

Healthcare Law UPDATE

FEDERAL UPDATE

OIG Issues Fraud Alert Concerning COVID-19 Scams

The U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued a [Fraud Alert](#) on March 15, 2021, alerting the public about fraud schemes related to COVID-19. According to the OIG:

Scammers are using telemarketing calls, text messages, social media platforms, and door-to-door visits to perpetrate COVID-19-related scams. Fraudsters are offering COVID-19 tests, HHS grants, and Medicare prescription cards in exchange for personal details, including Medicare information. However, these services are unapproved and illegitimate. These scammers use the coronavirus pandemic to benefit themselves, and beneficiaries face potential harm. The personal information collected can be used to fraudulently bill federal health care programs and commit medical identity theft.



The OIG offers a number of suggestions for how individuals may protect themselves from these scammers, including:

- Using care in disposal of COVID-19 materials such as syringes, vials, vial box containers, vaccination record cards, and shipment or tracking records;
- Not sharing photos of COVID-19 vaccination cards on social media;
- Being suspicious of unsolicited requests for personal, medical, and financial information; and

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- Not responding to or opening hyperlinks in text messages about COVID-19 from unknown senders.

Anyone suspecting COVID-19 healthcare fraud should report it immediately online [through the OIG online complaint portal](#) or by calling 800-HHS-TIPS (800-447-8477).

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Multiple Agencies Issue FAQs on COVID-19 Testing and Vaccine Coverage By Health Plans

On February 26, 2021, the U.S. Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments) issued [Frequently Asked Questions](#) (FAQs) that clarify health plans' and health insurance issuers' obligations under the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The FFCRA and the CARES Act require plans and issuers to provide benefits for certain items and services related to testing, detection, or diagnosis of COVID-19 without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements. Notably, the FAQs address the following points:

- Plans and issuers are required to cover COVID-19 diagnostic tests provided through state or locally administered testing sites;
- Plans and issuers must not use medical screening criteria to deny (or impose cost sharing on) a claim for COVID-19 diagnostic testing for an asymptomatic person who has no known or suspected exposure to COVID-19. Plans and issuers cannot require the presence of symptoms or a recent known or suspected exposure, or otherwise impose medical screening criteria on coverage of tests;
- Plans and issuers must cover qualifying coronavirus preventive services without cost sharing starting no later than 15 business days (not including weekends or holidays) after the date the United States Preventive Services Task Force or Advisory Committee on Immunization Practices (ACIP) of the Centers for

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Disease Control and Prevention makes an applicable recommendation regarding a qualifying coronavirus preventive service;

- Plans and issuers must provide coverage without cost sharing for all COVID-19 vaccines with a recommendation that makes them a qualifying coronavirus preventative service; and
- Plans and issuers may not deny coverage of recommended COVID-19 vaccines because a participant, beneficiary, or enrollee is not in a category recommended for early vaccination by ACIP.

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OSHA Issues COVID-Related Guidance to Employers

Effective March 12, 2021, the Occupational Safety and Health Administration (OSHA) issued guidance on a [National Emphasis Program focused on COVID-19 safety](#) (the NEP). The NEP seeks to ensure that employees in high-hazard industries are protected from contracting COVID-19.

The NEP includes programmed and unprogrammed inspections. Programmed inspections are generally conducted for randomly selected employers based on OSHA criteria. Unprogrammed inspections are generally performed in response to reports of alleged unsafe conditions. The NEP programmed inspections are aimed at increasing safety in industries at high risk for COVID-19 exposure, such as healthcare facilities, warehouses, stores, restaurants, and manufacturing plants. Targeted healthcare industries include physician offices, dentist offices, home health services, hospitals, assisted living facilities, and ambulance services. The NEP unprogrammed inspections may be in response to complaints, referrals, and severe incident reports. In particular, employers with COVID-19 fatalities are a priority.

Enforcement is expected to begin imminently. The inspections may be conducted on site or remotely. Although the NEP does not outline exactly what the inspectors will be looking for, it is expected that OSHA would review the implementation of policies and procedures related to worker protection, including the availability and proper use of personal protective equipment (PPE) and sanitation protocols.

Finally, the NEP adds employee retaliation protections to include distributing anti-retaliation information during inspections, outreach opportunities, and prompt referrals of any allegations to the Whistleblower Protection Program. These steps are directed at making sure employees share information about unsafe or unhealthy working conditions.

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CMS Eases Nursing Home Visitor Guidance

On March 10, 2021, the Centers for Medicare & Medicaid Services (CMS) issued revised [guidance](#) (QSO-20-39-NJ) concerning nursing home visitation during the COVID-19 public health emergency. The publication revises guidance previously issued by CMS in March and September 2020, including the impact of COVID-19 vaccination.



The guidance emphasizes proper screening of all who enter the nursing facility for signs and symptoms of COVID-19 and denial of entry to those with signs or symptoms or those who have had close contact with someone with COVID-19 in the prior 14 days, regardless of the visitor's vaccination status. The guidance also stresses core principles of COVID-19 infection prevention, consistent with Centers for Disease Control (CDC) guidance for nursing homes, which must be adhered to at all times.

The CMS guidance sets forth a person-centered approach to nursing home visitation that puts the focus on each resident's physical, mental, and psychological well-being. Under the person-centered approach and applying the core principles of COVID-19 infection prevention, CMS advises that while outdoor visitation is preferred, facilities should allow indoor visitation at all times and for all residents even during an outbreak of COVID-19. Certain visitation limitations should be imposed during times assessed as high risk of COVID-19 transmission.

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Substance Abuse Treatment Facility Agrees to \$10 Million+ False Claims Settlement

On March 5, 2021, the United States Department of Justice [announced](#) that Oglethorpe Inc. and three of its substance abuse treatment facilities located in Ohio (Cambridge Behavioral Hospital, Ridgeview Behavioral Hospital, and The

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Woods at Parkside) agreed to pay \$10.25 million to settle allegations that it violated the federal Anti-Kickback Statute and the federal False Claims Act.

Oglethorpe is a Florida-based company that operates inpatient psychiatric hospitals in various states, including Ohio. The claims arose from allegations from the qui tam (or whistleblower) provisions of the False Claims Act by a former client advocate at Cambridge. See *United States ex rel. Baker v. Oglethorpe, Inc., et al.*, No. 2:16-cv-1040 (S.D. Ohio). The [settlement agreement](#) explains that, after investigation into the matter, the United States contended that the defendants knowingly submitted false claims to Medicare during the period August 1, 2013 through June 20, 2019, for: “(1) inpatient hospital stays at Cambridge, Ridgeview, and Parkside that were tainted by illegal kickbacks, in the form of free transportation provided to beneficiaries, in violation of the Anti-Kickback Statute; and (2) inpatient hospital stays at Cambridge and Ridgeview for psychiatric services that were also medically unnecessary.”

The settlement will be paid over a period of five years and is personally guaranteed by three officers of Oglethorpe and its founder. The settlement terms also require Oglethorpe to enter into a corporate integrity agreement with the U.S. Department of Health & Human Services and to retain an Independent Review Organization to review all of its claims to Medicare and Medicaid for a period of time. The settlement does not release the defendants from any liability under the Internal Revenue Code or from criminal liability. The settlement is an indication that the Justice Department continues to take seriously claims involving unlawful Medicare payments and False Claims actions. Acting Assistant Attorney General Brian M. Boynton of the Justice Department’s Civil Division stated in the release “[t]he Justice Department is committed to pursuing unlawful remunerations in whatever form they occur to safeguard taxpayer funded health care benefits.”

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STATE UPDATE

New Jersey Non-Profit Hospitals Must Make Community Service Payments to Retain Property Tax Exemption

On February 22, 2021, Governor Murphy signed into [law](#) legislation that allows non-profit hospitals, as well as satellite emergency care facilities owned by hospitals, to retain their property tax exemption while they are assessed an annual community service contribution to be paid to the municipality in which the hospital or facility is located.

The law addresses a 2015 Tax Court [ruling](#) which found that Morristown Medical Center, a tax-exempt non-profit corporation, did not meet the legal standard to be a non-

profit due to its web of non-profit and for-profit activities and, therefore, was not exempt from property taxation. The Tax Court also found that if other non-profit hospitals operated similarly, their non-profit status was a “legal fiction” and they too should be subject to property taxation. The court explained that it was up to the legislature to clarify the terms and conditions for property tax exemption.

Under the new law, for tax year 2021, non-profit hospitals must pay \$3.00 per day for each licensed bed at the hospital, and satellite emergency care facilities must pay \$300 per day. The per-day amount will increase by two percent in each subsequent tax year. If any portion of a hospital or satellite emergency care facility property is leased to a for-profit organization or is otherwise used for purposes that are not tax-exempt, that portion of the property is subject to property taxation. The law allows hospitals to seek an exemption from the community service contribution if the hospital did not bill in the previous year any patient for inpatient or outpatient professional or technical services provided at the hospital, and if the hospital provided community benefits over the prior three years averaging at least twelve percent of the hospital’s total expenses. Hospitals and facilities may also reduce the required contributions by any amounts paid to municipalities under voluntary agreements.

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New Jersey Legislative Update

New Rule Permits Midwives to Administer Nitrous Oxide – Effective March 1, 2021, New Jersey-licensed midwives will be permitted to administer or facilitate the administration of [nitrous oxide](#) for pain relief during the intrapartum and postpartum stages of labor and delivery when they are providing services in a healthcare facility licensed by the Department of Health. The New Jersey State Board of Medical Examiners had previously received a request from a healthcare facility to permit licensed midwives to administer nitrous oxide as labor analgesia. Upon reviewing the request, the Board determined that the administration of nitrous oxide is within the training and scope of a licensed midwife, and that it is therefore appropriate for midwives to administer nitrous oxide for pain relief both during labor and after delivery, so long as they do so only in healthcare facilities licensed by the Department of Health.

Bill Introduced to Require Licensure of Pharmacy Benefits Managers – On March 1, 2021, [Bill A5410](#) was introduced in the New Jersey Assembly to require the licensure of pharmacy benefits managers. Under the Bill, the Department of Banking and Insurance (DOBI) would create an application for a license to operate in New Jersey as a pharmacy benefits manager (PBM) and would charge application fees and renewal fees. DOBI would also establish financial standards and reporting requirements for PBMs. The Bill would also provide that in

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any participation contracts between PBMs and pharmacists or pharmacies providing prescription drug coverage for health benefit plans, no pharmacist or pharmacy would be prohibited, restricted, or penalized in any way from disclosing to any covered person any healthcare information that the pharmacist or pharmacy deems appropriate regarding the nature of treatment, risks, or alternatives, the availability of alternate therapies, consultations, or tests, the decision of utilization reviewers to authorize or deny services, the process that is used to authorize or deny healthcare services or benefits, or information on financial incentives and structures used by the insurer. In addition, PBMs would not be able to prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the insured if a more affordable alternative is available.

Bill Introduced to Require Additional Imaging when Ordering Mammograms – On March 15, 2021, [Bill A5477](#) was introduced in the New Jersey Assembly to require any healthcare provider engaged in the diagnosis or treatment of breast cancer to concurrently order an ultrasound evaluation, magnetic resonance imaging scan, three dimensional mammography, or other additional testing when ordering a mammogram examination if a woman has additional risk factors for breast cancer or other indications as determined by the provider. The bill would also require health insurers

to cover the additional required imaging when concurrently ordered with a mammogram examination.

Three New Jersey Boards Propose Telemedicine Rules – On March 15, 2021, the [State Board of Marriage and Family Therapy Examiners Alcohol and Drug Counselor Committee](#), the [State Board of Respiratory Care](#), and the [Occupational Therapy Advisory Council](#) each published proposed rules for the provision of services through telemedicine and telehealth. The proposed rules would permit the applicable New Jersey licensee to provide telemedicine and telehealth services if: (i) the licensee is located in New Jersey and provides services to any patient/client located in or out of New Jersey by means of telemedicine or telehealth, or (ii) the licensee is located outside of New Jersey and provides services to any patient/client located in New Jersey by means of telemedicine or telehealth. The proposed rules contain requirements for (a) the standard of care; (b) establishing the licensee-patient relationship or licensee-client relationship, as applicable, for telemedicine and telehealth services; (c) the provision of telemedicine and telehealth services; (d) recordkeeping; (e) protocols for prevention of fraud and abuse; and (f) privacy policies and practices.

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ATTORNEY SPOTLIGHT

Welcome to this new feature in the *Healthcare Law Update* designed to help you get to know the faces and stories of the people behind the articles in each issue. This month, we invite you to meet Member Lani M. Dornfeld and Counsel Edward Hilzenrath.



Lani Dornfeld

Lani Dornfeld represents a broad range of healthcare entities including hospitals, nursing homes, home health agencies, hospices, and other healthcare facilities. She also counsels medical and dental practices and individual healthcare providers. Lani provides legal

guidance on corporate and business matters, the purchase and sale of healthcare businesses, regulatory compliance matters, bioethics and difficult patient management issues, and guardianships. She is certified in healthcare privacy compliance, coordinates and creates HIPAA compliance policies and programs, and manages breach investigations and reporting.

In her spare time, Lani enjoys spending time outdoors, walking and bicycling. She is also an avid cook and likes to experiment with new recipes for family and friends. The bigger the cooking challenge, the better!



Edward Hilzenrath

Ed Hilzenrath represents various healthcare providers across a spectrum of healthcare-related legal matters, including corporate, transactional, and regulatory issues. His clients include hospitals, physicians, physician groups, ambulatory surgical centers, and

imaging centers. He advises clients on practice formations and sales; buy-sell agreements; employment issues; practice mergers; fraud and abuse; anti-kickback and Stark law compliance; HIPAA compliance; and professional board matters. In addition, Ed proactively counsels clients about the impact of new healthcare legislation.

Outside of the office, Ed serves on the Environmental Commission of Millburn Township, NJ and has been active in drafting local ordinances to address environmental issues. Ed also enjoys playing tennis and golf and skiing. Over the years he has spent a significant amount of time coaching his children's baseball, basketball, and soccer teams.

Brach Eichler In The News

The following Healthcare Law Members were named 2021 New Jersey Super Lawyers! Congratulations to John D. Fanburg, Carol Grelecki, Joseph M. Gorrell, and Keith J. Roberts. Counsel Shannon Carroll was named a NJ Rising Star.

On March 17, Healthcare Law Member Lani M. Dornfeld issued a client alert about the new Open Notes Rule, "Get Ready to "Open" Your Records: Cures Act Open Notes Rule Takes Effect April 5."

Labor and Employment Co-Chair Matthew M. Collins authored an article in the New Jersey Law Journal, "Are Mandatory COVID-19 Vaccines A Healthy Choice for Employers?" on March 11.

HIPAA CORNER

CISA Recommends Immediate Searching and Patching Vulnerabilities in Microsoft Exchange Server – On March 12, 2021, the U.S. Cybersecurity and Infrastructure Security Agency (CISA) issued an Updated Alert (AA21-062A) about attackers exploiting vulnerabilities in Microsoft’s Exchange Server.

Attackers were using vulnerabilities in Microsoft’s Exchange Server to gain permanent access to execute arbitrary code, write files to any path on the server, and access mailboxes and read sensitive information on the server. CISA recommends that organizations use the technical tools detailed in the Updated Alert and read Microsoft’s advisory and security blog posts to search for this malicious activity and immediately apply patches.

This is critical for health facilities that use Microsoft’s Exchange Server to ensure that their confidential information, including

protected health information, is not subject to unauthorized use or disclosure.

OCR Provides Additional Time to Comment on Proposed Changes to HIPAA Privacy Rule – On March 9, 2021, the Office of Civil Rights of the U.S. Department of Health and Human Services (OCR) extended the period for all stakeholders to submit comments to OCR’s proposed changes to the HIPAA Privacy Rule.

As previously detailed in our December 2020 Healthcare Law Update, the proposed changes include strengthening patients’ rights to access their own health information, improving information sharing for care coordination and case management, enhancing flexibilities for disclosures during public health emergencies, such as COVID-19 and the opioid crisis, and reducing the administrative burden of covered entities.

The deadline to submit comments was extended from March 22, 2021, to May 6, 2021.

Comments may be submitted by regular, express, or overnight mail to:

U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW, Washington, DC 20201
Attention: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945-AA00.

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