

Healthcare Law UPDATE

FEDERAL UPDATE

Regulators Issue Part II Interim Final Rule Implementing No Surprises Act

Several Federal agencies, including the Departments of Health and Human Services, Labor, and Treasury, recently released [Part II](#) of the interim final rule implementing the independent dispute resolution provisions of the No Surprises Act (NSA). The NSA, which was adopted as part of the Consolidated Appropriations Act of 2021, provides protection to patients from receiving surprise medical bills when seeking emergency services or certain other types of services from out-of-network providers at in-network facilities. The interim final rule is the second in a series of three interim final rules to be issued to implement the terms of the NSA. Comments to the interim final rule must be submitted by December 6, 2021, and the policies outlined in the interim final rule become effective as of January 1, 2022.

The interim final rule establishes the process for the independent dispute resolution to determine the applicable rate for disputed out-of-network items or services. Before initiating the independent dispute resolution process, the disputing parties must engage in a 30 day open negotiation period to negotiate a payment rate. If the parties are not able to negotiate a payment rate after 30 days, the parties may then submit for the independent dispute resolution. The parties may jointly select an independent certified dispute resolution entity (IDRE), and if they cannot agree, the agency administering the dispute resolution process will select an IDRE. The parties will each submit their offer for payment of the disputed claim along with supporting documentation to the IDRE, and the IDRE will issue a binding determination setting one of the disputing parties' offers as the final payment. When making a payment determination, the IDRE must select the offer closest to the payor's median contracted rate for that item or service, known as the qualified payment amount (QPA), unless a party clearly demonstrates that the value of the item or service is materially different from the QPA.

The interim final rule establishes the procedures for an entity to become certified as an IDRE and the process by which a party can petition for the denial or revocation of certification of an IDRE. The interim final rule also provides guidelines for providers to provide good faith estimates of expected

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charges for items and services to an uninsured or self-pay individual, and a dispute resolution process to determine a payment amount in cases where the actual charged amount exceeds the good faith estimate. The interim final rule also establishes criteria for determining when an external review is available to patients regarding claims under the NSA.

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P-Stim Fraud Cases Lead to Recovery of Millions by USAO

On October 14, 2021, the United States Attorney's Office for the Eastern District of Pennsylvania (USAO) [announced](#) that it had settled with three parties and initiated a complaint against a fourth under the False Claims Act, in connection with schemes to improperly bill federal healthcare programs for P-Stim electro-acupuncture devices, also characterized as implantable neuro-stimulators (P-Stim Devices). According to the USAO, "[t]hese are the latest actions in the national investigation into the scheme of improper billing involving P-Stim electro-acupuncture devices. P-Stim is also branded as, among other things, ANSiStim, Stivax, NeuroStim, and NSS-2 Bridge." P-Stim Devices are not reimbursable by federal healthcare programs.



According to the USAO, the enforcement actions “involve certain parties who sold P-Stim devices and/or promoted them as billable to Medicare and other federal healthcare programs, which then caused providers to submit fraudulent claims. The United States alleges that these promoters profited by conspiring together to make false representations to providers that P-Stim was reimbursable under billing codes that paid thousands of dollars per procedure. Those codes were meant for legitimate, surgically implanted neuro-stimulators to manage chronic pain. However, P-Stim devices can be applied in a few minutes in an office setting without anesthesia by someone with minimal training. The promoters allegedly had knowledge that the P-Stim devices were not reimbursable by federal healthcare programs but pushed the non-surgical devices anyway.”

In addition to monetary penalties, the three parties who settled the allegations against them agreed to exclusions from federal healthcare programs, with 20-year exclusions against two parties and a 7-year exclusion against the third.

The False Claims Act case involves a chiropractor who allegedly promoted himself as a medical reimbursement consultant, made coding recommendations relating to P-Stim Devices, and promoted them as reimbursable by Medicare, causing providers to submit thousands of fraudulent claims for P-Stim Devices to Medicare and other federal healthcare programs.

Per the USAO, “[t]his ongoing national effort to identify and combat P-Stim fraud is a collaboration between this District, the Centers for Medicare & Medicaid Services’ (“CMS”) Center for Program Integrity, the Department of Health and Human Services Office of Inspector General (“HHS-OIG”), other federal healthcare programs, state partners, and sister U.S. Attorney’s Offices around the country.”

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HHS OCR and USAO Settle Disability Discrimination Case with Hospital

The U.S. Department of Human Services, Office for Civil Rights (OCR) along with the U.S. Department of Justice through the U.S. Attorney’s Office for the District of Connecticut (DOJ) entered into a [Voluntary Resolution Agreement](#) with William W. Backus Hospital (Backus) arising from a complaint by a deaf individual (complainant) who uses American Sign Language (ASL) as the primary means of communication. The complainant alleged that Backus failed to provide appropriate auxiliary aids and services when necessary to ensure effective communication during hospitalization, in violation of Title III of the Americans With Disabilities Act (ADA) and its implementing regulations.

According to the background facts as outlined in the resolution agreement, although the hospital provided ASL interpreters upon admission and for discharge planning, at all other times, personnel attempted to communicate with

the complainant through the exchange of written notes. The complainant alleged he was unable to communicate effectively in this manner due to his limited ability to read and write in English. In addition, on some occasions, personnel were unable to operate Backus’ video remote interpreting system.

While not admitting any liability, fault or wrongful or illegal activity, Backus agreed in the resolution agreement to take steps to ensure the availability of auxiliary aids and services and to monitor such steps. In addition, Backus agreed to pay the complainant \$7,500 in compensatory relief for matters the complainant could have pursued under the ADA.

This resolution should serve as a reminder to healthcare providers of the need to ensure compliance with the ADA and other discrimination and related laws requiring the provision of auxiliary aids and services to deaf, hard of hearing, and other patients who require them.

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Federal Bill Would Require Ransomware Victims to Disclose Ransom Payments to the Government

On October 5, 2021, Senator Elizabeth Warren and Representative Deborah Ross [introduced](#) a federal [bill](#) that would, if passed into law, require victims of ransomware attacks to disclose to the Department of Homeland Security (DHS) ransom payments made to cyber attackers.

If passed into law, the “Ransom Disclosure Act” would:

- Require ransomware victims (excluding individuals) to disclose information about ransom payments no later than 48 hours after the date of payment, including the dates and amount of ransom demanded and paid, the type of currency used for payment of the ransom, any known information about the entity demanding the ransom, and whether the victim that paid the ransom receives federal funds.
- Require DHS to make public the information disclosed during the previous year, excluding identifying information about the entities that paid ransoms.
- Require DHS to establish a website through which individuals can voluntarily report payment of ransoms.
- Direct the Secretary of Homeland Security to conduct a study on commonalities among ransomware attacks and the extent to which cryptocurrency facilitated these attacks and provide recommendations for protecting information systems and strengthening cybersecurity.

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EEOC Updates Technical Assistance on COVID-19 Vax Religious Exemption

On October 25, 2021, the U.S. Equal Employment Opportunity Commission (EEOC) issued a [press release](#) regarding its expanded and updated technical assistance relating to COVID-19 and the Americans with Disabilities Act (ADA), the Rehabilitation Act, and other EEO laws. The expanded [technical assistance](#) provides new information regarding the application of Title VII of the Civil Rights Act of 1964 when a job applicant or employee seeks a religious exemption to an employer's COVID-19 vaccination requirement, based on sincerely held religious beliefs, practices, or observances. Key updates to the guidance include:

- Employees and applicants must inform their employers if they seek an exception to an employer's COVID-19 vaccine requirement due to a sincerely held religious belief, practice, or observance.
- Title VII requires employers to consider requests for religious accommodations but does not protect social, political, or economic views, or personal preferences of employees who seek exceptions to a COVID-19 vaccination requirement.
- Employers that demonstrate "undue hardship" are not required to accommodate an employee's request for a religious accommodation.

The EEOC guidance covers topics such as disability-related inquiries and medical exams, confidentiality of medical information, hiring and onboarding, reasonable accommodation, pandemic-related harassment due to national origin, race, or other protected characteristics, furloughs and layoffs, return to work, age, caregivers/family responsibilities, pregnancy, and vaccinations and non-discrimination laws. Although HIPAA generally does not cover confidentiality of medical information in employment records, with limited exceptions, the ADA requires employers to keep confidential any medical information they learn about any applicant or employee. See the article below in our HIPAA Corner about HIPAA and COVID-19 information in the workplace.

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STATE UPDATE

Cannabis Regulatory Commission Assumes Regulation of Medical Cannabis

Effective September 29, 2021, the [New Jersey Cannabis Regulatory Commission](#) (CRC) has assumed all powers, duties and responsibilities for the regulation and oversight of activities authorized by the New Jersey Compassionate Use Medical Marijuana Act from the New Jersey Department of Health. The Cannabis Regulatory Commission will be responsible for further development, expansion, regulation, and enforcement of activities associated with the medical use

of cannabis. The CRC also has responsibility for regulation and oversight of the recreational cannabis industry in New Jersey.

Continuing Education Waiver Extended for Health Officers and Health Specialists

The New Jersey Department of Health (DOH) has extended the continuing education (CE) [waiver](#) for active health officers and registered environmental health specialists (REHSs). On October 13, 2020, due to the demands caused by the COVID-19 public health emergency, the DOH issued a waiver of the CE requirements for active health officers and REHSs who were renewing their licenses as active for the 2021 licensing period. The purpose of the waiver was to provide active licensed health officers and REHSs a reprieve from the CE obligation so they could focus on the public response to COVID-19 in New Jersey and to ensure that the State maintained a sufficient number of active licensed health officers and REHSs to carry out essential public health services and respond to the public health emergency. Due to the continuing demands caused by the COVID-19 pandemic, the DOH has determined that an extension of the CE requirement waiver is necessary and appropriate for active licensed health officers and REHS. Accordingly, the DOH will continue to waive the CE requirement for active licensees for the 2022 licensing period. Individuals with an active health officer or REHS license in good standing for the 2021 licensing period may renew their respective license for the 2022 licensing period without completing the required 15 contact hours of CE credits so long as they satisfy all other requirements for licensure renewal.

New Law Establishes Pediatric Cancer Research Fund

On September 16, 2021, Governor Phil Murphy signed [Bill S1431](#) into law to establish the "Pediatric Cancer Research Fund." As part of the new law, each New Jersey taxpayer will have the opportunity to indicate on the taxpayer's New Jersey gross income tax return that a portion of the taxpayer's refund or an enclosed contribution be deposited in the fund. All contributions deposited into the fund will be annually appropriated to the New Jersey State Commission on Cancer Research (Commission) for pediatric cancer research projects. The Commission will solicit, receive, evaluate and approve applications from qualifying research institutions for grants from the fund to finance pediatric cancer research projects. Qualifying pediatric cancer research projects include research projects which focus on the causes, prevention, education, screening, treatment, or cure of pediatric cancer, or the symptoms or effects experienced by patients following completion of a course of treatment for pediatric cancer. In conjunction with the establishment of the fund, Governor Murphy also signed into law Bill S3724 which appropriates \$5 million for the new fund.

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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 Counsel Shannon Carroll and Counsel Edward Yun.



Shannon Carroll

Shannon Carroll's practice focuses on healthcare litigation, complex commercial litigation, compliance, and healthcare fraud. She has experience in all aspects of litigation from the client intake process through trial.

Shannon represents doctors and other healthcare providers in civil and administrative actions involving fraud allegations, reimbursement issues, and contract disputes. She has also successfully represented healthcare clients in disputes involving restrictive covenants, shareholder oppression, and unfair competition.

On the weekend Shannon likes to run half marathons and spend time with her daughters, including leading their Girl Scout troops.



Edward J. Yun

Edward Yun helps his clients resolve the broad spectrum of legal challenges that confront the healthcare industry. He represents licensed professionals, multispecialty practices, ambulatory care facilities, clinical laboratories,

pharmacies, hospitals, and other health-related entities. Edward counsels healthcare providers in regulatory compliance matters and represents healthcare providers in licensing applications, managed care agreements, commercial transactions, mergers and acquisitions, and day-to-day business relations. He frequently advises healthcare providers regarding the prohibition against self-referrals, kickbacks, fee splitting, false claims, and healthcare fraud, as well as claims processing and reimbursement issues. Edward also provides guidance to healthcare providers with respect to shareholder disputes and restrictive covenants.

In his spare time, Ed enjoys music, hiking, skiing, and motorcycle riding.

Brach Eichler In The News

On October 14, Healthcare Law Members **John D. Fanburg**, **Lani M. Dornfeld**, **Joseph M. Gorrell**, and **Carol Grelecki** issued a client alert, "[The NJDOH Issues Executive Directive 21-011 Setting Forth Protocols for COVID-19 Testing and Vaccination Reporting for Covered Settings.](#)"

Labor and Employment Co-Chair **Matthew M. Collins** was quoted in an article in the *New Jersey Law Journal*, "[Best Practices for Documenting the COVID-19 Vaccination Status of Employees](#)" on October 7.

On October 21, Healthcare Member **Lani M. Dornfeld** addressed the Home Care & Hospice Association of NJ on "[Best Practices in Getting Ready for a Buy/Sell Transaction Today.](#)"

Healthcare Member **Lani Dornfeld**, quoted in *ASC Focus – The ASC Journal*, about the seven steps to consider when developing an effective ASC compliance plan.

HIPAA CORNER

OCR Issues Guidance on HIPAA, COVID-19 Vaccinations, and the Workplace – On September 30, 2021, the U.S. Department of Health & Human Services (HHS), Office for Civil Rights (OCR) issued [guidance](#) to help the public understand when the HIPAA Privacy Rule (HIPAA) applies to disclosures and requests for information about whether a person has received a COVID-19 vaccine.

In the guidance, OCR reminds the public that HIPAA does not apply to employment records. This is because HIPAA applies only to covered entities (health plans, healthcare clearinghouses, and healthcare providers that conduct standard electronic transactions), and, in some cases, to their business associates. OCR also reminds organizations that even if HIPAA applies, it regulates the use and disclosure of protected health information (PHI) by covered entities and their business associates, but not the ability to request information from the individual who is the subject of the information. As such:

- HIPAA does not prohibit any person (e.g., an individual or an entity such as a business) from asking whether an individual has received a particular vaccine, including the COVID-19 vaccine.
- HIPAA does not regulate the ability of covered entities and business associates to request information from patients or visitors. That is, the covered entity or business associate may ask whether an individual (e.g., a patient or visitor) has received a particular vaccine, including the COVID-19 vaccine.
- HIPAA does not prohibit the release by a medical provider that is a HIPAA covered entity from disclosing an individual's PHI, including COVID-19 vaccination status, without a written authorization from the individual, unless an exception under HIPAA applies (e.g., a disclosure to a health plan to obtain payment for a healthcare service).



- Similarly, HIPAA does not apply when an individual:
 - Is asked about their vaccination status by an employer, store, restaurant, entertainment venue, or another individual.
 - Asks another individual, his/her doctor, or a service provider whether he/she is vaccinated.
 - Asks a company, such as a home health agency, whether its workforce members are vaccinated.
- HIPAA does not prevent any individual from disclosing whether that individual has been vaccinated against COVID-19 or any other disease. HIPAA does not apply to individuals' disclosures about their own health information.
- HIPAA does not prohibit an employer from requiring a workforce member to disclose to the employer, clients, or other parties whether he/she has received a COVID-19 vaccine; however, other federal and state laws may be implicated such as anti-discrimination laws.
- HIPAA does not prohibit a covered entity or business associate from requiring its workforce members to disclose to the employer or other parties whether the workforce members have received a COVID-19 vaccine. For example, HIPAA does not prohibit a covered entity or business associate from requiring or requesting each workforce member to:
 - Provide documentation of COVID-19 or flu vaccination to the workforce member's current or prospective employer.
 - Sign a HIPAA authorization for the release of the workforce member's COVID-19 or varicella vaccination record to the employer.
 - Wear a mask while in the employer's facility, on the employer's property, or in the normal course of performing duties at another location.

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OCR List Serve Guidance on Hacking and Ransomware

On September 21, 2021, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) distributed to its list serve a number of "ransomware resources for HIPAA regulated entities." Due to the importance of this information, the following is the OCR list serve message in its entirety:

The HHS Office for Civil Rights (OCR) is sharing the following information to ensure that HIPAA regulated entities are aware of the resources available to assist in preventing, detecting, and mitigating breaches of unsecured protected health information caused by hacking and ransomware.

HHS Health Sector Cybersecurity Coordination Center Threat Briefs:

- [Sector Alerts](#)
- [January 28, 2021 - ATTACK for Emotet](#)
- [March 12, 2021 - New Ryuk Variant Analyst Note](#)
- [April 8, 2021 - Ryuk Variants](#)
- [May 25, 2021 - Conti Ransomware Analyst Note](#)
- [June 3, 2021 - Ransomware Trends 2021](#)
- [July 8, 2021 - Conti Ransomware](#)
- [July 8, 2021 - Phobos Ransomware Analyst Note](#)
- [August 5, 2021 - Qbot/QakBot Ransomware](#)
- [August 6, 2021 - Lazio Ransomware Attack Analyst Note](#)
- [August 19, 2021 - REvil Update](#)
- [August 24, 2021 - OnePercent Group Ransomware Alert](#)
- [August 25, 2021 - IOCs Associated with Hive Ransomware Alert](#)
- [September 2, 2021 - Demystifying BlackMatter](#)

HHS Resources on Section 405(d) of the Cybersecurity Act of 2015:

- [Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients](#)
- [Cybersecurity Reports and Tools](#)

OCR Guidance:

- [Ransomware Fact Sheet](#)
- [Cybersecurity Guidance Material](#)
- [Guidance on Risk Analysis Requirements](#)

[HHS Security Risk Assessment Tool](#)

[CISA Protecting Sensitive and Personal Information from Ransomware-Caused Data Breaches:](#)

- [Stop Ransomware Government Website](#)
- [Protecting Sensitive and Personal Information](#)

[CISA Ransomware Guide](#)

FBI Ransomware Resources:

- [Scams and Safety: Common Scams and Crimes](#)
- [High-Impact Ransomware Attacks](#)

OCR Cybersecurity Newsletters:

- Making a List and Checking it Twice: HIPAA and IT Asset Inventories ([Summer 2020 Cybersecurity Newsletter](#))
- What Happened to My Data?: Update on Preventing, Mitigating and Responding to Ransomware ([Fall 2019 Cybersecurity Newsletter](#))
- Phishing ([February 2018 Cybersecurity Newsletter](#))

- Plan A... B... Contingency Plan! ([March 2018 Cybersecurity Newsletter](#))
- Cybersecurity Incidents will happen... Remember to Plan, Respond, and Report! ([May 2017 Cybersecurity Newsletter](#))

REMINDER: A ransomware attack may result in a breach of unsecured protected health information that triggers reporting requirements under the HIPAA Breach Notification Rule. HIPAA covered entities and business associates should review [OCR's ransomware guidance](#) for information regarding potential breach notification obligations following a ransomware attack.

With the continuous uptick of hacking, ransomware and other cyber attacks on healthcare providers, it is critical that HIPAA covered entities and their business associates have in place a current and compliant privacy and security program, which includes active and engaged privacy and security officers, frequent and meaningful education, and ongoing auditing and monitoring activities.

For more information or assistance with your privacy and security program or managing a breach incident, contact:

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