

# Healthcare Law UPDATE

## FEDERAL UPDATE

### HHS Announces Prohibition on Sex Discrimination Includes Discrimination on the Basis of Sexual Orientation and Gender Identity

On May 10, 2021, the U.S. Department of Health & Human Services (HHS) [announced](#) that the Office for Civil Rights (OCR) will interpret and enforce prohibitions on discrimination based on sex contained in Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. The announcement was made in light of the U.S. Supreme Court's decision in [Bostock v. Clayton County](#) and subsequent court decisions. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability

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in covered health programs or activities. Title IX prohibits sex-based discrimination in any school or other education program that receives federal money. HHS Secretary Xavier Becerra stated, "Fear of discrimination can lead individuals to forgo care, which can have serious negative health consequences. It is the position of the Department of Health and Human Services that everyone – including LGBTQ people – should be able to access health care, free from discrimination or interference, period." Covered healthcare providers should revise their anti-discrimination policies consistent with HHS's interpretation.

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## CMS Issues Proposed Rule Regarding Hospice Payment Updates

On April 8, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a [proposed rule \(CMS-1754-P\)](#) that would update the hospice wage index, payment rates, and cap amount for Fiscal Year 2022. More specifically, proposals include:

- Revise labor shares for continuous home care, routine home care, inpatient respite care, and general inpatient care using 2018 Medicare cost report data for freestanding hospice facilities;
- Update the hospice wage index and make the application of the updated wage data budget-neutral for all four levels of hospice care;
- Clarify regulatory text regarding the election statement addendum requirements that were finalized in the FY 2020 Hospice Wage Index and Rate Updated final rule;
- Make permanent selected regulatory blanket waivers that were issued to Medicare-participating hospice agencies during the COVID-19 public health emergency; and
- Various proposals regarding the HQR.

Comments to the proposed rule are due by June 7, 2021, and may be submitted by regular or overnight mail or electronically at <http://www.regulations.gov>, with reference to file code CMS-1754-P.

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## CMS Proposes Changes to Hospital Rates and Payment Policies for 2022

On April 27, 2021, the Centers for Medicare & Medicaid Services (CMS) issued its [proposed rule](#) for the 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS). The proposed rule seeks to update Medicare's rates and payment policies for hospitals. Overall, CMS estimates that hospital payments will increase by \$2.5 billion.

Proposed changes include:

- Increasing hospital payments by 2.8% for successful participation in the Hospital Inpatient Quality Reporting (IQR) program and meaningful use of electronic health records (EHR);
- Using inpatient hospital utilization data from FY 2019 (instead of FY 2020) to estimate expected hospital utilization and establish inpatient hospital payment rates. FY 2020 data reflects increases in hospitalizations caused by the COVID-19 public health emergency (PHE) that CMS does not expect in FY 2022 due to increased COVID-19 vaccinations;
- Extending the New COVID-19 Treatments Add-On Payment (NCTAP) for eligible discharges through the end of the fiscal year 2022. CMS seeks to address inpatient cases of

COVID-19 beyond the end of the PHE and to minimize any potential payment disruptions immediately following the end of the PHE;

- Distributing an additional 1,000 new Medicare-funded medical residency positions to qualifying hospitals. CMS will prioritize applications from qualifying hospitals serving geographic areas and underserved populations with the greatest need. These new slots will be phased in at no more than 200 slots per year beginning in 2023;
- Terminating the requirement that hospitals report payer-specific rates for inpatient services negotiated with Medicare Advantage plans on their cost reports. This should reduce the hospitals' administrative burden with this reporting requirement; and
- Allowing CMS to suppress the use of certain measurement data under the Hospital Readmissions Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, and Hospital Value-Based Purchasing (VBP) Program if such data and resulting quality scores are impacted by the COVID-19 PHE.

Comments to the proposed rule are due by June 28, 2021, and may be submitted by regular or overnight mail or electronically at <http://www.regulations.gov>, with reference to file code CMS-1752-P.

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## New COVID Vaccine Requirements for Residents and Staff of Long-Term Care Facilities

On May 13, 2021, the Centers for Medicare & Medicaid Services (CMS) published an interim final [rule](#) with a comment period, requiring long-term care and intermediate facilities to report the COVID-19 status of their residents and staff weekly to the Centers for Disease Control and Prevention (CDC). The rule is effective on May 21, 2021. The rule also requires such facilities to develop policies and procedures that will educate residents and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine and offer the vaccine unless it is medically contraindicated or the resident or staff member has already been immunized.

The rule applies to long-term care and intermediate care facilities for individuals with intellectual disabilities, with the [stated goal](#) of reducing the spread of COVID-19 infections in such facilities. The rule also solicits public comments on the potential application of these requirements to other congregate living settings over which CMS has oversight authority, including assisted living facilities and group homes. CMS has also published a [QSO memo](#) regarding the interim final rule.

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## OIG Audit Reveals CMS Could Have Saved \$20 Million in Cholesterol Tests

On May 11, 2021, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) released a [report](#) regarding an audit of Medicare providers and their billing of direct-measurement, low-density lipoprotein (LDL) cholesterol test (LDL Tests), and lipid panels on the same day for the same Medicare beneficiary. In summary, OIG found:

*Payments made to providers for direct LDL tests that were billed in addition to lipid panels did not comply with Medicare requirements. Under certain circumstances, it may be medically necessary for a provider to perform both tests for the same beneficiary on the same date of service. However, CMS and Medicare contractors explained that these circumstances should happen with only limited frequency. We determined that some providers billed LDL tests in addition to lipid panels for the same beneficiary on the same date of service more than 75 percent of the time. (We refer to such providers as “at-risk providers.”) In total, we identified \$20.4 million of Medicare payments made to at-risk providers for direct LDL tests.*



In light of its findings, OIG recommended that CMS direct the Medicare contractors to (i) develop oversight mechanisms to identify at-risk providers and prevent improper payments to these providers, which could have saved up to \$20.4M for the OIG’s audit period, and (ii) educate providers on the billing of direct LDL tests in addition to lipid panels. CMS responded by stating that ordering direct LDL tests and lipid panels together is permissible under Medicare payment rules based on the physician’s clinical judgment and that CMS already has issued education on correct coding requirements for the proper use of modifiers on claim lines. In response to CMS, OIG maintained that its findings and recommendations are valid. Regardless of the disagreement between OIG and CMS, providers should use caution when ordering LDL tests in addition to lipid panels and ensure adequate documentation

of medical necessity and rationale based on the physician’s professional judgment.

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## Class Action Lawsuit Filed Against Maker of Invisalign

On May 3, 2021, a [class-action lawsuit](#) was filed by purchasers of Invisalign, a plastic form of dental braces known as aligners, against the product’s manufacturer, Align Technology, Inc. (Align). The lawsuit accuses Align of a scheme to monopolize the market for aligners since at least 2017, in violation of federal antitrust and various consumer protection laws. Before 2017, Align controlled 80% of the aligner market, in large part due to the protection of its intellectual property rights. Faced with the loss of its patent exclusivity in 2017, Align is alleged to have implemented a scheme to block competition from other manufacturers of aligners and from the manufacturers of a digital scanner used to take images to create the customized aligner. As a result of the scheme, the lawsuit alleges, patients, pay up to \$8,000 for the full course of treatment for Invisalign aligners, most of which is not covered by insurance.

Specifically, the class action alleges that Align accomplished its monopolistic scheme by (i) terminating Align’s longstanding and profitable agreement with 3Shape, Align’s primary scanner competitor, thereby sacrificing short-term profits for the anticompetitive effects; (ii) entering into exclusive dealing contracts with two of the largest dental service organizations (“DSO”) that effectively prevented DSO members from dealing with Align’s competitors in the aligner and scanner markets; and (iii) establishing a program for dentists which bundles Align’s scanner and Invisalign sales together with attractive pricing and substantial penalties if a minimum threshold of Invisalign sales are not met, effectively preventing dentists from ordering aligners or scanners from rivals.

Through its “closed-system,” the complaint alleges, (i) Align drives dentists toward Invisalign and away from rivals; and (ii) a competing aligner manufacturer looking to compete against Invisalign would need to offer below-cost prices to offset the penalties and overcome the restrictions Align placed on dentists through the alleged scheme. It is alleged that Align now controls more than 90% of the aligner market.

The lawsuit follows [another class action](#) filed last year by two dental practices against Align in federal court in California, and 3Shape has also filed an [antitrust suit](#) against Align in federal court in Delaware.

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## STATE UPDATE

### New Jersey Legislative Update

#### *Nurse Licensure Compact Regulations Adopted –*

On May 17, 2021, the New Jersey State Board of Nursing adopted [regulations](#) to implement P.L. 2019, c. 172, which entered New Jersey into the Nurse Licensure Compact (Compact). The Compact is an agreement among states in which nurses licensed in one member state (home state) may work in another member state (remote state) without obtaining a license in the remote state. To work in a remote state, a nurse would have to obtain a license with multistate privileges from his or her home state, which must be the nurse's primary state of residence. To effectuate the Compact, the Board of Nursing adopted amendments to its existing rules and established new rules and procedures for applying for licenses with multistate privileges. The Interstate Commission of Nurse Licensure Compact Administrators recognizes that applicants for certification as advanced practice nurses or forensic nurses-certified sexual assault (FN-CSA), who are licensed as registered professional nurses to obtain certification, must meet the licensure requirement by holding a license with multistate privileges in a remote state.

#### *Audiologists Permitted to Dispense and Fit Hearing Aids –*

Effective May 17, 2021, the New Jersey Division of Consumer Affairs adopted [amendments](#) to the audiology regulations to expand the scope of practice of licensed audiologists to include dispensing and fitting hearing aids. New Jersey law permits licensed audiologists to dispense and fit hearing aids, as long as the audiologist has completed coursework and clinical training in the dispensing and fitting of hearing aids that meet the requirements established by the



Division of Consumer Affairs Audiology and Speech-Language Pathology Advisory Committee (Committee). The Committee reviewed the educational programs for audiologists and determined that all such education programs contain content that prepares graduates to dispense and fit hearing aids.

#### *Pharmacy Board Proposes Amendments to Permit Interns and Externs to Administer Injectable Medications and Vaccinations*

– On May 3, 2021, the New Jersey State Board of Pharmacy, in consultation with the New Jersey Board of Medical Examiners, proposed [amendments](#) to its regulations to implement P.L. 2018, c. 143, to allow pharmacy interns and externs to

administer injectable medications and vaccinations under the direct supervision of a pharmacist. A pharmacy intern is an individual who graduated from a school or college of pharmacy, has applied for licensure by reciprocity and needs to satisfy the Board's practice of pharmacy requirements, or is a graduate student participating in an American Society of Health-System Pharmacists (ASHP) accredited post-graduate pharmacy residency program and who is awaiting licensure. A pharmacy extern is a person who is in the fifth or sixth college year, or the third or fourth professional year, at an American Council of Pharmaceutical Education (ACPE)-approved school or college of pharmacy, who is acquiring practical experience under the supervision of the school or college. As with pharmacists, the pharmacy interns and pharmacy externs must meet the qualifications established by the Board. Comments on the proposed amendments must be submitted by July 2, 2021.

#### *“COVID-19 Vaccinating, Reaching and Contacting Everyone Act” Introduced in New Jersey Senate –*

On April 26, 2021, the “COVID-19 Vaccinating, Reaching, and Contacting Everyone Act” was introduced in the New Jersey Senate. Under the proposed [Act](#), the Department of Health would coordinate with federally qualified health centers, hospitals, nonprofit organizations, and schools of medicine and nursing to establish mobile COVID-19 vaccination centers inside motorbuses, recreational vehicles, and other vehicles deemed appropriate by the Department. The

Department would issue and prioritize grants from available federal funds to a mobile COVID-19 vaccination center if the mobile center: (1) operates in a geographic location where there are low rates of COVID-19 vaccination, high levels of poverty, and low rates of health insurance coverage; and (2) employs individuals who reside within such geographic location.

#### *New Amendments to Rule Governing Hospices Acceptance and Disposal of Prescription Medication*

– Effective May 3, 2021, the New Jersey Department of Health (DOH), with the approval of the Health Care Administration Board, [amended](#) the existing regulation to authorize hospices to accept prescription

medication for disposal from hospice care patients who cease to use medication or receive services from a hospice. More specifically, the rule requires that hospices that elect to accept surrendered medication must establish written policies and procedures for the acceptance and disposal of prescription medication. The DOH anticipates that these requirements will have a positive social impact in New Jersey by facilitating the proper disposal of unused prescription medication, thus mitigating negative environmental impacts associated with improper disposal methods and preventing misappropriation.

## BRACH EICHLER

**Amendments Made to Accreditation Rules for Radiation Oncology Facilities** – Effective May 3, 2021, the New Jersey Department of Health (DOH) adopted [amendments](#) to its regulations to include the American Society for Radiology Oncology (ASTRO) as an accrediting organization for radiation oncology facilities. The DOH found the ASTRO accreditation standards to be comparable to the existing accreditation standards of the American College of Radiology and the American College of Radiation Oncology. Further, the new amendments require radiation oncology facilities to file accreditation certificates from ASTRO within 45 days of receipt. These amendments should help to ensure the continuing availability of appropriately accredited radiology programs and services at radiation oncology facilities in New Jersey.

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## Brach Eichler In The News

Brach Eichler LLC is pleased to announce that the firm's Healthcare Law and Real Estate practices have again been recognized by [Chambers USA \(2021\)](#) as among New Jersey's top law practices. In addition to the firm's overall recognition,

four of the firm's attorneys, **John D. Fanburg** (Band 1, Healthcare), **Joseph M. Gorrell** (Band 2, Healthcare), **Alan R. Hammer** (Band 1, Real Estate), and **Allen J. Popowitz** (Band 2, Real Estate) have been highly ranked this year as well.

On May 20, Healthcare Law Member **Lani M. Dornfeld**, spoke to *News 12 New Jersey* about HIPAA Laws, in "[Can your employer require you to get the COVID-19 vaccine? Here's what you need to know.](#)"

On May 14, Managing Member and Healthcare Law Chair **John D. Fanburg** talked about the actively changing healthcare market in "[Modern Healthcare.](#)"

On May 12, **John D. Fanburg**, **Keith Roberts**, and **Matthew Collins** spoke at [NJAASC's 11th Annual Ambulatory Surgery Conference.](#)

On May 10, Litigation Co-Chair **Rose Suriano** along with Associate **Lauren Adornetto Woods**, issued a client alert discussing "[Legal Questions Surrounding Vaccine Passports.](#)"

Click on the link if you missed HPRG's May 25 webinar "[Pandemic Impact - PPP Questions Addressed, New HHS Funding Opportunities and Employee Tax Deferral and Related Considerations](#)" with Healthcare Law Chair, **John D. Fanburg**, and Labor and Employment Co-Chair **Anthony Rainone**. HPRG is a newly formed multidisciplinary collaborative comprised of well-experienced firms and individuals providing comprehensive support for all aspects of your practice – legal, financial, operational, and strategic.

## 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 John D. Fanburg and Associate Susan E. Frankel.



### John D. Fanburg

John D. Fanburg has been hailed as the go-to attorney in New Jersey on healthcare law issues and for his exemplary vision and leadership role in handling four major private equity deals representing four different kinds of practices:

pediatrics, perinatal medicine, ophthalmology, and a laparoscopic bariatric surgery practice. John provides strategic legal guidance to a wide range of healthcare organizations and providers responding to the challenges and opportunities of the rapidly changing American healthcare system.

On the weekends, John enjoys spending time with his wife and two sons, golfing, traveling, and exploring new cities. He is also a music enthusiast and is eager to safely attend live concerts in the future.



### Susan E. Frankel

Susan Frankel's practice is focused on healthcare corporate, transactional, and regulatory matters, representing physicians, physician groups, ambulatory surgical centers (ASCs), hospitals, and other healthcare providers and facilities. Uniquely, Susan

is also experienced in healthcare and commercial litigation, thereby offering a beneficial perspective to her advisory role.

In her spare time, Susan enjoys bicycling and hiking with her husband and walking her two French Bulldogs around her charming town of Warwick, New York. She loves every opportunity for a Starbucks run with her two teenage daughters.

## HIPAA CORNER

**OCR Warns of Marketing Postcards Disguised as Official OCR Communication** – On April 26, 2021, the Department of Health & Human Services, Office for Civil Rights (OCR), the HIPAA enforcement agency, published a listserv notice to alert healthcare organizations “of postcards being sent to health care organizations informing the recipients that they are required to participate in a “Required Security Risk Assessment” and they are directed to send their risk assessment to [www.hsaudit.org](http://www.hsaudit.org). The link directs individuals to a non-governmental website marketing consulting services.” OCR advised that the postcard did not come from the OCR, and that covered entities and their business associates “can verify that a communication is from OCR by looking for the OCR address or email address, which will end in @hhs.gov, on any communication that purports to be from OCR and asking for a confirming email from the OCR investigator’s hhs.gov email address.” OCR advises that any suspected incidents

of individuals posting as federal law enforcement should be reported to the Federal Bureau of Investigation.

**Call for Comments on Update to NIST Security Rule Implementation Guide** – On April 29, 2021, the National Institute for Standards and Technology (NIST) published a [Call for Comments](#) regarding anticipated revision of NIST Special Publication (SP) 800-66, Revision 1, [An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act \(HIPAA\) Security Rule](#) (“Resource Guide”). NIST acknowledges that NIST’s cybersecurity resources have evolved since the 2008 publication of the Resource Guide and that stakeholders will benefit from an update that includes references to updated resources. Comments must be submitted by June 15, 2021, to [sp800-66-comments@nist.gov](mailto:sp800-66-comments@nist.gov) with “Resource Guide for Implementing the HIPAA Security Rule Call for Comments” in the subject field.

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