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Healthcare Law UPDATE

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FEDERAL UPDATE

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 will go into effect on January 19, 2021, except for the regulation regarding the special rule on profit shares and productivity bonuses, which will go into effect January 1, 2022.

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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 will go into effect on January 19, 2021.

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Big Pharma Pleads Guilty in the War on Opioids

On November 24, 2020, the U.S. Department of Justice announced that opioid manufacturer Purdue Pharma pled guilty in federal court to conspiracies to defraud the United States and violate the federal Anti-Kickback Statute.

Purdue admitted to providing healthcare providers with its dangerous opioid drugs which it knew or had good reason to know were being diverted to those abusing the drug.

Purdue further admitted to conspiring to defraud the DEA for approximately ten years by impeding the DEA in its duty and purpose. Additionally, Purdue admitted to violating the Anti-Kickback Statute between 2009 and 2017, when the company made payments to two doctors through Purdue's doctor speaker program to induce them to write more prescriptions of Purdue's opioid products, and further by making payments to an electronic medical records company in exchange for referring, recommending, and arranging for the ordering of Purdue's opioid products.

The plea deal also imposed the largest penalty ever against a pharmaceutical manufacturer, including a criminal fine of $3.544 billion and an additional $2 billion in criminal forfeiture. Purdue has agreed to pay $225 million towards its $2 billion criminal forfeiture. The Justice Department has agreed to forgive the rest if Purdue completes a bankruptcy reorganization, in which Purdue will dissolve and shift assets to a "public benefit company" which is designed to benefit the American public. The money shall be used to assist state and local programs with their opioid abatement programs. This is only the beginning for Purdue, as the plea deal does not resolve any debtors or other third parties' ability to recover for fraudulent transactions, nor does it resolve any claims that states may have against Purdue or the owners of the company, the Sackler family.

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OIG Issues Special Fraud Alert on Drug and Device Speaker Programs

The 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.

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STATE UPDATE

NJ Legislature Introduces Bill that Permits Corporate Reorganization of Horizon

This month S3218/A5119 was enacted by the New Jersey legislature, and signed by Governor Phil Murphy on December 23. The bill, if passed into law, would provide for the reorganization of a health service corporation into a not-for-profit mutual holding company. The bill 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 will be required to file with the New Jersey Department of Banking and Insurance information related to its operations. The bill allows for the reorganization of Horizon Blue Cross Blue Shield, which is currently a health service corporation, and will enable Horizon to invest in emerging technologies.

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New Jersey Legislative Update

Health Care Transparency Act Becomes Law – On December 14, 2020, Governor Phil Murphy signed into law the New Jersey Health Care Transparency Act. "Healthcare professionals" (HCPs) under the new law include, but are not limited to, individuals regulated by the following New Jersey professional licensing boards and advisory councils or committees: Medicine and Surgery, Nursing, Dentistry, Optometrists, Pharmacy, Chiropractic, Acupuncture, Physical Therapy, Orthotics and Prosthetics, Psychology, Ophthalmic Dispensers and Technicians, Audiology and Speech-Language Pathology, Occupational Therapy, and Psychoanalysts. The following are not "healthcare professionals" under the law: (i) individuals licensed in veterinary medicine, or (ii) healthcare professionals working in non-patient care settings and who do not have any direct patient care interactions.

The law requires, among other things:

- Advertisements for healthcare services must exclude deceptive or misleading information relating to the HCP, including, any affirmative communication or representation that misstates, falsely describes, holds out, or falsely details the professional's skills, training, expertise, education, public or private board certification, or licensure;
- Advertisements for healthcare services that include the name of a HCP must identify the type of professional license and professional degree issued to the healthcare professional;
- HCPs must communicate, when providing in-person care, the professional license and professional degree the HCP holds. This information may be communicated through a name tag or embroidered identification. The name tag or embroidery must include, at a minimum, the full name of the HCP and the professional degree and professional license of the HCP. If the HCP is providing direct patient care at a hospital, the HCP must wear a recent photograph, unless otherwise directed by hospital administrators;
- A poster or other signage, in sufficiently sized font, which identifies the professional license and professional degree held by the HCP, must be placed at the office or offices where the HCP provides healthcare services to scheduled patients in an ambulatory setting;
- A medical doctor or doctor of osteopathic medicine who supervises or participates in collaborative practice agreements with non-physician HCPs at the same practice location must post clearly and conspicuously in each office when the medical doctor or doctor of osteopathic medicine is present; and
- Medical doctors and doctors of osteopathic medicine are prohibited from advertising or holding themselves out to the public as being board certified unless the board is a member of the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA) or is a non-ABMS or non-AOA board that requires following certain prerequisites for issuing certification.

Bill Requiring Electronic Transmission of Prescriptions Moving Forward in New Jersey Legislature – A bill that, if passed into law, would require the electronic transmission of prescriptions, originally introduced in the New Jersey Senate on January 14, 2020, is gaining support and was recently introduced in the New Jersey Assembly. The bill (S390) would require that every prescription for a controlled dangerous substance, prescription legend drug, or other prescription item be transmitted electronically using an electronic health records system. The electronic prescription requirement would not apply to: a practitioner administering a prescription drug or item directly to a patient; a practitioner prescribing a drug or item to be dispensed by an institutional pharmacy or to a patient in hospice care; a situation in which the electronic prescribing system is not operational or is temporarily inaccessible; a situation in which the patient requests the prescription be transmitted to a pharmacy that is unable to receive and process electronic prescriptions; or a practitioner who has been granted a waiver due to technological limitations or other exceptional circumstances.

New Law Revises Requirements for Healthcare Service Firms to Report Financial Information to DCA – On December 14, 2020, Governor Phil Murphy signed into law revised requirements for healthcare service firms (HCSFs) to report financial information to the New Jersey Division of Consumer Affairs (DCA). Under the new law, all HCSFs will be required to submit annual financial statements prepared by the firm to the DCA, and these statements are to be consistent with the firm's tax filings with the state. Additionally, any HCSF that receives more than $250,000 for the provision of New Jersey Medicaid Personal Care Assistance (PCA) services must submit to the DCA an audit the third calendar year after the date of registration or on December 30, 2022, whichever date is later, and every third year thereafter. Additionally, HCSFs that generate $10 million or more in gross revenue in a year will be required to submit an audit for that year. For a HCSF with gross revenue for the year that is between $1 million and $10 million, and which receives less than $250,000 for the provision of PCA services, the HCSF will, in lieu of an audit, be required to submit a report for that year that is prepared by an independent third-party practitioner based on a review of the HCSF's financial statements and records, general management, and internal controls.

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Brach Eichler In The News

Litigation Chair and Healthcare Law Member **Keith J. Roberts** was quoted in *ROI-NJ* December 17 about recent litigation allowing Horizon Blue Cross and Blue Shield to change its corporate form, thereby permitting the company to invest in emerging technologies.

On December 4, Managing Member and Health Law Chair **John D. Fanburg** commented in *Modern Healthcare* about the Federal Trade Commission's opposition to the Hackensack Meridian Health/Englewood Health merger.

John D. Fanburg also moderated a session, "Board and Governance Considerations for Healthcare," at this year's Withum Healthcare Symposium, held virtually on December 2 for members of New Jersey's healthcare community.

In a November 17 article in *Medscape*, **John D. Fanburg** was quoted extensively about the sale of medical practices.

Healthcare Law Member **Lani M. Dornfeld** commented in *Modern Healthcare* about HIPAA, patient data, and marketing on November 14.

HIPAA CORNER

OCR "Right of Access Initiative" Settlements Now Up to Unlucky 13 – As reported in our previous *Healthcare Law Updates*, the U.S. Department of Health & Human Services (DHHS), Office for Civil Rights (OCR) has placed a heavy focus this year 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 22nd, the OCR's 13th, resulted in similar penalties to the prior 12 settlements: monetary fine, a corrective action plan, and ongoing monitoring. The settlement is yet another reminder 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 (OCR) 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:

- Adding definitions for the terms electronic health record (EHR) and personal health application;
- Modifying provisions on the individuals' right of access (to view and obtain copies) to PHI, including by:
  - 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);

  - Requiring covered entities to inform individuals that they retain their right to obtain or direct copies of PHI to a third party when a summary of PHI is offered in lieu of a copy;
  - Specifying when electronic PHI (ePHI) must be provided to the individual at no charge;
  - Amending the permissible fee structure for responding to requests to direct records to a third party; and
  - Requiring covered entities to post estimated fee schedules on their websites for access and for disclosures with an individual's valid authorization and, upon request, provide individualized estimates of fees for an individual's request for copies of PHI, and itemized bills for completed requests.
- Clarifying the scope of covered entities' abilities to disclose PHI to social services agencies, community-based organizations, home and community-based service (HCBS) providers, and other similar third parties that provide health-related services, to facilitate coordination of care and case management for individuals;
- 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);
- Modifying the content requirements of the NPP to clarify for individuals their rights with respect to their PHI and how to exercise those rights;
- Expressly permitting disclosures to Telecommunications Relay Services (TRS) communications assistants for persons who are deaf, hard of hearing, or deafblind, or who have a speech disability, and modifying the definition of business associate to exclude TRS providers; and
- Expanding the Armed Forces permission to use or disclose PHI to all uniformed services, which then would include the U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps.

Comments to the NPRM will be due 60 days after publication in the Federal Register.

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

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