BRACH | EICHLER LLC

Healthcare Law UPDATE

October 2019

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FEDERAL UPDATE

CMS and OIG Issue Proposed Amendments to Regulations under Federal Stark Law and Federal Anti-Kickback Statute

The federal Department of Health & Human Services, Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG) issued proposed rules to amend the current regulations under the federal Stark Law and the federal Anti-Kickback Statute. In summary, the former law prohibits certain physician referrals of "designated health services" to an entity in which the physician (or immediate family member) has a financial interest, and billing federal programs for such services. Generally, the latter law makes it a crime to solicit or receive referrals of, or arrange for, items and services paid for by governmental healthcare programs, in exchange for any type of remuneration. The proposed amendments would attempt to modernize these laws and add more flexibility for coordinated and improved "value-based" patient care.

See Brach Eichler's Health Law Alert discussing the proposed amendments.

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CMS Issues New Rule to Increase Scrutiny of Affiliates of Known Bad Actors

On September 5, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a final rule with comment period to expand its ability to terminate or deny provider enrollment to providers and suppliers based on affiliation with known "bad actors" (as defined below). The new rule takes effect on November 4, 2019.

Under the new rule, Medicare, Medicaid, and Children's Health Insurance Program (CHIP) providers must disclose any current or prior direct or indirect affiliation with a provider or supplier that (i) has uncollected debt; (ii) has been or is subject to a payment suspension under a federal healthcare program; (iii) has been or is excluded by the Office of Inspector General (OIG) of the Department of Health & Human Services (HHS) from Medicare, Medicaid, or CHIP; or (iv) has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked (a "bad actor"). The rule will permit the Secretary of HHS to deny enrollment based on such an affiliation if the Secretary determines that the affiliation poses an undue risk of fraud, waste, or abuse. CMS declared that the new rule will help put an end to the "pay and chase" scenarios by "stopping fraudsters before they get paid." The final rule also revises various provider enrollment provisions of 42 CFR Part 424 and 42 CFR Parts 405, 455, and 457.

CMS reports that the rule will improve its fraud-fighting ability through increased authorities, including:

- CMS may revoke or deny Medicare enrollment if a provider or supplier:
  - Circumvents program rules by coming back into the program, or attempting to come back in, under a different name (e.g., the provider attempts to "reinvent" itself)
  - Bills for services/items from non-compliant locations
  - Exhibits a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, services, or drugs
  - Has an outstanding debt to CMS from an overpayment that was referred to the Treasury Department
- CMS may prevent applicants from enrolling in Medicare for up to three years if a provider or supplier is found to have submitted false or misleading information in its initial enrollment application
- CMS may block providers and suppliers who are revoked from re-entering the Medicare program for up to ten years (up from the previous three-year block)
- If a provider or supplier is revoked from Medicare for a second time, CMS may block that provider or supplier from re-entering the program for up to 20 years.

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OIG Advisory Opinion: Provider Purchase of Real Estate from Excluded Individual Permitted

The Department of Health & Human Services, Office of Inspector General (OIG) recently issued an Advisory Opinion (AO 19-05) regarding a federally funded community health center's proposed real estate purchase from a limited liability company owned and managed, in part, by an individual excluded from Medicare, Medicaid, and other federal healthcare programs. The community health center sought the advisory opinion to determine if the transaction would be subject to a civil monetary penalty under Section 1128A(a)(6) of the Social Security Act. The law prohibits arrangements or contracts with an individual or entity that is excluded from participation in a federal healthcare program "for the provision of items or services for which payment may be made under such a program." (42 U.S.C. 1320a–7a(a)(6).)

While the real estate site, which includes a medical clinic, could be an "item" under the law if the community health center were to submit a claim to or request payment from any federal healthcare program for the purchase of the property, OIG determined that the proposed real estate

transaction would not violate the law because the purchaser certified that no such claim or request for payment would be made, and other safeguards against abuse would be instituted.

In addition, because the community health center receives grant funding from a federal healthcare program and would be enrolled in Medicare as a Federally Qualified Health Center, the purchaser further certified that (i) it would not use any federal grant funds to purchase the property; (ii) it would not receive any financing from the selling company or the excluded individual for the purchase; and (iii) neither the selling company nor the excluded individual would have any ongoing financial, ownership, control, management, or other relationship with the community health center following the purchase, and therefore would not be providing any items or services to the health center that may be paid for by any federal healthcare program. As a further protection, the community health center stated it would obtain an independent appraisal of the site and use the appraised value as the purchase price for the site.

Although OIG advisory opinions are limited to the specific requestor and facts set forth in the opinion, the advisory opinion nonetheless may be instructive for parties to other similar transactions.

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OIG Advisory Opinion: Healthcare Technology Marketplace Proposal Approved

As technology companies become a larger participant in the healthcare marketplace, the providers of such technology need to be cognizant of federal and state laws and regulations in order to avoid possible sanctions. Technology companies are providing services to patients and healthcare providers alike which, without proper guidance, could trigger sanctions under various laws and regulations including the federal Anti-Kickback Statute and the civil monetary provisions of the Social Security Act. The Department of Health & Human Services, Office of Inspector General (OIG), recently issued an Advisory Opinion (AO-19-04) regarding a technology company's proposal to provide to users, regardless of their insurance status, access to view the company's website and mobile application marketplace. The virtual marketplace would allow users to view and search the company's online healthcare directory, where users could schedule medical appointments and where healthcare providers would post sponsored ads. The company sought the OIG's opinion as to whether the services provided, and the fees requested, could cause imposition of sanctions under federal law.

The company certified that it would not charge patients any fees to use the marketplace. Healthcare providers would be charged either a monthly subscription fee, per-booking fee, or per-click fee, depending on the state where the services are being offered. The eventual plan would be to eliminate the monthly subscription fee and charge all healthcare providers either per-booking or per-click fees depending on the state in which the healthcare provider is operating. Healthcare providers also have the ability to purchase banner advertisements to be displayed near the patients' search results in the marketplace. Currently, the banner advertisements are only displayed for patients who are not beneficiaries of federal healthcare programs. The company wants to have these banner advertisements displayed to all users of the marketplace. In addition to payment for the banner advertisements, the company also charges healthcare providers a per-impression fee for banner advertisements. A per-impression fee is generated when the advertisement is viewed by a user.

The OIG analyzed the proposed marketplace functionality and arrangement and determined that the arrangement did not implicate Section 1128A(a)(5) of the Social Security Act (monetary penalty provision prohibiting inducements to beneficiaries) and, therefore, no civil monetary penalties would be imposed. Further, the OIG opined that, although the proposed arrangement might implicate the federal Anti-Kickback Statute by potentially generating prohibited remuneration under the law, the OIG would not impose sanctions since the arrangement contained sufficient safeguards against abuse.

The OIG reasoned that the marketplace provided the same user experience to all users, regardless if one is a federal healthcare program beneficiary, and the structure of the marketplace would not influence a patient to select a particular healthcare provider. The OIG stated there are "many factors [that] influence someone's decision to seek items and services from a health care professional," and access to the marketplace alone would not likely influence a federal healthcare beneficiary's decision to receive items or services from a particular healthcare provider. Further safeguards would include, in summary:

- Although the fee per new-patient appointment booking would vary, and the fee per click would vary, by medical specialty, geographic location, and in certain circumstances other relevant factors affecting fair market value, such fees would be set in advance, would not exceed fair market value, nor take into account the value or volume of any healthcare business that would be generated
- The company is not a provider or supplier, so its relationship to the target population under the arrangement is distinguishable from potentially problematic arrangements involving marketing by healthcare providers and suppliers
- The company's advertising activities would not specifically target federal healthcare program beneficiaries
- The marketing activities would not relate to any specific item or service users may obtain from healthcare providers as a result of appointments booked through the marketplace
- The potential marketplace user base is the general public, not specifically targeted to federal healthcare program beneficiaries
- The company would not provide anything of value to federal healthcare program beneficiaries, other than the inherent functionality and convenience of using the marketplace

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CMS Issues New Rules for Discharge Planning and Burden Reduction

On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published two new rules, both effective on November 29, 2019. The first rule (Discharge Planning Rule) revises requirements for discharge planning for hospitals, critical access hospitals (CAHs) and home health agencies (HHAs), and includes other changes to promote innovation, flexibility, and improvement in patient care. The second rule (Burden Reduction Rule) reforms Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on healthcare providers and suppliers; updates certain fire safety standards for Medicare- and Medicaid-participating end-stage renal disease (ESRD) facilities; and updates Medicare and Medicaid participation requirements for hospitals and CAHs.

According to CMS, the Discharge Planning Rule "empowers patients to be active participants in the discharge planning process and complements efforts around interoperability that focus on the seamless exchange of patient information between healthcare settings." The rule applies to hospitals (short-term acute, long-term acute, rehabilitation, psychiatric, children's, and cancer), critical access hospitals, and home health agencies.

In summary, the Discharge Planning Rule requires affected providers to have in place an effective discharge planning process. For hospitals, this includes, among other requirements, identifying, "at an early stage in hospitalization, those patients who are likely to suffer adverse consequences upon discharge in the absence of adequate discharge planning," and the provision of "a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician." Evaluations must be made on a timely basis and must include an evaluation of a patient's likely need for post-hospital services. The discharge planning process for CAHs must include a focus on the patient's goals and include the patient and his or her caregiver in the process. For HHAs with patients who are transferred to another HHA or who are discharged to a skilled nursing facility, rehabilitation facility, or long-term acute care hospital, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing certain data on quality measures and resource use. The rule requires all affected providers to provide appropriate access to medical records to assist in the transaction between healthcare settings and providers.

The goal of the Burden Reduction Rule is to identify unnecessary, obsolete, or excessively burdensome regulations on healthcare providers, suppliers, and beneficiaries in order to increase the ability of healthcare professionals to devote resources to improving healthcare. This includes, for example: (i) replacing the requirement that ambulatory surgery centers (ASCs) have written transfer agreements or privileges with the local hospital with a requirement that each ASC must periodically provide the local hospital with written notice of its operation and patient population served; (ii) removing the current Medicare requirement on ASCs for a history and physical within 30 days of a procedure, and replacing the requirement with requirements that defer to clinical judgment and ASC policy; (iii) amending certain hospice medication management rules and rules concerning hospice orientation at other facilities; (iv) removing the requirements with respect to the re-approval process for transplant centers; and (v) allowing hospitals the flexibility to establish a medical staff policy describing the circumstances under which such hospitals can utilize a pre-surgery/pre-procedure assessment for an outpatient, instead of a comprehensive medical history and physical examination. According to CMS, the new rule changes balance patient safety and quality, while also providing broad regulatory relief for providers and suppliers, and reducing the associated burden on patients.

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STATE UPDATE

New Jersey Legislative Update

Proposed Bill to Extend Length of Medicaid Postpartum Coverage – On September 12, 2019, Bill S4111/A5782 was introduced in the New Jersey legislature to extend the length of time of postpartum comprehensive Medicaid coverage for eligible pregnant women to a 180-day period beginning on the last day of pregnancy. Under current New Jersey law, comprehensive Medicaid coverage for eligible pregnant women is provided for a 60-day period beginning on the last day of the pregnancy, which complies with federal regulations regarding the minimum time length for postpartum Medicaid coverage. The bill also codifies that the income threshold for eligibility must not exceed the highest income eligibility level established for pregnant women under the state Medicaid plan - currently 194 percent of the federal poverty level.

Ambulatory Care Facility Online Payments Now Available – On September 30, 2019, the New Jersey Department of Health (DOH) announced that ambulatory care facilities (ACFs) can now make their ACF assessment payments through the DOH's web-based portal. Payments can be made by credit card or by electronic check payment. In addition to making secure, online payments, the portal allows authorized users a safe, convenient way to submit their HFEL-5 financial reports, view payment history, and check unpaid balances. For those ACFs that are not able to submit electronically, the DOH will continue to allow traditional mail submissions and payment by check or electronic payment. However, the DOH is encouraging all ACFs to sign up for the portal and submit the information electronically as soon as possible. ACFs can sign up to use the portal by following the instructions attached to this link.

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Brach Eichler In The News

Please join us for a live webinar, "Navigating the New PIP Regulations" on November 6 at 2:30 p.m. Hosted by **Keith J. Roberts** and **John D. Fanburg**, the session will cover the guidelines established by the new law, who it applies to and under what conditions, and how the law defines a "complete" medical bill. The webinar will also feature a discussion of the Haines case. To register, click here.

Congratulations to **John D. Fanburg** who was named a top Healthcare Influencer in New Jersey by *ROI-NJ* on October 7.

John D. Fanburg was featured in the *New Jersey Law Journal* on September 29 in an article highlighting Brach Eichler's impressive growth.

To view a full listing of recent news items and to read the articles mentioned above, please click here.

HIPAA CORNER

Medical Images and Data for Millions of Americans Exposed on the Internet

On September 17, 2019, ProPublica and Bayerischer Rundfunk co-reported the results of their investigative finding that "[m]edical images and health data belonging to millions of Americans, including X-rays, MRIs, and CT scans, are sitting unprotected on the internet and available to anyone with basic computer expertise," including more than five million patient records in the U.S. and "millions more around the world." ProPublica is a non-profit newsroom that investigates abuses of power, and Bayerischer Rundfunk is a German public broadcaster.

In the investigation, the companies identified 187 servers in the United States containing medical records (including X-rays, MRIs, and CT scans) that are sitting on the internet unprotected by passwords or other basic security measures. The identified medical records did not require any

hacking to obtain access — they were stored on servers that lacked even the most basic security precautions, making the images and private data accessible for viewing with the use of free software or a basic web browser.

Most of the unprotected data found were maintained by independent radiologists, medical imaging centers, or archiving services. Per ProPublica: "Experts say it's hard to pinpoint who's to blame for the failure to protect the privacy of medical images. Under U.S. law, healthcare providers and their business associates are legally accountable for securing the privacy of patient data. Several experts said such exposure of patient data could violate the Health Insurance Portability and Accountability Act, or HIPAA, the 1996 law that requires healthcare providers to keep Americans' health data confidential and secure." Some medical providers started tightening their security after being alerted by ProPublica of the investigative findings.

ProPublica further reported that researchers have found that picture archiving and communication systems (PACS) servers implementing the Digital Imaging and Communication in Medicine (DICOM) standard may be at risk. DICOM is the international standard for handling, storing, and transmitting medical imaging data. Such systems should be protected through a VPN connection and password requirement.

The findings of this investigation highlight the importance — now more than ever due to the increasing number of security breaches and cyber criminal activity — of every healthcare provider and organization ensuring that it has in place an effective, meaningful, and compliant data privacy and security program. This includes periodic risk and gap assessments to identify electronic weaknesses and vulnerabilities, and a security management program to address them.

If you need assistance in developing or updating your HIPAA compliance program, in providing staff training, in managing a breach incident, or in fulfilling any required reporting, please contact:

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HEALTH LAW ALERT OCTOBER 2019

CMS AND OIG ISSUE PROPOSED AMENDMENTS TO STARK AND ANTI-KICKBACK REGULATIONS

The Focus is on Value-Based and Coordinated Care

On October 17, 2019, the U.S. Department of Health & Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) issued its highly anticipated proposed rule updating regulations under the federal self-referral law known as the Stark Law, titled "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" (referred to in this alert as the "Stark Rule Proposal"). On the same date, the HHS, Office of Inspector General (OIG), in conjunction with the HHS's Regulatory Sprint to Coordinated Care, issued a second proposed rule to amend the safe harbors under the federal Anti-Kickback Statute, titled "Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (referred to in this alert as the "AKS Rule Proposal").

Modernizing the Stark Law for Value-Based Care

According to CMS, the Stark Rule Proposal "supports the CMS 'Patients over Paperwork' initiative by reducing unnecessary regulatory burden on physicians and other healthcare providers while reinforcing the Stark Law's goal of protecting patients from unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician's financial self-interest." The Stark Rule Proposal adds three new statutory exceptions for value-based care compensation arrangements which would permit "physicians and other healthcare providers to design and enter into these arrangements without the fear that legitimate activities to coordinate and improve quality of care and lower costs would violate the Stark Law."

Full Financial Risk Exception

The "full financial risk" exception would apply to value-based arrangements between participants that have assumed ''full financial risk'' for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population of the arrangement. To meet this exception, the participants must be financially responsible for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Such an arrangement may take the form of capitation payments or global budget payment from a payor that covers a predetermined period of time.

Meaningful Downside Financial Risk Exception

The "meaningful downside financial risk" exception would protect remuneration paid under a value-based arrangement between an entity furnishing designated health services and a physician where the physician is at meaningful downside financial risk for failure to achieve the value based purposes of the arrangement, such as coordinating and managing the care of a target patient population, improving the quality of care for a target patient population, or appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population. CMS proposes to define "meaningful downside risk" to mean that the physician is responsible for paying the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement.

Value-Based Arrangements Exception

The "value-based arrangements" exception would permit any value-based arrangement, regardless of risk level, so long as the requirements of the exception are satisfied.

Other Provisions of Proposed Rule

The Stark Rule Proposal contains additional provisions addressing indirect compensation arrangements to which the proposed new exceptions are applicable and price transparency in the context of the Stark Law. In addition, the proposal addresses "fundamental terminology and requirements," including a definition of "commercially reasonable," bright-line rules for the "volume and value" and "other business generated" standards, revised definitions of "fair market value" and "general market value," and revisions to group practice rules. Finally, the proposal includes an exception for limited remuneration to a physician (less than $3,500/year), and would eliminate the sunset provision of the EHR exceptions.

Federal Anti-Kickback Statute: Focus on Value-Based and Coordinated Care

Under the AKS Rule Proposal, HHS would create three new safe harbors for certain remuneration exchanged between or among eligible participants in a value-based arrangement that fosters better care coordination and managed patient care: (i) care coordination arrangements aimed at improving quality and outcomes; (ii) value-based arrangements with substantial downside financial risk; and (iii) value-based arrangements with full financial risk. The safe harbors vary by the types of remuneration protected, level of financial risk undertaken by the parties, and types of safeguards implemented.

Similar to the Stark Rule Proposal, the AKS Rule Proposal contains new "value-based" terminology for key terms to be used in the rules, and contains specific elements that must be satisfied in order to fit within each new safe harbor.

In addition, the AKS Rule Proposal includes:

- A proposed new safe harbor for certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency
- A proposed new safe harbor for certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS-sponsored models
- A proposed new safe harbor for donations of cybersecurity technology and services
- Proposed modifications to the existing safe harbor for electronic health records items and services to add protections for certain cybersecurity technology included as part of an electronic health records arrangement, to update provisions regarding interoperability, and to remove the sunset date
- Proposed modifications to the existing safe harbor for personal services and management contracts to add flexibility with respect to outcomes-based payments and part-time arrangements
- Proposed modifications to the existing safe harbor for warranties to revise the definition of "warranty" and provide protection for warranties for one or more items and related services
- Proposed modifications to the existing safe harbor for local transportation to expand and modify mileage limits for rural areas and for transportation for discharged patients
- Codification of the statutory exception to the definition of "remuneration" related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program

What's Next?

Comments to each of the rule proposals are due by December 31, 2019. Once the rules are finalized, it is anticipated that providers will have significant opportunities to put together new arrangements focused on value-based and coordinated care. At the same time, however, providers will need to review existing arrangements for compliance with new definitions and revisions to existing rules.

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