating to gift card arrangements to federal health care program beneficiaries and shows that the OIG is poised to address all types of gift card programs. Healthcare providers interested in developing gift card arrangements for patients should carefully consider OIG’s analysis of such arrangements.

***For more information, contact:***

**John D. Fanburg, Chair** | 973.403.3107 | [jfanburg@bracheichler.com](mailto:jfanburg@bracheichler.com)  
**Carol Grelecki** | 973.403.3140 | [cgrelecki@bracheichler.com](mailto:cgrelecki@bracheichler.com)  
**Edward J. Yun** | 973.364.5229 | [eyun@bracheichler.com](mailto:eyun@bracheichler.com)

## Department of Justice Charges Defendants Nationwide for COVID-19 Health Care Fraud

**O**n April 20, 2023, the Department of Justice the DOJ **criminally charged** eighteen defendants with COVID-19 healthcare fraud schemes. The schemes resulted in \$490 million in false billing to federal programs and theft from federally funded pandemic programs. Defendants charged by the DOJ include:

- A lab owner allegedly added claims for respiratory pathogen panel tests, even though ordering providers and facility administrators did not want or need them.
- A doctor allegedly submitted over 70 fraudulent loan applications through the Paycheck Protection Program and Economic Injury Disaster Loan (EIDL) Program and obtained over \$3 million in loan funds.
- A doctor and a marketer allegedly purchased Medicare beneficiary identification numbers and shipped COVID-19 over-the-counter tests to beneficiaries who did not request the tests, causing over \$8.4 million in claims to Medicare.
- Three medical professionals at a small midwife practice allegedly distributed nearly 2,700 forged COVID-19 vaccination record cards to individuals who were not vaccinated.

***For more information, contact:***

**Isabelle Bibet-Kalinyak** | 973.403.3131 | [ibibetkalinyak@bracheichler.com](mailto:ibibetkalinyak@bracheichler.com)  
**Riza I. Dagli** | 973.403.3103 | [rdagli@bracheichler.com](mailto:rdagli@bracheichler.com)  
**Edward Hilzenrath** | 973.403.3114 | [ehilzenrath@bracheichler.com](mailto:ehilzenrath@bracheichler.com)

## Envision Awarded \$91.2M in Arbitration Against UnitedHealthcare

**A**n independent arbitration panel recently awarded \$91,270,257.00 to Envision Healthcare (Envision), a private equity-backed national medical group and physician services company, in its arbitration against UnitedHealthcare (UHC) for underpayment for essential medical care. While Envision has other lawsuits against UHC that are still pending, the award stems from UHC’s unilateral reduced reimbursement to Envision clinicians in violation of the parties in-network agreement. In response to Envision’s lawsuit, UHC claimed that it had approached Envision before litigation about alleged upcoding and deceptive practices regarding emergency care provided by Envision and that Envision responded by rushing the subject lawsuit and filing first to beat UHC to the courthouse. The arbitration panel ultimately decided in favor of Envision.

In 2021, UHC was involved in a similar dispute with TeamHealth Holdings (TeamHealth), in which UHC alleged that TeamHealth engaged in fraud by billing for over-inflated medical codes to get greater reimbursement. TeamHealth countersued against UHC, alleging that the insurer's shared savings plan encouraged the underpayment or termination of physician contracts. Ultimately, a Nevada jury agreed with TeamHealth and awarded them \$60 Million, finding that UHC engaged in unfair reimbursement practices by deliberately failing to pay frontline emergency room doctors adequately for care provided to patients.

*For more information, contact:*

**Keith J. Roberts** | 973.364.5201 | [kroberts@bracheichler.com](mailto:kroberts@bracheichler.com)

**Richard Robins** | 973.447.9663 | [robins@bracheichler.com](mailto:robins@bracheichler.com)

**Shannon Carroll** | 973.403.3126 | [scarroll@bracheichler.com](mailto:scarroll@bracheichler.com)



## Texas Laboratory Agrees to Pay \$5.9 Million to Settle Allegations of Kickbacks to Third-Party Marketers and for Unnecessary Drug Tests

**G**enotox Laboratories Ltd., of Austin, Texas, agreed to pay approximately \$5.9 million to resolve [False Claims Act allegations](#) that from 2014 to 2020 it paid volume-based commissions to third-party marketers in violation of the Anti-Kickback Statute and submitted claims to federal health care programs for unnecessary drug tests.

The Department of Health and Human Services Office of Inspector General (OIG) alleged that Genotox paid kickbacks to independent contractor sales representatives and marketing firms to arrange for or recommend the ordering of Genotox's laboratory testing, in violation of the Anti-Kickback Statute. Specifically, the independent contractors were paid a percentage of the revenue Genotox received from billing Medicare, the Railroad Retirement Board (RRB), and TRICARE for laboratory testing orders facilitated or arranged for by those contractors.

The OIG also alleged that Genotox submitted claims to

Medicare, RRB, and TRICARE for laboratory tests that were not covered and/or not reasonable and necessary, including blanket orders and routine standing orders of drug testing for all patients in a provider's practice. Specifically, Genotox offered health care providers order forms known as "custom profiles" for each provider to pre-select the tests to order, which Genotox then performed and billed, for all or nearly all of the provider's patients, generally at the highest reimbursement categories, such as definitive drug testing for 22 or more drug classes.

In connection with the settlement, Genotox entered into a five-year Corporate Integrity Agreement (CIA) with the OIG. The CIA requires, among other things, that Genotox maintain a compliance program, implement a risk assessment program, and hire an Independent Review Organization to review Medicare and Medicaid claims submitted by Genotox.

*For more information, contact:*

**Isabelle Bibet-Kalinyak** | 973.403.3131 | [ibibetkalinyak@bracheichler.com](mailto:ibibetkalinyak@bracheichler.com)

**Jonathan J. Walzman** | 973.403.3120 | [cjwalzman@bracheichler.com](mailto:cjwalzman@bracheichler.com)

**Carol Grelecki** | 973.403.3140 | [cgrelecki@bracheichler.com](mailto:cgrelecki@bracheichler.com)

## Updated CMS Guidance on Home Dialysis Services in Nursing Homes

**O**n March 22, 2023, CMS issued [updated guidance](#) for home dialysis services performed in a skilled nursing facility or nursing home. The updated guidance emphasizes having written agreements outlining arrangements between an End Stage Renal Dialysis (ESRD) facility and a nursing home and provides that an agreement establishes a connection between both entities and fosters accountability that is vital to patient health and the success of the care plan. The revised guidance also clarifies that the ESRD facility should collaborate with the nursing home to develop and implement protocols for the delivery of dialysis services, and to the extent possible, ensure that nursing home dialysis patients are provided the same standard of care as dialysis patients receiving treatments in a dialysis facility. The updated guidance also covers qualifications and training of any dialysis administering personnel and coordination of care.

*For more information, contact:*

**Isabelle Bibet-Kalinyak** | 973.403.3131 | [ibibetkalinyak@bracheichler.com](mailto:ibibetkalinyak@bracheichler.com)

**Caroline J. Patterson** | 973.403.3141 | [cpatterson@bracheichler.com](mailto:cpatterson@bracheichler.com)

**Lani M. Dornfeld, CHPC** | 973.403.3136 | [ldornfeld@bracheichler.com](mailto:ldornfeld@bracheichler.com)





## Florida Health Center Settles Discrimination Complaint with HHS for Ineffective Communication with Patient’s Caregiver

**M**CR Health, Inc., a Federally Qualified Health Center in Florida, voluntarily agreed to resolve a [disability discrimination complaint](#) filed by an individual who is deaf and hard of hearing, alleging that MCR Health failed to provide her with auxiliary aids and services when she requested an interpreter for her husband’s post-surgical medical appointment. As part of the agreement, MCR Health agreed to provide auxiliary aids and services to patients and companions who are deaf or hard of hearing, review its policies, document assessments, create an auxiliary aid and service denial log, give primary consideration to requests from patients or companions who are deaf or hard of hearing, and train all staff to ensure effective communication with patients and companions.

*For more information, contact:*

**John D. Fanburg, Chair** | 973.403.3107 | [jfanburg@bracheichler.com](mailto:jfanburg@bracheichler.com)  
**Joseph M. Gorrell** | 973.403.3112 | [jgorrell@bracheichler.com](mailto:jgorrell@bracheichler.com)  
**Shannon Carroll** | 973.403.3126 | [scarroll@bracheichler.com](mailto:scarroll@bracheichler.com)

## Changes to the Stark Law and Anti-Kickback Statute Address Physician Mental Health

**T**he federal Stark Law and Anti-Kickback Statute (AKS), which prohibit physician self-referrals and kickbacks, have changed for calendar year 2023. Notably, there is a new Stark Law exception and an AKS safe harbor for healthcare entities offering mental health programs to physicians, which includes counseling, mental health services, suicide prevention, and substance use disorder programs. The new Stark Law exception for physician-focused mental health programs requires a written policy and must be offered by a healthcare entity with a formal medical staff to all physicians in the geographic area served by the entity and without regard to the volume or value of referrals or other business generated by a physician for the entity. The new AKS safe harbor is similar to the Stark Law exception. However, the new AKS safe

harbor also applies to non-physician clinicians, thereby permitting healthcare entities to provide mental health and behavioral health improvement or maintenance programs to physicians and other clinicians.

*For more information, contact:*

**Isabelle Bibet-Kalinyak** | 973.403.3131 | [ibibetkalinyak@bracheichler.com](mailto:ibibetkalinyak@bracheichler.com)  
**Caroline J. Patterson** | 973.403.3141 | [cpatterson@bracheichler.com](mailto:cpatterson@bracheichler.com)  
**Carol Grelecki** | 973.403.3140 | [cgrelecki@bracheichler.com](mailto:cgrelecki@bracheichler.com)

## HIPAA CORNER

### HHS Provides Cybersecurity Resources to Help Address Cyber Threats

**O**n April 17, 2023, the U.S. Department of Health and Human Services [announced](#) the release of various resources to assist the health and public health sector to address the ongoing and growing cybersecurity concerns in such industries. These include:

[Knowledge on Demand](#) – a new online cybersecurity educational platform designed to assist health care facilities of various sizes across the country and that offers free cybersecurity trainings to improve cybersecurity awareness. The trainings address the top five cybersecurity threats to the health and public health industry: social engineering, ransomware, loss or theft of equipment data, accidental, intentional or malicious data loss, and attacks against connected medical devices.

[Health Industry Cybersecurity Practices \(HICP\) 2023 Edition](#) – consensus-based best practices to strengthen an organization’s cybersecurity defenses against cyber threats, and designed for organizations of different sizes.

[Hospital Cyber Resiliency Initiative Landscape Analysis - PDF](#) – a multi-agency collaborative report on domestic hospitals’ current state of cybersecurity preparedness.

One of the goals of these resources is to help organizations in the health and public health sector, including health care providers of all types, to develop and implement cybersecurity “best practices” and not only meet regulatory requirements but stay ahead, as best as possible, of the growing market of national and international cyber threat actors.

*For more information or assistance with your privacy and security program, contact:*

**Isabelle Bibet-Kalinyak** | 973.403.3131 | [ibibetkalinyak@bracheichler.com](mailto:ibibetkalinyak@bracheichler.com)  
**Lani M. Dornfeld, CHPC** | 973.403.3136 | [ldornfeld@bracheichler.com](mailto:ldornfeld@bracheichler.com)  
**Edward J. Yun** | 973.364.5229 | [eyun@bracheichler.com](mailto:eyun@bracheichler.com)

# ATTORNEY SPOTLIGHT

Get to know the faces and stories of the people behind the articles in each issue. This month, we invite you to meet Member Isabelle Bibet-Kalinyak and Member Caroline J. Patterson.



## ISABELLE BIBET-KALINYAK

A seasoned and creative problem-solver, Isabelle Bibet-Kalinyak, Esq., concentrates her national healthcare practice representing clients in complex business transactions including private equity transactions, mergers, and strategic partnerships, HIPAA privacy and security compliance matters, ownership and compensation arrangements, employment and partnership negotiations, medical staff matters, and fraud and abuse issues including compliance with the Stark Law and the Anti-Kickback Statute. She works with management teams and boards of directors on the legal and strategic implications associated with various forms of corporate entities and healthcare integration models.

Isabelle leverages her keen affinity for the healthcare industry and her deep knowledge of that sector to serve as a trusted legal advisor to health systems, specialty hospitals, telemedicine virtual platforms, physician group practices, medical societies, transactions, M&A, ambulatory surgical centers, dialysis facilities, laboratories, long-term care facilities, and individual physicians on a broad range of complex healthcare matters involving corporate compliance, licensing, fraud and abuse, HIPAA, business alignment, life cycle management, Medicare and Medicaid rules, and other payor matters.

She combines a focus on results with a client-centric approach when counseling on the business and compliance aspects of healthcare law in connection with transactional, corporate, regulatory, and governance matters. The depth of Isabelle's experience enables her to assist clients in evaluating both the legal and business ramifications of transactions, contracts, agreements, negotiations, and compliance issues.

Isabelle is legal counsel to the following medical societies:

- The New Jersey Obstetrical & Gynecological Society (NJOGS)
- The New Jersey Society of Pathologists (NJSP)
- New Jersey Association of Ambulatory Surgery Centers (NJAASC)
- New Jersey Academy of Ophthalmology (NJAOC)
- North Jersey Orthopaedic Specialists (NJOS)

Isabelle is a frequent speaker at national conferences such as the American Health Lawyers Association (AHLA), the Medical Group Management Association (MGMA), and the American Academy of Ophthalmology (AAO) and lectures on advanced topics related to healthcare, mergers and acquisitions, private equity and business immigration. In 2019, she was appointed by the French Government as Honorary Consul with jurisdiction over northern and central Ohio until March 2022.



## CAROLINE J. PATTERSON

Caroline Patterson concentrates her practice on the representation of healthcare providers and other business organizations in a wide variety of transactional and corporate matters, including acquisitions and sales, mergers, strategic partnerships, private equity investments, HIPAA compliance, ownership and compensation arrangements, and employment negotiations. Caroline also has extensive experience advising investigators and clinical institutions on clinical trial agreements and clinical research law.

Caroline's clients include physician practices, management service organizations, life science and other healthcare consulting companies, dental practices, physical therapists, ambulatory surgery centers, and individual healthcare professionals.

Prior to joining Brach Eichler, Caroline worked at both a large Philadelphia law firm in the areas of corporate and securities law and at a small national boutique law firm specializing in corporate, healthcare, regulatory, and employment law matters.

On May 4, Labor and Employment Member **Jay Sabin** issued a Law Alert entitled "[Saliva Testing Now Acceptable.](#)"

On May 2, Healthcare Law Member **Isabelle Bibet-Kalinyak** discussed how doctors can limit exposure to criminal liability in Modern Healthcare, "[How malpractice insurers are navigating abortion bans.](#)"

Join us for the **12th Annual New Jersey Healthcare Market Review**, September 28-29, 2023 at the Borgata Hotel Casino & Spa, Atlantic City, NJ! Connect with over 200 attendees comprised of hospital and ASC executives and stakeholders, physicians, practice owners/managers, and healthcare administrators. During this two-day event, industry experts will discuss timely topics and trends in the healthcare and legal space ranging from legislative issues to operating and business strategies for greater profitability. To learn more and register, please visit [www.njhmr.com](http://www.njhmr.com). For questions or additional information, please reach out to **Ilana Schackman** at [ischackman@bracheichler.com](mailto:ischackman@bracheichler.com).

The following Brach Eichler Healthcare Law Members were named to the "**2023 New Jersey Super Lawyers**" list by Super Lawyers: **Lani M. Dornfeld, John D. Fanburg, Joseph M. Gorrell, Carol Grelecki and Keith J. Roberts. Shannon Carroll and Emily Harris** were each named to the "**NJ Rising Stars**" list by Super Lawyers. Congratulations to all! *\*No aspect of this advertisement has been approved by the Supreme Court of New Jersey. Click [here](#) for the Awards and Honors Methodology.*



Attorney Advertising: This publication is designed to provide Brach Eichler LLC clients and contacts with information they can use to more effectively manage their businesses. The contents of this publication are for informational purposes only. Neither this publication nor the lawyers who authored it are rendering legal or other professional advice or opinions on specific facts or matters. Brach Eichler LLC assumes no liability in connection with the use of this publication.

## HEALTHCARE LAW PRACTICE | 101 EISENHOWER PARKWAY, ROSELAND, NJ 07068

### MEMBERS

**Isabelle Bibet-Kalinyak** | 973.403.3131 | [ibibetkalinyak@bracheichler.com](mailto:ibibetkalinyak@bracheichler.com)  
**Shannon Carroll** | 973.403.3126 | [scarroll@bracheichler.com](mailto:scarroll@bracheichler.com)  
**Riza I. Dagli** | 973.403.3103 | [rdagli@bracheichler.com](mailto:rdagli@bracheichler.com)  
**Lani M. Dornfeld** | 973.403.3136 | [ldornfeld@bracheichler.com](mailto:ldornfeld@bracheichler.com)  
**John D. Fanburg, Chair** | 973.403.3107 | [jfanburg@bracheichler.com](mailto:jfanburg@bracheichler.com)  
**Joseph M. Gorrell** | 973.403.3112 | [jgorrell@bracheichler.com](mailto:jgorrell@bracheichler.com)  
**Carol Grelecki** | 973.403.3140 | [cgrelecki@bracheichler.com](mailto:cgrelecki@bracheichler.com)

**Edward Hilzenrath, HLU Editor** | 973.403.3114 | [ehilzenrath@bracheichler.com](mailto:ehilzenrath@bracheichler.com)  
**Caroline J. Patterson** | 973.403.3141 | [cpatterson@bracheichler.com](mailto:cpatterson@bracheichler.com)  
**Keith J. Roberts** | 973.364.5201 | [kroberts@bracheichler.com](mailto:kroberts@bracheichler.com)  
**Richard Robins** | 973.447.9663 | [robins@bracheichler.com](mailto:robins@bracheichler.com)  
**Jonathan J. Walzman** | 973.403.3120 | [jwalzman@bracheichler.com](mailto:jwalzman@bracheichler.com)  
**Edward J. Yun** | 973.364.5229 | [eyun@bracheichler.com](mailto:eyun@bracheichler.com)

### COUNSEL

**Colleen Buontempo, CPC** | 973.364.5210 | [cbuontempo@bracheichler.com](mailto:cbuontempo@bracheichler.com) | **Debra W. Levine** | 973.403.3142 | [dlevine@bracheichler.com](mailto:dlevine@bracheichler.com)

### ASSOCIATES

**Vanessa Coleman** | 973.364.5208 | [vcoleman@bracheichler.com](mailto:vcoleman@bracheichler.com) | **Erika R. Marshall** | 973.364.5236 | [emarshall@bracheichler.com](mailto:emarshall@bracheichler.com)  
**Paul J. DeMartino, Jr.** | 973.364.5228 | [pdemartino@bracheichler.com](mailto:pdemartino@bracheichler.com) | **Sally Olson** | 973.403.3102 | [solson@bracheichler.com](mailto:solson@bracheichler.com)  
**Emily J. Harris** | 973.364.5205 | [eharris@bracheichler.com](mailto:eharris@bracheichler.com) | **Harshita Rathore** | 973.364.8393 | [hrathore@bracheichler.com](mailto:hrathore@bracheichler.com)  
**Cynthia J. Liba** | 973.403.3106 | [cliba@bracheichler.com](mailto:cliba@bracheichler.com)

Roseland, NJ | New York, NY | West Palm Beach, FL | [www.bracheichler.com](http://www.bracheichler.com) | 973.228.5700