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Don't Overlook Prescription Drug Reporting to CMS

Each year, a bright light is cast on providing individuals with annual Medicare Part D notices detailing the creditable status of their employer-provided prescription drug coverage. Lurking in the shadows is another annual requirement: reporting to the Centers for Medicare & Medicaid Services (CMS) whether the prescription drug coverage is creditable or not. These tips will help employers better understand this lesser-known Medicare Part D compliance obligation.

When

Plan sponsors must input their disclosures to CMS every year, no later than 60 days following the start of a new plan year. Thus, calendar year plan sponsors must report their plans' creditable status by March 1. Plan sponsors also must alert CMS within 30 days after terminating the prescription drug plan or coverage, or if the creditable status changes.

Plan sponsors must use CMS's creditable coverage portal to complete and file the necessary creditable coverage disclosure form. CMS offers no paper alternative to satisfy this disclosure requirement absent one of a few rare and limited exceptions. The good news is that the CMS portal includes helpful hyperlinks to agency guidance and simple step-by-step instructions.

Conclusion

It is easy to forget creditable coverage reporting during the hectic ACA and W-2 reporting season. Also, HR professionals tend to be swamped with participant inquiries at the outset of a new plan year, so it can be easy to miss a basic compliance obligation like creditable coverage reporting. Plan sponsors with calendar year plans should set a reminder each year to ensure they complete this task by March 1.

Departments Propose Rule to Expand ACA Preventive Services

The U.S. Department of Health & Human Services (HHS) and the Departments of Labor and the Treasury (Departments) have proposed a rule that aims to expand access to birth control coverage under the Affordable Care Act (ACA), which requires most group health plans to cover such services with no out-of-pocket cost. According to a press release from the Centers for Medicare & Medicaid Services, the proposed rule stems from efforts by the Biden-Harris Administration to expand access to no-cost birth control.

The ACA has long required non-grandfathered health plans to include women's preventive services, including birth control and contraceptive counseling, at no cost. But in 2018, final regulations expanded exceptions to this coverage based on religious beliefs and moral convictions. This expansion allowed a number of private health plans and insurers to exclude contraceptive services altogether. The 2018 regulations did provide for an optional accommodation whereby an objecting employer could opt out of providing these services but still ensure those enrolled in their plans could access such services at no charge.

Under the proposed rule, individuals who desire contraceptive services but are enrolled in plans offered by rejecting entities will be able to seek care from any willing provider or facility at no cost. The Departments state that this new pathway – referred to as an individual contraceptive arrangement – will permit women and covered dependents to get birth control services free of charge even where their insurer or plan has a religious objection and has not elected an optional accommodation under prior final regulations.

The new rule will eliminate the moral exemption rule and will allow a provider or facility that provides contraceptive coverage in accordance with the individual contraceptive arrangement to be reimbursed through an arrangement with an issuer on a federally facilitated exchange or state-based exchange.

The proposed rule is in keeping with the Biden-Harris Administration's stated commitment to ensuring ongoing access to reproductive health services. This is one of the efforts to protect reproductive rights in the wake of last year's Supreme Court ruling in *Dobbs v. Jackson Women's Health Organization*.

The proposed rule is subject to a 60-day public comment period, which is sure to generate numerous comments. The Departments will generate a final rule that would likely not be effective until plan years starting on or after January 1, 2024, at the earliest.

2023 Federal Poverty Level Released, Impacts ACA Affordability Safe Harbor

The U.S. Department of Health & Human Services (HHS) has released its updated federal poverty level (FPL) guidance for 2023. The mainland FPL increases in 2023 to $14,580 (the FPL for Alaska will be $18,210, and for Hawaii will be $16,770). Applicable large employers (ALEs) should take note of the new mainland FPL as it could impact future affordability calculations under the Affordable Care Act (ACA).

The ACA requires ALEs to offer group health coverage to full-time employees that is affordable and meets minimum value. ALEs who offer coverage that is deemed unaffordable must pay an employer shared responsibility penalty (ESRP) for any affected individual who elects Marketplace coverage and receives a corresponding premium tax credit.

ACA affordability requires the lowest-tier single-only coverage option to cost no more than a stated percentage (9.12% for 2023) of an employee's household income. Because an employer typically does not know an employee's actual household income, ACA rules created three affordability safe harbors an ALE can use to determine affordability.

One of the affordability safe harbors is the FPL safe harbor, which states that coverage is affordable if an individual does not have to pay more than a stated percentage (9.12% for 2023) of the mainland federal poverty level published within six months of the start of the applicable plan year. Non-calendar year plans starting during 2023 can use the newly announced FPL to determine affordability. So, coverage will be deemed affordable if it costs no more than $110.81 monthly. Calendar year plans will not be able to use the new FPL amount, so coverage is affordable in 2023 if it costs no more than $103.28 per month. Non-calendar year plans starting in 2022 will rely on older FPL figures and will be affordable for the remainder of the current plan year if they charge no more than $108.83 per month.

ALEs are not required to use the FPL safe harbor, and many choose not to since it typically yields a higher employer contribution for coverage. However, any employers who do use the FPL safe harbor should be aware of how the newly announced amounts will impact their plans and planning for the upcoming plan year.

EBSA Announces Priorities for 2023

The Office of Management and Budget (OMB) recently released its 2022 Unified Regulatory Agenda and Regulatory Plan (Agenda), which outlines regulatory actions federal agencies are considering in the coming year. The Agenda provides insight into rulemaking priorities at the Employee Benefit Security Administration (EBSA) that employers will need to be prepared to address as EBSA proposes and finalizes rules that will impact employee benefit plans.

Retirement Plan Disclosures. EBSA plans to explore ways to improve the effectiveness of retirement plan disclosures required under Title I of the Employee Retirement Income Security Act (ERISA), balanced with the cost to plans and plan participants and beneficiaries of providing such disclosures. EBSA intends to canvass participant representatives, employer plan sponsors, and retirement plan service and investment providers to explore alternatives for improving the understandability and effectiveness of these disclosures. More specifically, the review will explore whether, and how, the content, design, and delivery of such disclosures may be reimagined, improved, consolidated, standardized, and simplified to enhance participants' disclosure experiences, promote greater participant engagement, and improve outcomes.

Advance Explanation of Benefits (AEOB). This proposed rule would implement the provisions under the Consolidated Appropriations Act, 2021 (CAA, 21) that require plans and providers to issue an explanation of benefits prior to receiving medical treatment or services. The departments sought public comment last fall, and they continue to wade through comments received from interested parties. We anticipate that they will issue final rules this year to help plans and carriers understand the parameters surrounding AEOB, including content, timing, and how plans might be able to rely on carriers to meet their AEOB obligations.

Mental Health Parity. There have been a number of legislative enactments related to the Mental Health Parity and Addiction Equity Act (MHPAEA) since issuance of the 2014 final rules, including the 21st Century Cures Act, the Support Act, and the CAA, 21. EBSA plans to propose amendments to the final rules implementing MHPAEA to clarify plans' and issuers' obligations under the law, promote compliance with MHPAEA, and update requirements to consider experience with MHPAEA in the years since the rules were finalized as well as amendments to the law recently enacted as part of the CAA, 21.

Employer Association Health Plans. EBSA plans to consider withdrawing, or withdrawing and replacing, its final rule regarding the criteria for determining when an employer association may act indirectly in the interest of an employer to establish a multiple employer group health plan. The United States District Court for the District of Columbia vacated portions of the final rule in a 2019 decision, and EBSA therefore plans to reevaluate the criteria for a group or association of employers to be able to sponsor a multiple employer group health plan.

Air Ambulance Services. This rule would provide the form and manner in which group health plans, health insurance issuers offering group or individual health insurance coverage, and providers of air ambulance services would report information regarding air ambulance services.

OCR Warns of HIPAA Pitfalls in Using Online Tracking Technologies

The Office for Civil Rights (OCR) at the U.S. Department of Health & Human Services (HHS) has released a bulletin emphasizing the duties covered entities and business associates must meet when using online tracking technologies to collect and analyze information about how users interact with regulated entities' websites or mobile apps. Such use often will contain protected health information (PHI) and present unique HIPAA compliance challenges.

OCR cautions that some regulated entities may be sharing sensitive information with online tracking technology vendors in ways that lead to unauthorized disclosures of PHI. For example, disclosures of PHI to tracking technology vendors for marketing purposes, without individuals' HIPAA-compliant authorizations, would constitute impermissible disclosures that also may create wide-ranging additional harms to the individual. An impermissible disclosure of PHI may result in identity theft, financial loss, discrimination, stigma, mental anguish, or other serious negative consequences to the reputation, health, or physical safety of the individual or to others identified in the individual's PHI.

It has always been true that regulated entities may not impermissibly disclose PHI to tracking technology vendors. However, because of the rapid expansion and increased use of tracking technologies it is becoming increasingly important for regulated entities to be sure to disclose PHI only as expressly permitted or required by the HIPAA Privacy Rule.

What is a tracking technology?

Generally, a tracking technology is a script or code on a website or mobile app used to gather information about users. After collecting information through a tracking technologies website or mobile app, owners, or even third parties, analyze the information to create insights about users' online activities. Such insights could be used in beneficial ways to help improve care or patient experiences, but could also be misused to promote misinformation, identity theft, stalking, and harassment.

Websites commonly use tracking technologies such as cookies, web beacons or tracking pixels, session replay scripts, and fingerprinting scripts to track and collect information from users. Mobile apps generally include or embed tracking code to enable the app to collect information directly provided by the user, and apps may also capture the user's mobile device-related information. Finally, tracking technologies developed by third party tracking technology vendors send information directly to the third parties who developed such technologies and may continue to track users and gather information about them even after they navigate away from the original website to other websites.

How do the HIPAA Rules apply to a health plan's use of tracking technologies?

A health plan can disclose a variety of information to tracking technology vendors through tracking technologies placed on its website, portal, or mobile app. This information might include an individual's medical record number, home or email address, or dates of appointments, as well as an individual's IP address or geographic location, medical device IDs, or any unique identifying code. This information generally is PHI, even if the individual does not have an existing relationship with the regulated entity and even if the information does not include specific treatment or billing information like dates and types of health care services. This is because the information connects the individual to the plan and thus relates to the individual's past, present, or future health or health care or payment for care.

Tracking on user-authenticated webpages

A group health plan might require a user to log in before they are able to access a patient or health plan beneficiary portal or a telehealth platform. Tracking technologies on a plan's portal will likely have PHI including an individual's IP address, medical record number, home or email addresses, dates of appointments,

or other identifying information that the individual may provide when interacting with the webpage. Tracking technologies within user-authenticated webpages may even have access to an individual's diagnosis and treatment information, prescription information, billing information, or other information within the portal. Therefore, the plan must configure any user-authenticated webpage to allow a tracking technology to only use and disclose PHI in compliance with the HIPAA Privacy Rule and must ensure that the electronic protected health information (ePHI) collected through its website is protected and secured in accordance with the HIPAA Security Rule.

OCR also reminds health plans that tracking technology vendors are business associates if they create, receive, maintain, or transmit PHI on behalf of a plan for a covered function (e.g., health care operations) or provide certain services to or for a covered entity (or another business associate) that involve the disclosure of PHI. In these circumstances, plans must ensure that disclosures made to such vendors are permitted by the Privacy Rule and enter into a business associate agreement (BAA) with these tracking technology vendors to ensure that PHI is protected in accordance with the HIPAA Rules.

Tracking within mobile apps

Mobile apps that regulated entities offer to individuals (e.g., to help manage their health information, pay bills) collect a variety of information provided by the app user, including information typed or uploaded into the app, as well as information provided by the app user's device, such as fingerprints, network location, geolocation, device ID, or advertising ID. Such information collected by a regulated entity's mobile app is PHI, and thus the regulated entity must comply with the HIPAA Rules for any PHI that the mobile app uses or discloses, including any subsequent disclosures to the mobile app vendor, tracking technology vendor, or any other third party who receives such information. For example, the HIPAA Rules apply to any PHI collected by a covered health clinic through the clinic's mobile app used by patients to track health-related variables associated with pregnancy (e.g., menstrual cycle, body temperature, contraceptive prescription information).

HIPAA compliance obligations for group health plans when using tracking technologies

Regulated entities are required to comply with the HIPAA Rules when using tracking technologies as follows:

- Ensure all disclosures of PHI to tracking technology vendors are specifically permitted by the Privacy Rule and that, unless an exception applies, only the minimum necessary PHI to achieve the intended purpose is disclosed.

  Regulated entities may identify the use of tracking technologies in their website or mobile app's privacy policy, notice, or terms and conditions of use. However, the Privacy Rule does not permit disclosures of PHI to a tracking technology vendor based solely on a regulated entity informing individuals in its privacy policy, notice, or terms and conditions of use that it plans to make such disclosures. Regulated entities must ensure that all tracking technology vendors have signed a BAA and that there is an applicable permission prior to a disclosure of PHI. Further, website banners that ask users to accept or reject a website's use of tracking technologies, such as cookies, do not constitute a valid HIPAA authorization.

Further, it is insufficient for a tracking technology vendor to agree to remove PHI from the information it receives or de-identify the PHI before the vendor saves the information. Any disclosure of PHI to the vendor without individuals' authorizations requires the vendor to have a signed BAA in place and requires that there is an applicable Privacy Rule permission for disclosure.

- Execute a BAA with any tracking technology vendor that is a Business Associate. A plan should evaluate its relationship with any tracking technology vendor to determine whether the vendor meets the definition of a business associate and ensure that the disclosures made to the vendor are permitted by the Privacy Rule. The BAA must specify the vendor's permitted and required uses and disclosures of PHI and provide that the vendor will safeguard the PHI and report any security incidents, including breaches of unsecured PHI, to the plan.

  If a plan does not want to create a business associate relationship with these vendors, or the chosen tracking technology vendor will not provide written satisfactory assurances in the form of a BAA that it will appropriately safeguard PHI, then the plan cannot disclose PHI to the vendors without individuals' authorizations.

- Address the use of tracking technologies in the regulated entity's Risk Analysis and Risk Management processes, as well as implement other administrative, physical, and technical safeguards in accordance with the Security Rule (e.g., encrypting ePHI that is transmitted to the tracking technology vendor; enabling and using appropriate authentication, access, encryption, and audit controls when accessing ePHI maintained in the tracking technology vendor's infrastructure) to protect the ePHI.

- Provide breach notification to affected individuals, the HHS Secretary, and the media (when applicable) of an impermissible disclosure of PHI to a tracking technology vendor that compromises the security or privacy of PHI when there is no Privacy Rule requirement or permission to disclose PHI and there is no BAA with the vendor. In such instances, there is a presumption that there has been a breach of unsecured PHI unless the regulated entity can demonstrate that there is a low probability that the PHI has been compromised.

IRS Updates Mileage Rates

IRS has issued Notice 2023-03 in which it provides the new adjusted amounts taxpayers may use in computing certain costs of operating an automobile for business, charitable, medical, or moving expense purposes. There is nothing groundbreaking in the announced rates, which include 65.5 cents per mile for all miles of business use. However, employers who have chosen to provide travel benefits for abortion and abortion-related services in the wake of last year's Supreme Court decision overturning *Roe v. Wade* should be aware that reimbursement for travel expenses related to receiving such care as covered under Code Section 213(d) cannot exceed certain IRS limits, including the newly announced limit on mileage reimbursement for medical travel. Thus, any medical travel reimbursement benefit that reimburses for mileage must cap that reimbursement at 22 cents per mile for expenses paid or incurred on or after January 1, 2023.

Illinois Law Would Require Most Employers to Provide Paid Leave for Any Reason

The Illinois Generally Assembly has passed a measure that, if the governor signs it into law as expected, will require most employers to begin providing up to 40 hours of paid leave starting January 1, 2024.

The Paid Leave for All Workers Act (Act) will allow employees to accrue one hour of paid leave for every 40 hours worked, up to a maximum accrual of 40 hours in a 12-month period. Employees may begin to use the paid leave after 90 calendar days of employment and do not have to provide their employers with any reason for needing the leave.

Employees must give employers at least seven days' advance notice for any foreseeable leave. The Act requires employees to notify their employers as soon as practicable if they need to take paid leave for some unforeseen reason, though employers can adopt a written policy that covers notice requirements for unforeseen leave.

The Act will permit employees to carry over up to 40 hours of accrued unused paid leave from one 12-month period to the next. However, employers who do not wish to track accruals may provide the 40 hours of paid leave up front. Employers choosing this method may also impose a rule requiring employees to use the leave during the applicable 12-month period or forfeit the leave. The Act does not require employers to pay out any accrued but unused leave when an employee terminates employment, but rehired employees must have paid leave accruals reinstated if rehired within 12 months.

Employers who already must comply with either the Chicago Minimum Wage and Paid Sick Leave Ordinance and the Cook County Earned Sick Leave Ordinance do not have to comply with the Act. Further, any future local ordinance governing paid leave must contain terms that are at least as favorable as those under the Act.

The Illinois Department of Labor will be providing a notice that employers must post in a conspicuous place and include in any written document that outlines the paid leave policy. Notices must be provided in a non-English language spoken by a significant portion of an employer's workforce.