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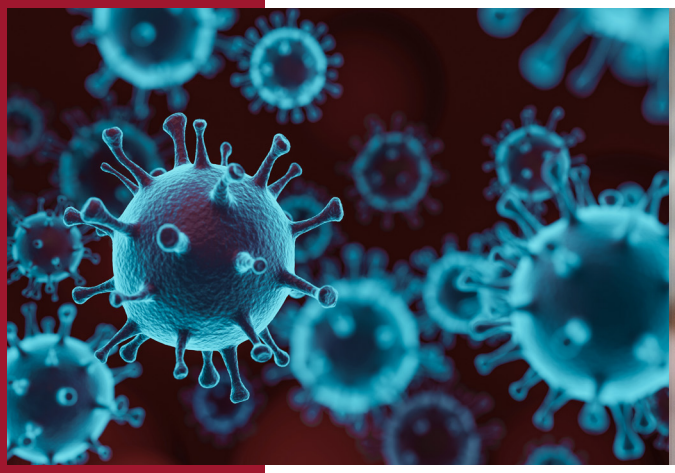


JAN | 2021

2020 Healthcare Law
Year in Review

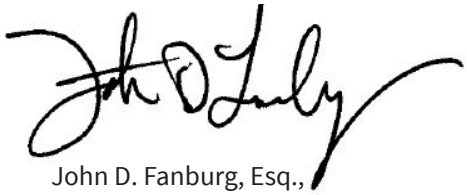
Welcome to the 12th annual *Healthcare Law Year in Review* produced by the Brach Eichler Healthcare Law Practice. The goal of this publication is to highlight some of the most important issues and developments in healthcare, both nationally and in New Jersey, over the past 12 months.

2020 was certainly one for the books with the advent of the COVID-19 pandemic and its continued impact and burden on New Jersey's healthcare providers. Many laws and regulations passed last year addressed its implications and sought to focus on the needs of both physicians and patients. Simultaneously, new developments in the Stark Law, the Anti-Kickback Statute, telemedicine, and HIPAA, among others, continued to make headlines.

Among the issues covered in this year's report are:

- The sweeping changes CMS made to Federal Stark Anti-Referral regulation;
- New law addressing COVID-19 telemedicine requirements;
- COVID-19-related HIPAA guidance; and
- OIG's final rule amending Federal Anti-Kickback Statute regulations.

As always, Brach Eichler's healthcare law attorneys are available to provide guidance and/or assist with mergers and acquisitions, labor and employment, contracts and agreements, and any other legal matters. The pandemic—including the ongoing vaccine rollout—will continue to be a dominant theme as we move forward in 2021. And we will be there to assist every step of the way in what continues to be uncharted territory. If you have any questions or would like additional information regarding any of the articles contained in the *2020 Healthcare Law Year in Review*, please do not hesitate contact me. Thank you for your continued support. Be well, be safe.



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FEDERAL UPDATE

Executive Order Expands Telehealth

On August 3, 2020, President Trump issued an Executive Order (EO) directing the U.S. 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 2020, compared with less than one percent in February 2020, before the public health emergency was declared. Even after in-person primary care visits were permitted to resume in May 2020 , 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 added more than 60 services to the Medicare telehealth list in the 2021 Medicare Physician Fee Schedule that will continue to be covered beyond the end of the COVID-19 public health emergency, and CMS will continue to gather more data and evaluate whether more services should be added in the future. These additions allow Medicare beneficiaries to continue to have access to telehealth services, including certain types of home visits, therapy services, psychological and neuropsychological testing, emergency department visits, and critical care services.

CMS Urges States to Take Action to Facilitate Value-Based Payments

In a guidance letter to state Medicaid directors on September 15, 2020 and a related press release, Centers for Medicare & Medicaid Services (CMS) encouraged states to take action to implement value-based payments for Medicaid programs. CMS already had begun implementing various value-based payment models for the Medicare program and encouraged states to use what they have learned in the process.

CMS generally layed out three recommended payment models for implementation in state Medicaid programs, each with varying degrees of deviation from the current fee-for-service payment architecture:

- Payment models built on fee-for-service architecture – direct payments on a fee-for-service basis, with (usually) retrospective adjustments for the cost and quality of services provided relative to benchmarks
- Episode of care payments – bundled payment for some or all services associated with episodes of care during a defined period of time, the amount of which may be established by comparing actual episode expenditures to an established benchmark price
- Payments involving total cost of care accountability – including bundled payments, fee-for-service, capitated payments or global payments, with healthcare providers held accountable for all populations or sub-populations for some or all services.

The underlying message is that value-based care will not happen until payers hold providers accountable through value-based payments. CMS promotes what it describes as an agile, staged approach to transform the healthcare payment landscape.

OIG Issues Special Fraud Alert on Drug and Device Speaker Programs

The U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued a Special Fraud Alert on November 16, 2020 regarding speaker programs by pharmaceutical and medical device companies. The Alert serves as a warning for physicians and other healthcare professionals who are paid by these companies to make speeches or presentations about a drug or device, or who are paid, often with free meals or alcohol, to attend such programs. OIG is cracking down on these speaker programs as violations of the federal Anti-Kickback Statute.

When any kind of remuneration, i.e., anything of value, is paid directly or indirectly to purposefully induce or reward referrals of items or services payable by a federal healthcare program, the Anti-Kickback Statute is implicated. OIG has investigated numerous allegations that pharmaceutical and medical device companies organize and pay generous compensation for speaker programs to induce physicians or healthcare professionals to prescribe or order the companies' products. Not only are the drug and device companies at risk for civil or criminal penalties for violations of the Anti-Kickback Statute, but the program speakers and attendees are subject to these penalties as well.

OIG's skepticism of speaker programs is not new. In 2003, OIG identified manufacturer compensation relationships with physicians related to marketing and sales activities, including speaking activities, as an area of potential fraud and abuse. The recent Alert, however, identifies with more specificity a list of suspect characteristics that will subject speaker programs to closer scrutiny:

- The company sponsors speaker programs where little or no substantive information is actually presented;
- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free);
- The program is held at a location that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues);
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially without a recent substantive change in relevant information;
- There has been a significant period of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;

- Physicians attend programs on the same or substantially the same topics more than once;
- Attendees include individuals who do not have a legitimate business reason to attend the program, such as friends, family members, or employees of the speaker or attendee;
- The company selects speakers or attendees based on past or expected revenue that the speakers or attendees will generate by prescribing or ordering the company's product(s); and
- The company pays speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the physician or healthcare professional.

Physicians and healthcare professionals should consider these factors and assess the potential risks before participating as a speaker or attendee of a drug or device speaker program.

CMS Makes Sweeping Changes to Federal Stark Anti-Referral Regulations

On November 20, 2020, U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services (CMS), issued sweeping changes to the federal law that prohibits physician self-referrals (Stark Law). These regulatory changes are designed to provide flexibility for care coordination and value-based arrangements, as well as reduce regulatory burdens for physicians and other healthcare providers.

The changes include:

- New exceptions for value-based healthcare delivery and payment models, including models based on full financial risk by a value-based enterprise, meaningful downside financial risk by physicians, and other value-based arrangements;
- New exceptions for non-abusive arrangements, such as an arrangement providing limited remuneration of up to $5,000 annually to a physician or the donation of cybersecurity technology and related services;
- Guidance on when an arrangement is considered "commercially reasonable," under what circumstances compensation takes into account the "volume or value of referrals or other business" generated between the parties, and what constitutes "fair market value;" and
- Revision of the special rule on profit shares and productivity bonuses for physicians in a group practice, including allowing physicians in a group practice to be rewarded for participation in value-based arrangements and limiting profit sharing pools to profits derived from all designated health services (DHS) (rather than profits derived from a particular DHS service line).

The regulations are effective on January 19, 2021, except for the regulation regarding the special rule on profit shares and productivity bonuses, which become effective on January 1, 2022.

OIG Issues Final Rule Amending Federal Anti-Kickback Statute Regulations

On November 20, 2020, the U.S. Department of Health & Human Services, Office of Inspector General (OIG) issued its final rule creating new safe harbors and modifying existing safe harbors under the federal Anti-Kickback Statute. These changes are designed to provide greater flexibility and reduce regulatory burdens, particularly with respect to care coordination and value-based arrangements. The changes include:

- New safe harbors for care coordination value-based arrangements with full financial risk, and value-based arrangements with substantial downside financial risk;
- New safe harbor for arrangements for the furnishing of certain tools and support for patients to improve quality, health outcomes, and efficiency;
- New safe harbor for CMS-sponsored model arrangements;
- New safe harbor for non-monetary remuneration for cybersecurity technology and related services;
- Revision to the electronic health records items and services safe harbor to allow for the donation of cybersecurity technology and to eliminate the December 31, 2021 sunsetting of the safe harbor; and
- Revision to the personal services and management contracts safe harbor to allow for outcome-based payment arrangements and to eliminate the requirement that part-time arrangements have a specified schedule set in advance.

These regulations are effective on January 19, 2021.

STATE UPDATE

Hospital Transparency Laws Enacted

Three New Jersey bills requiring hospitals to disclose additional information about their finances and transactions with related parties became law in January 2020. The bills were introduced in November 2019 after concerns arose over the possible closure of Bayonne Medical Center.

Bill A5916 authorizes the Commissioner of Health to notify elected officials of financial distress of certain hospitals. If the Commissioner determines that a hospital is in financial distress or at risk of being in financial distress, the Commissioner may provide notice of the hospital's financial state to the mayor, city administrator, and members of the Legislature who represent the municipality in which the hospital is located. If the Commissioner appoints a monitor to prevent further financial deterioration at the hospital, the Commissioner must provide notice of the appointment within 30 days to the mayor, city administrator, and members of the Legislature who represent the municipality in which the hospital is located.

Bill A5917 expands the Department of Health's (DOH) "Early Warning System," which detects signs that a hospital may be in or is approaching financial distress. In evaluating a hospital's finances, the DOH will be required to consider the amount of management fees, allocations, and other payments made to third-party entities, and the extent to which those fees, allocations, and payments reflect services actually rendered, with a particular focus on fees, allocations, and other payments made to a related or affiliated entity. The DOH will also be required to review both the hospital's operating margin and the operating margin adjusted to account for third-party management fees, allocations, and other payments.

Bill A5918 expands the information hospitals are required to report to the New Jersey Department of Health (DOH). In addition to monthly and quarterly unaudited financial information and annual audited financial statements which hospitals are currently required to provide to the DOH, hospitals will also be required to post on their internet websites Internal Revenue Service Form 990 and all schedules and supporting documentation. If a hospital is owned or managed by a for-profit entity, the hospital will be required to provide the DOH with certain additional information.

Law Requires Influenza Vaccinations for Healthcare Workers

On December 13, 2019, Bill A1576 became law requiring certain healthcare facilities to provide, and employees to receive, annual influenza vaccinations. The law requires hospitals, nursing homes, and home healthcare agencies to establish and implement an annual influenza vaccination program in accordance with the current recommendations of the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention and any rules and regulations adopted by the New Jersey Commissioner of Health. With limited exceptions, these facilities must provide an on-site or off-site influenza vaccination to each of its employees and each employee must receive an influenza vaccination annually.

Law Addresses COVID-19 Telemedicine Requirements

On March 19, 2020, Bill A3860 was enacted establishing certain requirements to use telemedicine and telehealth to respond to COVID-19. The law provides that, for the duration of the public health emergency declared in response to COVID-19, any healthcare practitioner will be authorized to provide and bill for services using telemedicine and telehealth, regardless of whether rules and regulations concerning the practice of telemedicine and telehealth have been adopted in New Jersey. The services authorized under the law will include the full range of services set forth in the definitions of telemedicine and telehealth under New Jersey law that are appropriate under the standard of care. In addition, the law provides that practitioners who are not licensed or certified to practice in New Jersey may provide healthcare services under the bill using telemedicine and telehealth if certain requirements are met.

The Division of Consumer Affairs Announced Proposed and Adopted Telemedicine Rules

On October 19, 2020, Attorney General Gurbir S. Grewal and the Division of Consumer Affairs (the Division) announced rule proposals and adoptions for several licensing boards and committees that provide healthcare services through telemedicine. Rules were adopted for the following licensing boards and committees: Acupuncture Examining Board, Audiology and Speech-Language Pathology Advisory Committee, Board of Nursing, Board of Physical Therapy Examiners, Board of Psychological Examiners, Board of Social Work Examiners, and Genetic Counseling Advisory Committee. Rules were proposed for the following licensing boards and committees: Board of Marriage and Family Therapy Examiners, Electrologists Advisory Committee, Physician Assistant Advisory Committee, and the Professional Counselor Committee. Comments to the proposed rules were due by December 18, 2020.

In summary, both the adopted and proposed rules permit the applicable New Jersey licensee to provide telemedicine services (i) if he/she is located in New Jersey and provides healthcare services to any patient/client located in or out of New Jersey by means of telemedicine or telehealth, or (ii) if he/she is located outside of New Jersey and provides healthcare services to any patient/client located in New Jersey by means of telemedicine or telehealth. The 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 requirements; (e) protocols for prevention of fraud and abuse; and (f) privacy policies and practices. In addition to the above, the proposed rules set forth by the Physician Assistant Advisory Committee and the adopted rules for the Board of Nursing contain requirements for prescribing through telemedicine or telehealth.

Law Enacted Requiring Insurance Coverage for COVID-19 Testing and Telemedicine

On March 20, 2020, Bill A3843 was enacted requiring health insurance carriers (health, hospital, and medical service corporations, health maintenance organizations, and insurance companies), as well as the state and School Employees' Health Benefits Programs and the State Medicaid program, to provide coverage for expenses incurred in: (1) the testing for COVID-19, provided that a licensed medical practitioner has issued a medical order for that testing; and (2) the delivery of healthcare services through telemedicine or telehealth in accordance with the provisions of the New Jersey telemedicine and telehealth laws. The requirements of the law remain in effect during the duration of the public health emergency declared in connection with COVID-19.

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.

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 denied the allegations through an answer filed in November 2020. In December 2020, the lab amended the complaint to make technical changes to the CARES allegations to seek relief under the Employee Retirement Income Security Act of 1974 (ERISA). Cigna must now respond to the amended complaint by January 25, 2021.

NJ Psychologist Suspension, $110,000 Sanction Upheld for Disclosing Sensitive Patient Information to Debt Collection Attorneys

In August 2018, the New Jersey State Board of Psychological Examiners (Board) suspended for two years (with one served as probation) the license of a New Jersey psychologist, after he disclosed sensitive patient information to his debt collection attorneys. The Board also imposed a $10,000 civil penalty and sanctioned the psychologist with $110,542.08 in attorneys' fees and costs. The psychologist appealed the Board's order, and on May 29, 2020, the appeals court upheld the order in its entirety.

The court held that the suspension, sanctions, and penalty were appropriate given the totality of the circumstances surrounding the psychologist's breach of confidentiality. The court found that by "providing the attorneys true bills with diagnostic and treatment codes, [the psychologist] overlooked the psychologist-patient privilege, regulations implementing the [Practicing Psychology Licensing Act], and his contractual commitments to his patients."

For 25 years, the psychologist had been providing to his debt collection attorneys bills containing patient diagnostic and treatment codes. The attorneys in turn attached the true bills to civil complaints filed in court, which then became public record. The psychologist argued that he did not know the bills would be attached to more than 80 filed lawsuits, and that he never received from his attorneys a copy of a filed complaint. He further explained that while

his collection attorneys told him they needed to see the full bills, had he known the bills would be attached to the complaints he would never have allowed it. Therefore, the psychologist argued, he should not be liable for the confidentiality breaches committed by his attorneys.

The court did not agree with the psychologist's arguments, finding that his intent was not relevant, and that the breach of confidentiality was his disclosure to his attorneys and not the attorneys' filing of the complaints. He did not need to provide the full bills to his attorneys, the court said, but rather he could have provided them with a transaction ledger containing just the patient's name, date of service, amount charged, and the billable party. Some of the bills provided to the attorneys even included the sensitive information of children, despite the fact that they were not financially responsible for the bill. Moreover, it was the psychologist's responsibility, explained the court, to review the complaints before they were filed to make sure they did not contain any sensitive information, but for 25 years, the psychologist did not review a single complaint. When a patient complained to the psychologist about the publicly disclosed information in the complaint, the psychologist refused to have it removed.

This case is a cautionary tale for healthcare providers to be extremely cautious in providing patient information to attorneys they retain to collect payment from patients.

New Law Permits Corporate Reorganization of Horizon

S3218/A5119 was signed into law by Governor Phil Murphy on December 23, 2020. The law provides for the reorganization of a health service corporation into a not-for-profit mutual holding company. The law defines a mutual holding company as a non-insurance, nonprofit entity that holds 100 percent interest in a subsidiary that takes on all health insurance duties and obligations. As the mutual holding company is not an insurer, it will not be subject to any investment limitations. The mutual holding company is required to file with the New Jersey Department of Banking and Insurance information related to its operations. The law allows for the reorganization of Horizon Blue Cross Blue Shield, which is currently a health service corporation, and enables Horizon to invest in emerging technologies.

HIPAA Highlights

DHHS Bulletin Regarding HIPAA Privacy and Novel Coronavirus – On February 3, 2020, the U.S. Department of Health & Human Services, Office for Civil Rights, published a special Bulletin: *HIPAA Privacy and Novel Coronavirus*, to "ensure that HIPAA-covered entities and their business associates are aware of the ways that patient information may be shared under the HIPAA Privacy Rule in an outbreak of infectious disease or other emergency situation, and to serve as a reminder that the protections of the Privacy Rule are not set aside during an emergency." The Bulletin provides information about sharing patient information for various purposes, including treatment; public health activities; to family, friends and others involved in an individual's care and for notification; to prevent a serious and imminent threat; and to the media or others not involved in the care of the patient. The Bulletin also includes information regarding HIPAA's minimum necessary standard, safeguarding patient information and application of HIPAA to covered entities and business associates.

COVID-Related HIPAA Guidance – The U.S. Department of Health & Human Services, Office for Civil Rights (OCR) was busy during 2020 sending out COVID-related HIPAA and other guidance. Highlights include:

- Limited waiver of HIPAA sanctions and penalties – sanctions and penalties for non-compliance with certain provisions of the HIPAA Privacy Rule have been waived during the public health emergency;
- Guidance relating to HIPAA privacy and disclosures in emergency situations, including for treatment purposes, public health emergencies, to family and friends, and to prevent or lessen a serious and imminent threat;
- OCR enforcement discretion during the COVID crisis, relating to the use of telehealth technology, including additional Q&A guidance;
- A reminder of non-discrimination obligations in the provision of healthcare, and bulletins concerning HIPAA flexibility during the COVID crisis;
- Additional notice of enforcement discretion concerning the good faith use and disclosure of protected health information by business associates for public health and oversight activities during the public health emergency;
- Alert concerning cybercriminal exploitation of COVID-19 and steps to mitigate risk; and
- Guidance relating to media access to healthcare facilities during the COVID-19 crisis, along with a reminder about the requirement to obtain written patient authorization for media disclosures.

Guidance on How Healthcare Providers Can Contact Former COVID-19 Patients About Blood and Plasma Donation Opportunities – On June 12, 2020, the The U.S. Department of Health & Human Services, Office for Civil Rights (OCR) issued an announcement and guidance on how healthcare providers can contact former COVID-19 patients about blood and plasma donation opportunities. The guidance explains that HIPAA permits covered healthcare providers to identify and contact patients who have recovered from COVID-19 for population-based activities relating to improving health, case management, or care coordination. The guidance emphasizes that, without patients' authorization, the providers cannot receive any payment from or on behalf of a blood and plasma donation center in exchange for such communications with a recovered patient. OCR stated it wants to make sure "misconceptions about HIPAA do not get in the way of a promising COVID-19 response."

OCR "Right of Access Initiative" Settlements Now Up to Unlucky 13 – The U.S. Department of Health & Human Services, Office for Civil Rights (OCR) placed a heavy focus in 2020 on the obligations of covered entities to comply, in a timely and complete manner, to patient requests for access to the patient's health records. The most recent settlement announced on December 22, 2020, the OCR's 13th, resulted in similar penalties to the prior 12 settlements: monetary fine, a corrective action plan, and ongoing monitoring. The settlements are intended to put HIPAA-covered entities on notice of how seriously the OCR is taking a patient's right to receive access to his/her medical records, including copies, in a timely manner and without delay or hindrance.

Proposed Amendments to HIPAA Aimed at Empowering Patients and Reducing Regulatory Burdens – On December 10, 2020, the U.S. Department of Health & Human Services (DHHS), Office for Civil Rights announced a Notice of Proposed Rulemaking (NPRM) that proposes changes to the HIPAA Privacy Rule "to support individuals' engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the health care industry." The proposed rules support the DHHS's Regulatory Sprint to Coordinated Care and would increase permissible disclosures of protected health information (PHI) and improve care coordination and case management by, among other things:

- Strengthening individuals' rights to inspect their PHI in person, which includes allowing individuals to take notes or use other personal resources to view and capture images of their PHI;
- Shortening covered entities' required response time to no later than 15 calendar days (from the current 30 days) with the opportunity for an extension of no more than 15 calendar days (from the current 30-day extension);
- Specifying when electronic PHI (ePHI) must be provided to the individual at no charge;
- Replacing the privacy standard that permits covered entities to make certain uses and disclosures of PHI based on their "professional judgment" with a standard permitting such uses or disclosures based on a covered entity's good faith belief that the use or disclosure is in the best interests of the individual;
- Expanding the ability of covered entities to disclose PHI to avert a threat to health or safety when a harm is "serious and reasonably foreseeable," instead of the current stricter standard which requires a "serious and imminent" threat to health or safety;
- Eliminating the requirement to obtain an individual's written acknowledgment of receipt of a direct treatment provider's Notice of Privacy Practices (NPP); and
- Modifying the content requirements of the NPP to clarify for individuals their rights with respect to their PHI and how to exercise those rights.

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