

## WISCONSIN COURT ANALYZES RELATIONSHIP BETWEEN 340B AND WISCONSIN MEDICAID REQUIREMENTS IN IMPORTANT OVERPAYMENT CASE

On June 12, 2018, the Wisconsin Court of Appeals (“Court”) affirmed a decision by a Wisconsin circuit court and held that a family planning clinic with multiple locations in Wisconsin (“Provider”) was not required to repay the Wisconsin Department of Health Services (“DHS”) a total of \$185,074.80 related to Medicaid fee-for-service claims submitted for prescription drugs.

In affirming the circuit court’s decision, the Court generally found that while DHS has the authority to recoup payments pursuant to **WIS. STAT. § 49.45(3)(f) (2015-16)** when a provider fails to maintain records required by DHS, the Provider was not required to maintain invoices documenting its purchase of prescription drugs that were dispensed to Medicaid patients. The state was therefore unable to prove excess reimbursement was paid due to non-compliance with actual acquisition cost (“AAC”) reporting requirements applicable to 340B participating entities. The Court also concluded that DHS did not have the authority to recoup payments because the Provider submitted claims with missing or invalid National Drug Codes (“NDCs”) since front-end edits should have been implemented denying these claims. DHS’s allegations (and the Court’s response) are unique in light of the way that DHS seeks to leverage both federal 340B Drug Pricing Program (“340B Program”) requirements and state Medicaid requirements and represents the first wave of state-based overpayment actions based on 340B Program requirements.

Notably, DHS attempted to argue that federal 340B Program guidance stating generally that relevant records should be maintained is binding with respect to state Medicaid documentation requirements. While the Court did not accept this argument, it nonetheless flags DHS’s attempt to use 340B Program standards to supplement its own documentation requirements. Next, the Court made it clear that while DHS has the authority to deny an improperly submitted claim (i.e., a claim missing a NDC), DHS should have implemented front-end edits and therefore does not have the authority to initiate a recoupment after a claim has been accepted, barring some other deficiency. Finally, DHS made it clear that it reviews and may continue to seek recoupment related to actual acquisition cost reporting as required for Medicaid fee-for-service claims filled using discounted 340B Program drugs. As such, 340B participating entities should carefully consider how they intend to comply with AAC reporting and recordkeeping requirements.

### BACKGROUND

DHS initiated an audit of the Provider on November 5, 2013 to investigate whether Wisconsin Medicaid and BadgerCare Plus members were properly billed for pharmacy services in 2010 and 2011. As a result of this audit, in August 2014, DHS alleged that the Provider: (1) failed to provide “documentation” listing its “acquisition cost” for drugs that it billed to Medicaid; (2) billed Medicaid for more than what the provider bought them for; and (3) submitted claims for provider-administered drugs with either missing or incorrect National Drug Codes (“NDCs”). In light of these alleged deficiencies, DHS “recommended” that the Provider make a repayment of \$1,169,837 for claims with billing errors.

The Provider challenged DHS’s determination, and in response DHS dropped the allegation that the Provider billed more than its acquisition cost for drugs covered by the 340B Program. In April 2015, DHS issued a “Notice of Intent to Recover” that included a significantly reduced repayment amount of \$185,074.80. The Provider then sought administrative review of DHS’s Notice of Intent to Recover resulting in an administrative hearing before an administrative law judge (“ALJ”), who ultimately upheld DHS’s Notice of Intent to Recover.

In that decision, the ALJ concluded that the Provider was required by law both to retain drug purchase invoices and to include NDCs on all claim forms submitted to Medicaid. Regarding the NDC issue, the ALJ conceded that while there was “no allegation the drugs in question were not properly dispensed” and DHS was “secondarily at fault” for paying claims that should have been denied, the claims at issue “still were deniable and thus must be recovered *regardless of fault*.”

When DHS subsequently adopted the ALJ’s decision as its final decision, the Provider petitioned for judicial review. The circuit court reversed the DHS/ALJ decision, holding that DHS can recoup payments previously made only when any of the following could not be verified: (1) the services were actually provided; (2) the appropriateness of the claim; and (3) the accuracy of the claim. According to the circuit court, the Provider had provided evidence at the administrative hearing illustrating that services were provided, which entitled them to the received payments. The failure to keep proper invoices and submission of claims with missing or incorrect NDCs did not alone justify recoupment as a

matter of law. DHS then appealed the circuit court's decision, which the Court affirmed.

## ANALYSIS

Upon review, the Court found that DHS has authority, pursuant to WIS. STAT. § 49.45(3)(f), to recoup payments made to a Medicaid provider who fails to maintain the required records regardless of whether a provider can show through other methods that the provider rendered the services in question. The Court also found that a provider has an obligation to make the required records available to DHS at the time of the audit to defeat a recoupment claim.

The Court here, however, held that the Provider was not required to maintain drug purchase invoices as part of its Medicaid record-keeping requirements, thereby denying DHS the authority to recoup payments for claims that allegedly lacked such records. The Court based this analysis on the fact that while providers have a general requirement to maintain "all evidence" necessary to support their claims, retaining purchase invoices "in and of themselves would not provide any evidence that the drugs were actually dispensed to Medicaid patients." Ultimately, the Court held that the general regulatory requirement that providers maintain "all evidence of claims for reimbursement ... cannot reasonably be interpreted as informing providers of a specific requirement that they retain invoices documenting their purchase of prescription drugs."

DHS also attempted to argue both that the prescription drugs should be considered medical supplies and equipment (which require the retention of purchase invoices) and that federal 340B Program guidance compels an entity that participates in the 340B Program (such as the Provider) to possess and retain manufacturer invoices for up to three years. The Court rejected both these arguments, finding that prescription drugs do not fall within the statutory definition of medical supplies and that the 340B Program guidance refers to 340B Program audits, not state Medicaid audits, which are governed by state law.

Further, the Court also held that DHS did not have the authority to recoup payments based on the Provider's submission of claims with missing or invalid NDCs. Through a careful parsing of the governing statutory language, the Court distinguished between "claim" and "records." The Court held that "claims" are submitted by the health care provider for DHS reimbursement and are distinct from records, which are documents to support the veracity of a claim. While DHS has the authority to deny an improperly submitted claim (i.e., a claim missing a NDC), DHS does not have the authority to initiate a recoupment for such claim after it has been accepted, barring some other deficiency. For example, DHS may recoup payments for claims that are not supported by adequate records or which DHS can prove were inappropriately or mistakenly paid. In the present matter, DHS could not demonstrate either of these facts. Finally, DHS's stated policy at the time of the audit informed providers only that claims with missing or invalid NDCs would be denied. DHS never informed providers that failure to include NDCs would result in recoupment of already paid claims.

## PRACTICAL TAKEAWAYS

While this is ultimately a provider-friendly decision, it nonetheless may indicate areas where DHS is likely to increase its scrutiny of claims submission and provider record-keeping requirements. In its initial request for recoupment, for example, DHS may have attributed close to \$1 million in alleged overpayments related to Provider's alleged failure to list the drug acquisition cost on the claim. While it's not clear why DHS ultimately dropped this claim, all Wisconsin Medicaid providers (but particularly those participating in the 340B Program) should ensure they can operationalize Medicaid acquisition reporting requirements. Further, given that the Court foreclosed DHS's right to recoup paid claims with missing/invalid NDCs, it is likely that DHS will place increased scrutiny on analyzing (and denying if needed) prescription drug claims with missing/invalid NDCs. Lastly, all Wisconsin Medicaid providers should pay close attention to transmittals/policy updates from DHS that seek to implement some aspects of DHS's arguments as policy.

If you have any questions or would like additional information about Wisconsin Medicaid pharmacy billing requirements, please contact:

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