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#### **EMPLOYEE BENEFITS**

# No Surprises Act Prescription Drug Cost Reporting Includes Wellness Program Reporting Component

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The No Surprises Act (NSA), the portion of the 2021 Consolidated Appropriations Act aimed at increasing cost transparency within the health care industry, requires health plans and issuers to report certain detailed data regarding prescription drug pricing to the Federal government (the "Rx drug reporting requirement"). We have previously authored several articles on the NSA, including a detailed article on this <u>reporting requirement</u> that was published after the <u>Interim Final Rules</u> were issued in November 2021. This article provides more in-depth information on the regulations' requirement to report on wellness spending, as detailed in the <u>CMS' Prescription Drug Data Collection (RxDC) Reporting Instructions.</u>

## The Wellness Program Component of the Rx Drug Reporting Requirement

As we mentioned in our previous article, health plans must report much more than prescription drug pricing under the Rx drug reporting requirement. Specifically, the reporting must also include data related to the health plan's total annual spending on health care services. Spending on wellness programs is included as part of health care services. DOL Reg. §2590.725-4 provides as follows:

- (b) Information for each state and market segment. The report required under § 2590.725–2 must include the following information with respect to plans or coverage for each State and market segment for the reference year unless otherwise specified:
- . . .

- (4) Total annual spending on health care services by the plan or coverage and by participants and beneficiaries, as applicable, broken down by the type of costs, including—
- (i) Hospital costs;
- (ii) Health care provider and clinical service costs for primary care and specialty care separately;
- (iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and
- (iv) Other medical costs, including wellness services.

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Notably, the regulations do not define "wellness services," do not detail what costs must be reported as part of the "other medical costs" category and do not discuss the details of the requirement to report wellness-related expenses.

However, the requirement is described in further detail in CMS' Prescription Drug Data Collection ("RxDC")

Reporting Instructions. The RxDC Reporting instructions provide that necessary reporting for "wellness services" consists of "expenses for activities primarily designed to implement, promote, and increase health and wellness and not billed as a claim." While the definition is quite vague, presumably to capture the varied nature of employer wellness programs, the instructions list the following specific examples:

- Wellness assessments
- Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements
- Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition
- Public health education campaigns performed in conjunction with state or local health departments
- Actual rewards, incentives, bonuses or reductions in cost sharing that are not already reflected in premiums or claims (but not expenses to administer these programs) to the extent permitted by section 2705 of the Public Health Service Act<sup>1</sup>
- Coaching or education programs and health promotion activities designed to change member behavior (for example, smoking, obesity)

These examples encompass many of the most common types of wellness programs sponsored by employers.

The instructions further clarify that expenses related to certain wellness plans, namely services or activities that are not a "quality improvement expense," should not be included in the reporting. Specifically, the instructions state:

Do not include any service or activity that is not an allowable quality improvement expense for the purposes of calculating the numerator of the federal MLR.

The Medical Loss Ratio (MLR) regulations (HHS Reg. §158.150) contain guidelines for determining whether an activity qualifies as a quality improvement activity for MLR calculation purposes. Based on those regulations, employersponsored wellness program expenses generally should not be included in the Rx drug reporting unless the wellness activity is "designed to (i) improve health quality; (ii) increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements; (iii) be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees; and (iv) be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations."

#### **Reporting Stand-alone Wellness Programs**

Some wellness programs are not tied to or part of a specific group health plan. Are the costs associated with such standalone wellness programs outside the Rx drug reporting requirements because the requirement applies only to group health plans and health insurance issuers? The instructions suggest not. They indicate that wellness expenses that cannot be tied to a specific plan, issuer, carrier, state, or market segment must be reported. The reporting entity must use a reasonable method to allocate expenses across states and market segments.<sup>2</sup> The instructions do not provide further guidance on what is considered a "reasonable method" to allocate wellness expenses in this situation.

<sup>1</sup> Section 2705 contains the HIPAA nondiscrimination rules, so this provision essentially provides that wellness incentives should be included only if they are compliant with the HIPAA wellness program requirements.

<sup>2</sup> As we indicated in our prior article, most of the required information that is reported to the government as part of the Rx drug reporting requirement will be reported on an aggregate basis by state and market segment, rather than at the plan level.



### What Actions Might an Employer Need to Take Regarding the Wellness Program Component of the Rx Drug Reporting Requirement?

While the Rx drug reporting requirement applies to group health plans, the agencies generally expect that insurers, TPAs and/or PBMs will provide the reporting on behalf of group health plans.<sup>3</sup> As mentioned above, most of the information will be reported on an aggregate basis by state and market segment. While insurers, TPAs, and PBMs typically possess most of the information required to be reported (prescription drug pricing information, spending on health care services, etc.), in many cases, third parties will not have information regarding wellness program expenses incurred by employers.

As an initial matter, employers will need to take an inventory of the wellness programs they offer and determine whether the costs incurred concerning the program are reportable under the Rx drug reporting requirements. If there is wellness program information that must be reported, the employer will then need to determine who will report this information - the employer, the plan's third-party administrator, insurer, pharmacy benefit manager, or the wellness program vendor (if any). If a third party will report the wellness program information on the employer's behalf, the employer should enter into a written agreement reflecting the third party's agreement to provide the reporting. Employers should also make arrangements to gather and supply that information to the third party in a timely manner (assuming the third party does not already have access to the necessary information). If no third party agrees to report this information, the employer will need to prepare to report it.

Plan sponsors should consult their legal counsel for specific advice regarding the scope of wellness program costs that must be included in this reporting based on the plan sponsor's specific wellness program(s). Plan sponsors should also consult their legal counsel for assistance negotiating and drafting written agreements with third parties to report this information on the employer's behalf and/or for assistance with self-reporting the information.



<sup>3</sup> As with other transparency requirements, the Interim Final Regulations allow a group health plan to comply with the Rx drug reporting requirement by entering a written agreement with a third party (insurer, TPA or PBM) under which the third party agrees to report the information on the plan's behalf.



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