

Healthcare Law UPDATE

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CMS Resumes Inspections on COVID Hold

On August 17, 2020, Centers for Medicare & Medicaid Services (CMS) issued a [memo](#) announcing it is resuming routine inspections of Medicare- and Medicaid-certified providers and suppliers, which were previously suspended by CMS in [prioritization of survey activities](#) and [suspension of survey activities](#) memos issued by CMS in March of this year. In the memo, CMS:

- Revises guidance on the expansion of survey activities to authorize onsite revisits and other survey types;
- Provides guidance to State Survey Agencies (SAs) on resolving enforcement cases;
- Temporarily expands the “desk review policy” to include review of continuing noncompliance following removal of Immediate Jeopardy findings; and
- Issues updated guidance for re-prioritization of routine SA Clinical Laboratory Improvement Amendments survey activity.

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Executive Order Expands Telehealth

On August 3, 2020, President Trump issued an [Executive Order](#) (EO) directing the Department of Health & Human Services (HHS) to continue the expansion of Medicare coverage of telehealth services, to increase access to, improve the quality of, and improve the financial economics of rural healthcare.

Centers for Medicare & Medicaid Services (CMS) temporarily expanded coverage of telehealth services during the COVID-19 public health emergency. Nearly half of Medicare fee-for-service primary care visits were provided through telehealth in April, compared with less than one percent in February, before the public health emergency was declared. Even after in-person primary care visits were permitted to resume in May, the frequency of telehealth visits continued. The Executive Order is premised on the fact that rural healthcare

providers, in particular, need the flexibility of telehealth services to provide continuous care to their patients.

The EO directs HHS to (i) extend Medicare telehealth services beyond the COVID-19 public health emergency; (ii) test innovative payment mechanisms to give rural providers flexibilities from existing Medicare rules, establish predictable financial payments, and encourage movement into high-quality, value-based care; (iii) develop a strategy to improve rural health by improving the physical and communications infrastructure for healthcare, such as broadband; (iv) report on initiatives to eliminate regulatory burdens that limit provider availability; and (v) develop rural-specific efforts to improve physical and mental health outcomes.

In response to the EO, CMS has [proposed](#), in the physician fee schedule for 2021, expanding the availability of certain telehealth services. These include home visits for the evaluation and management of a patient (in cases where the law allows telehealth services to originate from the patient’s home), and certain types of visits for patients with cognitive impairments. CMS also proposes to temporarily extend payment for other telehealth services, such as emergency department visits, through the calendar year in which the public health emergency ends, and is seeking public input on other services to permanently add to the telehealth list.

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CMS Proposes Rule Addressing 2021 Medicare PFS and Permanent Telehealth Changes

On August 3, 2020, Centers for Medicare & Medicaid Services (CMS) issued a [proposed rule](#) that updates the Medicare physician fee schedule (Medicare PFS) for calendar year (CY) 2021, proposes to permanently expand access to care through telehealth, and provides for changes to the CMS Quality Payment Program. Notably, under the proposed rule, CMS also proposes to:

- Reduce the CY 2021 Medicare PFS conversion factor to \$32.2605, a decrease of \$3.83 from the CY 2020 Medicare PFS conversion factor of \$36.0896.

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- Implement payment rate increases for office/outpatient evaluation and management codes and simplify coding and billing requirements for evaluation and management visits, effective January 1, 2021.
- Make certain services that were temporarily added to the Medicare telehealth list due to the COVID-19 public health emergency permanent additions to the telehealth list, including, Prolonged Services (CPT code 99XXX) Group Psychotherapy (CPT code 90853), and Home Visits (CPT codes 99347- 99348).
- Regarding telehealth expansion, CMS is seeking comment on whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value and whether separate payment for telephone-only services should be a provisional policy or if it should become a permanent Medicare PFS payment policy.
- Address substantive changes to 112 existing Merit-Based Incentive Payment System (MIPS) quality measures; remove 14 quality measures from the MIPS program; and propose 206 quality measures starting in 2021, inclusive of two new administrative claims outcome quality measures.
- Add Naloxone to the definition of Opioid-Use Disorder (OUD) treatment services in order to increase access to this important emergency treatment and to allow opioid treatment programs (OTPs) to be paid under Medicare for dispensing Naloxone to Medicare beneficiaries who are receiving other OUD treatment services from OTPs.
- Modify supervision and other requirements of the Medicare program that limit healthcare professionals from practicing at the top of their license.

Comments to the proposed rule are due by October 5, 2020.

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New FTC and DOJ Guidelines Signal Greater Scrutiny of Vertical Integration

On June 30, 2020, the [Federal Trade Commission](#) (FTC) and the federal [Department of Justice](#) (DOJ) collectively issued new guidance about vertical mergers. The term “vertical,” as used in the new [Vertical Merger Guidelines](#), broadly applies to vertical relationships that bring a company or assets a stage closer to (downstream) or further from (upstream) final consumers. To illustrate, this new guidance applies to (1) strictly vertical mergers that combine companies or assets at different stages of the same supply chain, (2) diagonal mergers that combine companies or assets at different stages of competing supply chains, and (3) vertical issues that may arise in mergers of complements.

Examples of vertical integration that would be subject to this new guidance include: a pharmaceutical company

merging with a manufacturer of chemicals that are used in its products; a health system merging with a CRM or data security provider; and a healthcare service provider merging with a health insurer, such as CVS’s acquisition of Aetna.

Given that many mergers often involve both a vertical and horizontal component, the FTC and DOJ advise that the Vertical Merger Guidelines should be read in conjunction with the [Horizontal Merger Guidelines](#) published in 2010.

The Vertical Merger Guidelines signal the increased attention that the FTC and DOJ are placing on vertical integration. The new Vertical Merger Guidelines provide greater transparency as to the analysis conducted by both the FTC and DOJ in making decisions on both enforcement actions and advance approvals of mergers. Specifically, the FTC and DOJ explain that when making these decisions, they will consider the following:

- Evidence of adverse competitive effect – whether the merger will substantially lessen competition;
- Impact of competition in the market – relevant market definition, related products, market shares, and concentration;
- Unilateral effects – ability and incentive to foreclose on others’ access to products and raise rivals’ costs;
- Coordinated effects – enablement or encouragement of post-merger coordinated interactions that harm consumers; and
- Procompetitive effects – potential benefit of encouraging competition which may lead to price efficiency.

The increased attention and guidance on vertical mergers may lead to a temporary decrease in the number and size of transactions in the healthcare arena, and increased delays in the approval process, as the dealmakers will have to provide more analytics on the appropriateness of proposed transactions going forward.

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STATE UPDATE

Who Pays for COVID-19 Testing?

A New Jersey medical provider filed a lawsuit on August 12, 2020 in the U.S. District Court for the District of New Jersey against Cigna Health Life Insurance Co. (Cigna), alleging Cigna failed to pay benefits for diagnostic testing and services related to COVID-19. (*Open MRI and Imaging of RP Vestibular Diagnostics, P.A. v. Cigna Health and Life Insurance Company, Case 2:20-cv-10345-KM-ESK*). The plaintiff provider alleges that it properly billed Cigna for rendering diagnostic testing and services to patients related to COVID-19, and Cigna has denied these claims submitted by the provider from February through July 2020. The provider alleges Cigna provided “unelaborate” details for such denials.

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The provider alleges that Cigna's denial of coverage for COVID-19 diagnostic testing and services is in violation of the [Families First Coronavirus Response Act](#) (Section 6001(a)) (FFRCA), as amended by Sections 3201 and 3202(a) of the [CARES Act](#).

The provider also alleges that Cigna has been unjustly enriched by wrongfully denying these claims; Cigna has been able to keep insurance premiums instead of paying out such claims to the provider for services actually rendered. The provider seeks compensation under an argument of *quantum meruit* (essentially, reasonable value of services). It also is seeking damages totaling \$398,665, in addition to attorney's fees, costs, and interest. Cigna must file its response to the plaintiff's allegations in early September 2020.

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New Jersey Legislative Update

Bill Introduced to Revise Licensure Requirements for Long-Term Care Facilities – On July 30, 2020, [Bill A4477](#) was introduced in the New Jersey Assembly to revise certain licensure, operational, and reporting requirements for long-term care facilities. In particular, the Bill revises a provision of current law that allows nursing homes to increase their total bed capacity by a limited amount without the need to obtain a certificate of need. The Bill provides that beds added in this manner may not be transferred to another nursing home without obtaining a certificate of need. In addition, the Bill prohibits the transfer of beds that are part of an unimplemented certificate of need to another nursing facility without obtaining a certificate of need. With regard to transfers of ownership of long-term care facilities, the Bill codifies an existing regulation providing that ownership transfers do not require a certificate of need except when the proposed owner does not satisfy the Department of Health's track record review.

Bill Introduced to Dedicate PPE to Long-Term Care Facilities – On July 30, 2020, [Bill A4485/S2784](#) was introduced in the New Jersey Legislature to require the Commissioner of Health, in consultation with the Director of the State Office of Emergency Management, to dedicate a percentage of the State's stockpiled personal protective equipment (PPE) to long-term care facilities in the State during public health emergencies. The goal of the Bill is to ensure that long-term care facilities have access to PPE during public health emergencies. During the COVID-19 pandemic of 2020, long-term care facilities accounted for a disproportionate amount of COVID-19-related deaths and many facilities suffered from a lack of PPE, but the cost of PPE places an additional burden on an already financially constrained long-term care facility industry. The Commissioner, in consultation with the Director of the State Office of Emergency Management, will determine the specific percentage allocation of PPE for long-term care facilities,

based on the nature of the public health emergency, the total number of patients, and the average rate of PPE use in long-term care facilities.

Bill Introduced to Establish Chief Executive Nurse Position – On August 13, 2020, [Bill A4535](#) was introduced in the New Jersey Assembly to establish a Chief Executive Nurse position within the Department of Health. Under the Bill, the Commissioner of Health will appoint a Chief Executive Nurse who is to serve at the pleasure of the Commissioner during the Commissioner's term of office. The duties of the Chief Executive Nurse will include: assisting the Commissioner as necessary on matters pertaining to nursing; collecting data and other information on nursing as determined by the Commissioner; consulting with nurses and healthcare facilities to determine which current or proposed regulations aid or impede nurses' ability to provide adequate healthcare; and evaluating current trends in nursing.

Physician Assistants and Advanced Practice Nurses Permitted to Order Home Health Services – In a letter addressed to home healthcare agencies on August 17, 2020, the New Jersey Department of Health (DOH) confirmed that physician assistants and advanced practice nurses are now permitted to order home healthcare services for their patients. Previously, Medicare rules only permitted physicians to order these services. However, the Coronavirus Aid, Relief and Economic Security (CARES) Act, enacted on March 27, 2020 in response to the coronavirus pandemic, permanently authorized advanced practice nurses and physician assistants to order home healthcare services for their patients. Specifically, the DOH deemed it consistent with New Jersey law for advanced practice nurses and physician assistants to order home health services, establish and review plans for home healthcare services, and certify eligibility for home healthcare services, notwithstanding any provisions of law to the contrary. In separate correspondence, the State Board of Medical Examiners and the New Jersey Board of Nursing each confirmed that these expanded duties are within the scope of practice of physician assistants and advanced practice nurses, respectively.

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Brach Eichler In The News

Member **Lani M. Dornfeld, CHPC**, spoke at the [HCAF HomeCareCon 2020 Annual Conference & Trade Show](#) on August 19 about current HIPAA concerns and trends.

Keith J. Roberts obtained a favorable decision on behalf of his ASC client vs. Cigna Insurance. An overview of the decision was covered in [Becker's ASC Review](#).

Seventeen Brach Eichler attorneys were included in The Best Lawyers in America® 2021. Four of those attorneys are members in our Healthcare Law Practice: **Lani M. Dornfeld, John D. Fanburg, Joseph M. Gorrell, and Carol Grelecki**. [Learn more about our attorneys.](#)

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During July, Brach Eichler co-hosted a three-part webinar series with Withum, “Post COVID-19 Considerations for Healthcare Organizations.” To view the on-demand webinars, please click the links below: [Return to Office Protocols for Healthcare](#), [Transaction and Valuation Issues for Healthcare](#), and [PPP Considerations for Healthcare](#).

HIPAA CORNER

Recent OCR Alert Communications – The U.S. Department of Health & Human Services, Office for Civil Rights (OCR) recently posted three separate alerts regarding cybersecurity, urging organizations to guard against the persistent malicious actions of cyber actors.

The first recent OCR [alert](#), issued August 6, 2020, advises HIPAA-covered entities and business associates to warn their employees about postcards being sent to healthcare organizations disguised as official OCR communications, claiming to be notices of a mandatory HIPAA compliance risk assessment. These communications are not from the OCR, but from a private entity. The postcards have a Washington, D.C. return address, and the sender uses the title “Secretary of Compliance, HIPAA Compliance Division.” They are addressed to the healthcare organization’s HIPAA compliance officer and prompt recipients to visit a URL, call, or e-mail to take immediate action on a HIPAA Risk Assessment. The link directs individuals to a non-governmental website marketing consulting services. In the alert, the OCR advised that you can verify that a communication is from the OCR by ensuring that the e-mail address ends in @hhs.gov and confirming the OCR’s HQ and Regional Office addresses on their [website](#). The OCR warned that posing as federal law enforcement is a serious crime and suspected incidents should be reported to the Federal Bureau of Investigations (FBI).

In the second recent OCR communication, the OCR shared an [update](#) with its listserv from the FBI, originally published on August 3, 2020. (FBI Private Industry Notification, PIN number 20200803-002, issued August 13, 2020). In the publication, the FBI warns that the FBI has observed cyber criminals targeting computer network infrastructures that are left vulnerable after a Windows 7 operating system achieves end-of-life status. Since Microsoft ended support for Windows 7, which includes security updates, continued use of Windows 7 creates the risk of cyber-criminal exploitation of a computer system. As time passes, Windows 7 becomes more vulnerable to exploitation due to lack of security updates and new vulnerabilities discovered. In order to avoid these risks, Microsoft and other industry professionals strongly recommend upgrading computer systems to an actively supported operating system.

In the third recent OCR alert, issued August 14, 2020, the OCR notified its listserv of an [alert issued by the Cybersecurity & Infrastructure Security Agency](#) (CISA), warning that CISA is currently tracing an unknown malicious cyber actor who is spoofing the Small Business Administration (SBA) COVID-19 loan relief webpage via phishing e-mails. These e-mails include a malicious link to the spoofed SBA website that the cyber actor is using for malicious re-directs and credential stealing. CISA analysts observed an unknown malicious cyber actor sending a phishing e-mail to various Federal Civilian Executive Branch and state, local, tribal, and territorial government recipients. Information on mitigations that can help strengthen the security posture of an organization’s system are available [here](#).

If you would like assistance with your HIPAA or 42 CFR Part 2 privacy and security program, in managing or reporting a breach incident, or in business associate analysis and contracting, contact:

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