I. COVID-19 LEGAL UPDATES

Brach Eichler has strived to keep abreast numerous legal developments that occurred during the nationwide novel coronavirus (COVID-19) public health emergency. Brach Eichler has created a COVID-19 Resource Center that consolidates our various important client alerts and webinar series information in one place. Please visit the Resource Center for updates at https://www.bracheichler.com/covid-19-resource-center/.

II. NEW JERSEY LEGAL DEVELOPMENTS

A. Amendments to Out of Network Arbitration Process Becomes Law

On July 29, 2022, Governor Phil Murphy signed into law Bill S1177 to amend certain aspects of the “Out-of-network Consumer Protection, Transparency, Cost Containment and Accountability Act” (the Act) relating to the arbitration process for claims involving health insurance carriers who are subject to the Act. Specifically, the amendments extend the amount of time that an insurance carrier and healthcare provider have to negotiate a settlement in the event of an inadvertent use of out-of-network services from 30 to 60 days, and extends the deadline for the carrier, provider, or covered person to initiate binding arbitration in the event of a failure to reach a settlement from within 30 days of the final offer to within 60 days of the final offer. The amendments also require an arbitrator to include detailed written findings with each arbitration decision. The detailed written findings are to be an analysis of the decision, including information concerning any databases, previous awards, or other documentation or arguments that contributed to the arbitrator’s decision.


On July 22, 2022, the New Jersey Division of Consumer Affairs (DCA) issued Administrative Order No. 2022-01 (AO 2022-01) setting forth modified requirements for health care professionals working in settings not requiring licensure by the New Jersey Department of Health (NJDOH), to practice in a manner that is consistent with current guidance issued by the
Centers for Disease Control and Prevention (CDC), NJDOH, the federal Occupational Safety and Health Administration (OSHA), and the health care professionals’ respective local health department. AO 2022-01 explicitly modifies Administrative Order No. 2021-11 (AO 2021-11).

AO 2021-11 (superseding DCA Administrative Order No. 2020-07) was entered on May 6, 2021, when the Public Health Emergency and State of Emergency, initially declared on March 9, 2020 pursuant to Executive Order 103, were both still in effect. When AO 2021-11 was entered, it included enforceable provisions for the delivery of health care in office-based settings not licensed by NJDOH, which were consistent with the then-current guidance from the CDC, NJDOH, and OSHA. AO 2021-11 mandated, among other things, that health care professionals utilize telemedicine to the greatest extent possible; screen and check temperatures of patient, companions, and staff before permitting entry into the office; require patients, companions, and staff to wear face coverings or face masks; facilitate social distancing to minimize person to person contact; adopt enhanced protocols for office cleaning and disinfection; and establish rigorous protections for staff.

While AO 2021-11 remains effective, DCA recognizes that some of the provisions within AO 2021-11 are no longer consistent with now-current and potential future CDC, NJDOH, OSHA, and local health department guidance and standards, and, as such, it is necessary to modify COVID-19 related mandates for health care professionals in office settings. In response, DCA has removed many of the specific, static requirements within AO 2021-11 and has chosen instead to mandate full compliance with all now-current (and future) guidance from CDC, NJDOH, OSHA, and local health departments.

The modified standards require that all health care professionals practicing in office settings do the following:

1. Provide in-person adult and pediatric services in an office and practice consistent with their scope of practice as well as applicable statutes and regulations except where conditions of practice have been and remain waived in connection with the State of Emergency;
2. Practice in a manner consistent with all applicable COVID-19 related guidance from the CDC, NJDOH, OSHA, and local health department guidance;
3. Stay informed about applicable CDC, NJDOH, OSHA, and local health department guidance;
4. Monitor the community spread of COVID-19 via the NJDOH’s Statewide Weekly COVID-19 Variant Surveillance Reports and the CDC Community Levels and adjust office practices in a manner consistent with CDC and NJDOH recommendations based on the level of community spread;
5. Protect staff from retaliation for engaging in conduct recommended by CDC, NJDOH, OSHA and their respective local health department; and
6. Ensure that health care practices in registered surgical practices required to be licensed as ambulatory surgery centers (ASCs) by NJDOH, but not yet licensed, perform in a manner consistent with all NJDOH imposed requirements for ASCs.

For purposes of AO 2022-01 and AO 2021-11, “office” means a health care practice setting not licensed by the NJDOH, including, but not limited to, health care professional offices, private practices, clinics, urgent care centers, and community medical centers.

C. New Law Protects Nondisclosure of Patient Information Relating to Reproductive Healthcare Services

Effective July 1, 2022, Governor Phil Murphy signed into law Bill A3975 to protect the disclosure of patient information relating to reproductive health care services, and to protect access to health care, medical services, and procedures related to an abortion for persons who come to New Jersey from jurisdictions in which these actions are illegal. “Reproductive health care services” is defined as all medical, surgical, counseling, or referral services relating to the human reproductive system, including services relating to pregnancy, contraception, or termination of a pregnancy. The new law generally provides that in any civil action, a medical provider is barred from disclosing the following communications or information, unless the patient explicitly consents in writing to the disclosure: (i) any communication made to the medical provider, or any information obtained by the medical provider from a patient relating to reproductive health care services; or (ii) any information obtained by personal examination of a patient relating to reproductive health care services that are permitted under New Jersey law.

III. FEDERAL LEGAL DEVELOPMENTS

A. OIG Issues Special Fraud Alert Regarding Telemedicine Arrangements

On July 20, 2022, the U.S. Department of Health and Human Services Office of Inspector General (OIG) released a special fraud alert (the Alert) highlighting the growth and prevalence of fraudulent and suspect arrangements within telemedicine and telehealth. The OIG stated that telehealth, telemedicine, and telemarketing services have carried out fraudulent schemes by aggressively recruiting physicians and non-physician practitioners (collectively, Providers) and paying kickbacks to Providers in exchange for the ordering of unnecessary items or services, including durable medical equipment (DME), genetic testing, wound care items, and other prescription items.

The following is a non-exhaustive list of seven “suspect characteristics” identified in the Alert that suggest a heightened risk of fraud and abuse:

1. Patients are identified and recruited through call centers, health fairs, recruiters, telemarketing channels, or social media by advertising free or low out-of-pocket cost items or services.

2. Lack of sufficient contact with or information from patient to assess the medical necessity of prescribed items or services.
3. Compensation based on volumes of items or services ordered or prescribed.

4. Refusal to accept insurance from payors not affiliated with federal healthcare programs.

5. Misrepresentation on whether the company actually bills federal healthcare programs.

6. Predetermining or limiting the types of products or services that clinicians can prescribe, such as restricting prescriptions to only certain DME or prescription creams.

7. Not expecting, enabling, or requiring clinicians to follow up with patients.

While telemedicine remains a useful, viable and encouraged modality for treatment, Providers must remain wary of fraudulent arrangements. In anticipation of enforcement and whistleblower activity that will attempt to leverage the Alert, Providers may consider reassessing the compliance of their operations with respect to furnishing services or ordering products, tests, and prescription drugs for telemedicine patients.

B. **36 Individuals Charged with $1.2B in Alleged Health Care Fraud**

On July 20, 2022, the Department of Justice (DOJ) announced that three dozen individuals were indicted for acts of allegedly accepting illegal monetary kickbacks, luring unsuspecting elderly individuals into criminal schemes and performing unnecessary medical tests for a cumulative $1.2 billion in fraudulent schemes. The coordinated investigations primarily targeted the alleged payment of kickbacks and bribes by lab operators in exchange for the referral of patients by medical professionals working with allegedly fraudulent telemedicine and digital health companies.

Some of the defendants are said by the DOJ to operate a telemarketing network that lured elderly and disabled patients into a criminal scheme. Marketers allegedly had telemarketers use deceptive techniques to induce Medicare beneficiaries to agree to cardiovascular genetic testing, and other genetic testing and equipment. The charges allege that these companies arranged for medical professionals to order expensive genetic tests and medical equipment regardless of whether the patients needed them, and that they were ordered without any patient interaction or with just a brief phone call. One case charged involved the operator of several clinical laboratories, who was charged in connection with a scheme to pay over $16 million in kickbacks to marketers who paid kickbacks to telemedicine companies and call centers in exchange for doctor orders.

While telemedicine companies may engage practitioners to provide telemedicine services to patients in a compliant way, practitioners can only order or prescribe items and/or services for patients whom they have examined and must ensure that such items and services are medical necessary and clinically appropriate. Telemedicine companies must pay careful attention to how they compensate their practitioners for providing virtual healthcare services and ensure that the compensation model complies with the law and does not induce a practitioner to prescribe or order an item or service.
C. **CMS Proposes 2.7% Increase to Hospital Outpatient Rates for 2023**

On July 15, 2022, the Centers for Medicare and Medicaid Services (CMS) released its 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule, which includes, among other things, updates to hospital outpatient payment rates. The Proposed Rule has a 60-day comment period (through September 13, 2022) and the final rule will be issued in early November 2022. Pursuant to the Proposed Rule, CMS is proposing to increase Hospital OPPS payment rates by 2.7% in 2023. The Proposed Rule also includes proposals aligned with several key goals of the Biden Administration, including advancing health equity in rural areas, promoting competition in the healthcare system, promoting behavioral health telemedicine remote services, and promoting safe, effective, and patient-centered care.

D. **CMS Proposes 4.43% RVU Conversion Factor Cut for 2023**

On July 7, 2022, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule for the 2023 Medicare Physician Fee Schedule (PFS). The proposed rule would decrease the PFS conversion factor by $1.53 to $33.08, a 4.43% drop in the current conversion factor of $34.61. The conversion factor is the dollar amount assigned to the Relative Value Unit (RVU) for each CPT code. A decrease in the conversion factor therefore translates in payment cuts for physicians at the reimbursement level and at the compensation level for physicians paid under an RVU-based methodology. CMS explained that the proposed reduction reflects the statutorily required update to the conversion factor for CY 2023 of 0%, the expiration of the 3% increase in PFS payments for CY 2022 as required by the Protecting Medicare and American Farmers From Sequester Cuts Act, and statutorily required budget neutrality adjustments.

In addition to the 4.43% reduction to the conversion factor, CMS’s regulatory impact analysis (RIA) estimates that radiologists will see a 3% decrease and interventional radiologists will see a 4% decreased in payments based on policy changes proposed for 2023. However, cumulative payment changes experienced by individual clinicians or practices will vary because actual payment depends on several factors, including locality-specific rates and the specific procedure codes billed. A detailed comparison of 2022 payment rates and proposed 2023 payment rates related to CPT codes prepared by the American College of Radiology is set forth in Exhibit A hereto.

E. **CMS Transparency in Coverage Rule Took Effect July 1, 2022**

The Transparency in Coverage Final Rule (the TiC Final Rule), a Trump-era initiative issued by the Centers for Medicare and Medicaid Services (CMS) on October 29, 2020, officially took effect on July 1, 2022, following a six-month delay in implementation to allow payors to come into compliance. The purpose of the TiC Final Rule is to help consumers understand healthcare pricing and curtail the rise in healthcare spending by enabling a participant, beneficiary, or enrollee to shop for items and services. CMS touts the TiC Final Rule as “a historic step toward putting healthcare price information in the hands of consumers.”
Effective July 1, 2022, the TiC Final Rule requires health plans to disclose online, in machine-readable files: (1) their negotiated rates with in-network providers; and (2) historical billed charges and allowed amounts paid to out-of-network providers. The machine-readable file requirements are applicable for plan years beginning on or after January 1, 2022. While the TiC Final Rule also intended that payors disclose negotiated rates for covered prescription drugs, the U.S. Department of Health and Human Services, Labor, and Treasury (the Departments) indefinitely deferred enforcement of the machine-readable file requirement for prescription drugs while they consider whether the requirement is appropriate.

Additional requirements will go into effect in 2023 and 2024. As part of a continued effort to assist individuals to effectively shop for items and services, beginning January 1, 2023, the TiC Final Rule requires that health plans to create a tool whereby their enrollees can receive real-time, personalized estimates of potential cost-sharing liability for 500 designated items and services. Beginning on January 1, 2024, the cost sharing tool must provide the same information for all covered items and services. Noncompliant payors could face fines of up to $100 per day for each violation and for each individual affected, with limited exceptions.