21st Century Cures Act

On December 13, 2016, President Obama signed the 21st Century Cures Act into law. The Cures Act has numerous components, but employers should be aware of the impact the Act will have on the Mental Health Parity and Addiction Equity Act, as well as provisions that will impact how small employers can use health reimbursement arrangements (HRAs). There will also be new guidance for permitted uses and disclosures of protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA).

Title XVIII - Health Reimbursement Arrangements

The Cures Act provides a method for certain small employers to reimburse individual health coverage premiums up to a dollar limit through HRAs called "Qualified Small Employer Health Reimbursement Arrangements" (QSE HRA). This provision will go into effect on January 1, 2017.

Previously, the Internal Revenue Service (IRS) issued Notice 2015-17 addressing employer payment or reimbursement of individual premiums in light of the requirements of the Patient Protection and Affordable Care Act (ACA). For many years, employers had been permitted to reimburse premiums paid for individual coverage on a tax-favored basis, and many smaller employers adopted this type of an arrangement instead of sponsoring a group health plan. However, these "employer payment plans" are often unable to meet all of the ACA requirements that took effect in 2014, and in a series of Notices and frequently asked questions (FAQs) the IRS made it clear that an employer may not either directly pay premiums for individual policies or reimburse employees for individual premiums on either an after-tax or pre-tax basis. This was the case whether payment or reimbursement is done through an HRA, a Section 125 plan, a Section 105 plan, or another mechanism.

The Cures Act now allows employers with less than 50 full-time employees (under ACA counting methods) who do not offer group health plans to use QSE HRAs that are fully employer funded to reimburse employees for the purchase of individual health care, so long as the reimbursement does not exceed $4,950 annually for single coverage, and $10,000 annually for family coverage. The amount is prorated by month for individuals who are not covered by the arrangement for the entire year. Practically speaking, the monthly limit for single coverage reimbursement is $412, and the monthly limit for family coverage reimbursement is $833. The limits will be updated annually.

Impact on Subsidy Eligibility. For any month an individual is covered by a QSE HRA/individual policy arrangement, their subsidy eligibility would be reduced by the dollar amount provided for the month through the QSE HRA if the QSE HRA provides "unaffordable" coverage under ACA standards. If the QSE HRA provides affordable coverage, individuals would lose subsidy eligibility entirely. Caution should be taken to fully education employees on this impact.

COBRA and ERISA Implications. QSE HRAs are not subject to COBRA or ERISA.

Annual Notice Requirement. The new QSE HRA benefit has an annual notice requirement for employers who wish to implement it. Written notice must be provided to eligible employees no later than 90 days prior to the beginning of the benefit year that contains the following:

- The dollar figure the individual is eligible to receive through the QSE HRA
- A statement that the eligible employee should provide information about the QSE HRA to the Marketplace or Exchange if they have applied for an advance premium tax credit
- A statement that employees who are not covered by minimum essential coverage (MEC) for any month may be subject to penalty

Recordkeeping, IRS Reporting. Because QSE HRAs can only provide reimbursement for documented healthcare expense, employers with QSE HRAs should have a method in place to obtain and retain receipts or confirmation for the premiums that are paid with the account. Employers sponsoring QSE HRAs would be subject to ACA related reporting with Form 1095-B as the sponsor of MEC. Money provided through a QSE HRA must be reported on an employee's W-2 under the aggregate cost of employer-sponsored coverage. It is unclear if the existing safe harbor on reporting the aggregate cost of employer-sponsored coverage for employers with fewer than 250 W-2s would apply, as arguably many of the small employers eligible to offer QSE HRA's would have fewer than 250 W-2s.

Individual Premium Reimbursement, Generally. Outside of the exception for small employers using QSE HRAs for reimbursement of individual premiums, all of the prior prohibitions from IRS Notice 2015-17 remain. There is no method for an employer with 50 or more full time employees to reimburse individual premiums, or for small employers with a group health plan to reimburse individual premiums. There is no mechanism for employers of any size to allow employees to use pre-tax dollars to purchase individual premiums. Reimbursing individual premiums in a non-compliant manner will subject an employer to a penalty of $100 a day per individual they provide reimbursement to, with the potential for other penalties based on the mechanism of the non-compliant reimbursement.

Title XIII - Mental Health Parity

Overall, the Act does not provide any substantive guidance or changes to the mental health parity rules or mental health and substance use disorder coverage requirements (collectively, mental health parity rules).

The Act provides only one clarification to mental health parity rules: if a group health plan or a health insurance issuer provides coverage for eating disorder benefits, including residential treatment, the plan or issuer must provide the benefits consistent with the mental health parity rules.

The Act directs the Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury (collectively, the Agencies) to issue compliance program guidance, share findings with each other, and issue guidance to group health plans and health insurance issuers to help them comply with the mental health parity rules.

The compliance program guidance must illustrate de-identified examples of compliance and non-compliance based on the Agencies' investigations of violations. In each of the Agencies' examples of a finding of compliance or non-compliance with nonquantitative treatment limitations requirements, the Agencies must provide sufficient detail to explain the finding, including a full description of the criteria for approving medical and surgical benefits and the criteria for approving mental health and substance use disorder benefits.

The compliance program guidance must also include recommendations to advance compliance and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.

The internal controls description may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits which fail to comply with nonquantitative treatment limitations on medical and surgical benefits.

The Act requires the Agencies to share compliance findings with each other and to seek agreements with states to share similar compliance findings. Further, the Agencies must update their compliance program guidance biennially to include illustrative, de-identified examples of previous findings of compliance and noncompliance.

The Agencies must also issue guidance to group health plans and health insurance issuers; the guidance must provide information and methods that plans and issuers can use when they are required to disclose information to participants, beneficiaries, contracting providers, or authorized representatives to ensure the plans' and issuers' compliance with the mental health parity rules.

The guidance to plans and issuers must include:

- Information regarding nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits.
- The processes, strategies, evidentiary standards, and other factors used in applying nonquantitative limitations.
- Methods for determining appropriate types of nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations for
    - medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative,
    - limitations on prescription drug formulary design, and
    - use of fail-first or step therapy protocols.
- Methods for determining
    - network admission standards (such as credentialing), and
    - factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as they apply to network adequacy.
- Examples of evidentiary standards for making determinations regarding the development and application of nonquantitative treatment limitations.
- Examples of specific factors, and the evidentiary standards used to evaluate such factors, used by plans or issuers in performing a nonquantitative treatment limitation analysis.
- Examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative.
- Examples of how specific evidentiary standards may be applied to each service category or classification of benefits.
- Methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques.
- Methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment.

- Additional examples of methods, processes, strategies, evidentiary standards, and other factors that the Secretary determines is necessary to improve compliance.

The Act authorizes the Agencies to determine whether a group health plan or health insurance issuer has violated the mental health parity requirements under the Public Health Service Act, ERISA, or the Internal Revenue Code. If a plan or issuer is cited five violations, then the agency will audit plan documents for that health plan or issuer to improve compliance.

The Agencies must issue the compliance program guidance and guidance to group health plans and health plan issuers within 12 months after the date that the Helping Families in Mental Health Crisis Reform Act of 2016 was enacted, or by December 13, 2017.

Title XI - Compassionate Communication on HIPAA

The Cures Act does not provide any substantive guidance or changes to the confidentiality of alcohol and drug abuse patient records under federal regulations or protected health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

However, the Act directs the Secretary of Health and Human Services (the Secretary) to issue guidance relating to the confidentiality of alcohol and drug abuse patient records, issue guidance relating to the permitted use or disclosure of protected health information (PHI), and develop and disseminate model training programs and materials on its guidance.

The Act requires the Secretary to finalize regulations updating existing sections on the confidentiality of alcohol and drug abuse patient records.

Further, the Act requires the Secretary to issue guidance clarifying the circumstances under which a health care provider or covered entity may use or disclose PHI consistent with HIPAA. The Secretary's guidance must address circumstances that:

- Require the patient's consent;
- Require providing the patient with an opportunity to object;
- Are based on the exercise of professional judgment regarding whether the patient would object when the opportunity to object cannot practicably be provided because of the patient's incapacity or an emergency treatment circumstance; and
- Are determined, based on professional judgment, to be in the patient's best interest when the patient is not present or is incapacitated.

For the circumstances listed above, the Secretary's guidance must clarify permitted uses and disclosures of PHI for:

- Adult patients, communicating with a patient's family members, caregiver, or other individual involved in the patient's care.
- Minor patients, communicating with the patient's parent or caregiver.
- The patient's family members, caregivers, or others involved in the patient's care or care plan, including facilitating treatment and medication adherence.
- Listening to the patient or receiving information with respect to the patient from the patient's family or caregiver.
- Communicating with a patient's family members, caregivers, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others.
- Communicating to law enforcement and a patient's family members or caregivers about the patient's admission to receive care at, or the release of a patient from, a facility for an emergency psychiatric hold or involuntary treatment.

The Act also directs the Secretary to develop and disseminate model programs and materials to train health care providers on permitted uses and disclosures of PHI of patients seeking or undergoing mental health or substance use disorder treatment.

The Secretary must issue guidance and disseminate model programs and materials within one year after the date that the 21st Century Cures Act was enacted, or by December 13, 2017.

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