

**COURT OF APPEALS
DECISION
DATED AND FILED**

June 12, 2018

Sheila T. Reiff
Clerk of Court of Appeals

NOTICE

This opinion is subject to further editing. If published, the official version will appear in the bound volume of the Official Reports.

A party may file with the Supreme Court a petition to review an adverse decision by the Court of Appeals. See WIS. STAT. § 808.10 and RULE 809.62.

Appeal No. 2017AP1432

Cir. Ct. No. 2016CV164

STATE OF WISCONSIN

**IN COURT OF APPEALS
DISTRICT III**

NEWCAP, INC.,

PLAINTIFF-RESPONDENT,

V.

DEPARTMENT OF HEALTH SERVICES,

RESPONDENT-APPELLANT.

APPEAL from an order of the circuit court for Oconto County:
JAY N. CONLEY, Judge. *Affirmed.*

Before Stark, P.J., Hruz and Seidl, JJ.

¶1 STARK, P.J. This appeal involves efforts made by the Wisconsin Department of Health Services (DHS) to recoup payments it made to Newcap, Inc., a family planning clinic. DHS claims it had legal authority to recoup the

amounts in question, pursuant to WIS. STAT. § 49.45(3)(f) (2015-16),¹ because Newcap failed to “maintain records as required by [DHS] for verification of provider claims for reimbursement.” *See* § 49.45(3)(f)1. In response, Newcap contends it was not actually required to maintain the specific records at issue in this case. Alternatively, Newcap argues its failure to maintain those records provided no basis for recoupment because other records—which were in Newcap’s possession either at the time of DHS’s audit or at the time of the subsequent hearing—showed that Newcap actually provided the services for which it was paid by DHS.

¶2 We conclude WIS. STAT. § 49.45(3)(f) gives DHS authority to recoup payments made to a Medicaid provider when that provider has failed to maintain the records required by DHS, regardless of whether the provider possesses other records that show the provider actually rendered the services in question. We further conclude the provider has an obligation to make the required records available to DHS at the time of DHS’s audit, and records subsequently submitted during an administrative hearing are insufficient to defeat DHS’s recoupment claim.

¶3 Nevertheless, we affirm the circuit court’s order, which reversed DHS’s decision requiring Newcap to repay DHS \$185,074.80. DHS concluded it was entitled to recover that amount based on two deficiencies in Newcap’s recordkeeping: (1) Newcap’s failure to retain invoices documenting its purchase of prescription drugs that it subsequently dispensed to Medicaid patients; and

¹ All references to the Wisconsin Statutes are to the 2015-16 version unless otherwise noted.

(2) Newcap’s failure to include correct National Drug Codes (NDCs)² on reimbursement claims it submitted to Medicaid. We conclude Newcap was not required to retain the invoices in question, and its failure to do so therefore did not give DHS authority to recoup payments under WIS. STAT. § 49.45(3)(f). We further conclude DHS lacked legal authority to recoup payments based on Newcap’s submission of claims with missing or invalid NDCs. We therefore affirm.

BACKGROUND

¶4 “Medicaid is a cooperative federal-state program through which the Federal Government provides financial assistance to States so that they may furnish medical care to needy individuals.” *Wilder v. Virginia Hosp. Ass’n*, 496 U.S. 498, 502 (1990). DHS administers Wisconsin’s Medicaid program, *see State v. Abbott Labs.*, 2012 WI 62, ¶3, 341 Wis. 2d 510, 816 N.W.2d 145, which is also referred to as “Medical Assistance” or “MA.” *See* WIS. STAT. § 49.45; WIS. ADMIN. CODE § DHS 101.01 (Dec. 2008). As a general matter, DHS is required to “reimburse providers for medically necessary and appropriate health care services ... when provided to currently eligible medical assistance recipients.” WIS. ADMIN. CODE § DHS 107.01(1) (June 2017).³

² An NDC is a unique, ten- or eleven-digit number that is assigned to “finished drug product[s]” and certain “unfinished drug[s].” 21 C.F.R. § 207.33(a)-(b)(1) (2018). A drug’s NDC identifies its “labeler, product, and package size and type.” 21 C.F.R. § 207.33(a) (2018).

³ All references to WIS. ADMIN. CODE ch. DHS 107 are to the June 2017 version, which is the current version of that chapter. Although this case involves services Newcap allegedly provided between January 2010 and December 2011, the relevant provisions of ch. DHS 107 have not changed since that time. For convenience, we therefore refer to the current version of that chapter.

¶5 Newcap operates a Medicaid-certified family planning clinic, which provides reproductive healthcare services to individuals in Brown, Florence, Forest, Marinette, Oconto, and Vilas Counties. On November 5, 2013, DHS initiated an audit of Newcap “to determine whether pharmacy services provided to Wisconsin Medicaid and BadgerCare Plus members were documented and billed appropriately” during the period between January 1, 2010, and December 31, 2011. DHS reviewed Newcap’s records from that period during a site visit on November 18 and 19, 2013.

¶6 On August 7, 2014, DHS issued its preliminary audit findings. It identified three deficiencies in Newcap’s billing and recordkeeping practices: (1) Newcap failed to provide “documentation” listing its “acquisition cost” for drugs that it billed to Medicaid; (2) Newcap billed Medicaid “for drugs at a price that was more than the acquisition cost”;⁴ and (3) Newcap submitted claims for provider-administered drugs with either missing or incorrect NDCs. Based on these deficiencies, DHS “recommended that Medicaid seek repayment of \$1,169,837.10 paid to [Newcap] for claims that were billed in error.”

¶7 Newcap submitted rebuttal materials challenging DHS’s preliminary audit findings. On April 15, 2015, DHS issued a “Notice of Intent to Recover” the significantly reduced amount of \$185,074.80. That amount was comprised of: (1) \$168,745.46, for 2,738 claims for which Newcap had failed to retain invoices documenting its purchase of prescription drugs; (2) \$1,366.64, for eleven

⁴ Newcap was a participant in the federal 340B Drug Pricing Program, which allows certain providers to purchase drugs at discounted rates. *See* UNITED STATES DEP’T OF HEALTH SERVICES, HEALTH RESOURCE AND SERVICES ADMINISTRATION, *340B Drug Pricing Program*, <https://www.hrsa.gov/opa> (last visited May 23, 2018).

claims that Newcap had submitted with invalid or incorrect NDCs; and (3) \$14,962.70, for twenty-seven claims that Newcap had submitted without NDCs. DHS abandoned its claim that it was entitled to recoupment based on Newcap having billed DHS for drugs at prices that exceeded their acquisition cost.

¶8 Newcap sought administrative review of DHS's Notice of Intent to Recover. An administrative hearing took place on February 23, 2016, before an administrative law judge (ALJ). During the hearing, Newcap presented the testimony of Jennifer Waloway, who was hired by Newcap as a nurse practitioner in November 2011 and became its director of community health services in 2014. Waloway conceded Newcap had failed to retain invoices for some of the prescription drugs for which it had billed Medicaid. However, she testified other records in Newcap's possession, such as patient charts, showed the medications in question were actually provided to Medicaid patients. In addition, Waloway testified she worked with Newcap's suppliers after the audit to obtain copies of some of the missing invoices, which were introduced into evidence during the administrative hearing. Waloway also conceded that Newcap had submitted claims to Medicaid with missing or incorrect NDCs. She testified, however, that Newcap had reviewed patient charts and determined Medicaid was properly billed for those medications.

¶9 Newcap ultimately raised three arguments in its posthearing brief. First, Newcap argued there was "no statute or regulation—or other Medicaid policy—that require[d] a family planning clinic to retain all invoices for prescription drugs it ha[d] purchased." Second, Newcap argued there was no statute or policy permitting DHS to recoup amounts it had previously paid for claims with missing or incorrect NDCs. Third, Newcap argued DHS was "not authorized to recoup payments made to the provider where the provision of

services has been verified.” Newcap contended, “The Legislature has not authorized [DHS] to recover funds due to any documentation shortcoming. Imperfections in the provider’s paperwork do not necessarily mean the provider received an overpayment, if in fact the service was authorized, the provider actually provided it, and the payment was appropriate for the service.”

¶10 On June 28, 2016, the ALJ issued a proposed decision upholding DHS’s Notice of Intent to Recover. With respect to the missing invoices, the ALJ concluded Newcap was required to retain those invoices under WIS. ADMIN. CODE § DHS 105.02(7)(b)3. (Feb. 2017).⁵ The ALJ rejected Newcap’s argument that DHS could not recoup payments because other evidence showed that the medications in question were actually provided to Medicaid patients. While acknowledging that argument was “reasonable,” the ALJ stated, in an apparent reference to WIS. STAT. § 49.45(3)(f)2., that DHS “‘may recover’ previously paid claims where the provider fails to keep records,” and “[i]f [DHS] chooses to recover, the rules do not authorize the Division of Hearings and Appeals to order [DHS] to take a different action.”

¶11 As for the missing and incorrect NDCs, the ALJ concluded Newcap was required by federal law to include NDCs on its claim forms, and DHS had informed Newcap that its failure to do so would result in the denial of claims. The ALJ conceded there was “no allegation” the drugs in question “were not properly dispensed.” The ALJ also conceded DHS was “secondarily at fault in paying

⁵ All references to WIS. ADMIN. CODE ch. DHS 105 are to the current, February 2017 version. Again, none of the relevant provisions of ch. DHS 105 have changed since January 2010, the beginning of the audit period at issue in this case.

[Newcap’s] claims that should have been denied.” However, the ALJ stated the claims “still were deniable and thus must be recovered *regardless of fault.*”

¶12 DHS subsequently adopted the ALJ’s proposed decision as its final decision. Newcap petitioned for judicial review, and the circuit court issued an order reversing DHS’s decision. The court reasoned that, under WIS. STAT. § 49.45(3)(f), DHS may recoup amounts previously paid to a provider only when “any of the following cannot be verified: (1) the actual provision of services; (2) the appropriateness of the claim; and (3) the accuracy of the claim.” The court concluded Newcap had “presented evidence at the [administrative] hearing that services were provided and it was entitled to payments received.” The court explained that, to the extent Newcap erred by failing to maintain proper invoices and by submitting claims with missing or incorrect NDCs, “these errors alone do not justify recoupment under the statute, as a matter of law.” DHS now appeals.

DISCUSSION

¶13 When a party appeals a circuit court order reviewing a decision made by an administrative agency, we review the agency’s decision, rather than that of the circuit court. *Gabler v. Crime Victims Rights Bd.*, 2017 WI 67, ¶24, 376 Wis. 2d 147, 897 N.W.2d 384. The scope of our review is set forth in WIS. STAT. § 227.57. As relevant here, that statute authorizes a court to “set aside or modify the agency action if it finds that the agency has erroneously interpreted a provision of law and a correct interpretation compels a particular action.” Sec. 227.57(5).

¶14 In the discussion below, we first address the parties’ arguments regarding whether WIS. STAT. § 49.45(3)(f) permits DHS to recoup payments based on a provider’s failure to maintain required records, even if other records

demonstrate that the provider actually rendered the services in question. We then address whether a provider may submit additional documentation following the audit period in order to demonstrate its compliance with DHS's recordkeeping requirements. Finally, we address whether Newcap was required to maintain invoices for the medications at issue in this case, and whether DHS had legal authority to recoup payments based on Newcap's submission of claims with missing or invalid NDCs.⁶

I. WISCONSIN STAT. § 49.45(3)(f)

¶15 The parties agree that DHS's recoupment authority is set forth in WIS. STAT. § 49.45(3)(f). That statute provides, in relevant part:

1. Providers of services under this section shall maintain records as required by the department for verification of provider claims for reimbursement. The department may audit such records to verify actual provision of services and the appropriateness and accuracy of claims.
2. The department may deny any provider claim for reimbursement which cannot be verified under subd. 1. or may recover the value of any payment made to a provider which cannot be so verified. The measure of recovery will be the full value of any claim if it is determined upon audit that actual provision of the service cannot be verified from the provider's records or that the service provided was not included in s. 49.46(2) or 49.471(11). In cases of mathematical inaccuracies in computations or statements of claims, the measure of recovery will be limited to the amount of the error.

⁶ The parties also dispute whether Newcap presented sufficient evidence at the administrative hearing to demonstrate that it actually dispensed the medications in question. We need not address this issue, in light of our conclusion that DHS may recoup based on a provider's failure to retain required records. See *Turner v. Taylor*, 2003 WI App 256, ¶1 n.1, 268 Wis. 2d 628, 673 N.W.2d 716 (court of appeals need only address dispositive issues).

Sec. 49.45(3)(f)1.-2. We conclude the plain language of these provisions demonstrates that DHS has authority to recover payments made to a provider when an audit reveals that the provider failed to maintain records as required by DHS.⁷ See *State ex rel. Kalal v. Circuit Court for Dane Cty.*, 2004 WI 58, ¶45, 271 Wis. 2d 633, 681 N.W.2d 110 (explaining that statutory interpretation begins with the plain language of the statute).

¶16 WISCONSIN STAT. § 49.45(3)(f)1. requires providers to “maintain records *as required by the department* for verification of provider claims for reimbursement.” (Emphasis added.) Section 49.45(3)(f)1. further states that DHS may audit “*such records* to verify actual provision of services and the appropriateness and accuracy of claims.” (Emphasis added.) The phrase “such records” clearly refers to the records referenced in the previous sentence of the statute—that is, the records DHS requires a provider to maintain. Thus, by stating DHS may audit “such records” to verify the actual provision of services and the appropriateness and accuracy of claims, § 49.45(3)(f)1. plainly indicates that, during an audit, the provision of services and appropriateness and accuracy of claims is determined only based on the records DHS required the provider to keep.

¶17 WISCONSIN STAT. § 49.45(3)(f)2. then states that DHS “may deny any provider claim for reimbursement *which cannot be verified under subd. 1.* or

⁷ Statutory interpretation presents a question of law, which we typically review independently. See *County of Dane v. LIRC*, 2009 WI 9, ¶14, 315 Wis. 2d 293, 759 N.W.2d 571. “However, depending on the circumstances, an agency’s interpretation of a statute is entitled to one of the following three levels of deference: great weight deference, due weight deference or no deference.” *Id.* Newcap contends DHS’s interpretation of WIS. STAT. § 49.45(3)(f) is entitled to no deference. DHS does not clearly indicate the level of deference it believes we should apply. We need not resolve this issue because, even applying no deference—the level most favorable to Newcap—we conclude DHS correctly interpreted § 49.45(3)(f).

may recover the value of any payment made to a provider *which cannot be so verified.*” (Emphasis added.) This language unambiguously allows DHS to deny a claim or recover a payment that cannot be verified “under subd. 1.”—that is, using the audit process discussed in subd. 1. In other words, DHS may deny a claim or recover a payment when the actual provision of services or the appropriateness and accuracy of the claim cannot be verified using the records DHS required the provider to maintain.

¶18 WISCONSIN STAT. § 49.45(3)(f)2. further states that the “measure of recovery will be the full value of any claim if it is determined upon audit that actual provision of the service cannot be verified from the provider’s records.” The “audit” referenced in § 49.45(3)(f)2. is plainly the same audit described in § 49.45(3)(f)1. Thus, when read in context with § 49.45(3)(f)1., the term “the provider’s records” in § 49.45(3)(f)2. clearly refers to the records subject to the audit discussed in subd. 1—that is, the records DHS required the provider to maintain. *See Kalal*, 271 Wis. 2d 633, ¶46 (explaining statutory language must be read in context, “in relation to the language of surrounding or closely-related statutes”).

¶19 When read together, WIS. STAT. § 49.45(3)(f)1. and 2. therefore demonstrate the following: (1) a provider must retain records as required by DHS; (2) DHS may audit the records it has required a provider to maintain in order to verify the actual provision of services and the appropriateness and accuracy of claims; and (3) DHS may deny a claim or recover a payment already made to a provider when it cannot verify the actual provision of services or the appropriateness and accuracy of claims based on the records DHS required the provider to maintain. It is self-evident that, if a provider fails to maintain the records DHS requires, DHS cannot use those records to verify the actual provision

of services and the appropriateness and accuracy of the provider's claims. Section 49.45(3)(f) therefore grants DHS authority to recoup payments under those circumstances.

¶20 Newcap disagrees, arguing WIS. STAT. § 49.45(3)(f) permits DHS “to audit the records maintained by providers to *verify that services were actually provided* and permits DHS to recover *only if the provision of services cannot be so verified*.” This interpretation, however, fails to account for the fact that § 49.45(3)(f)1. states providers must maintain records “as required by” DHS, and DHS may audit “such records”—i.e., the records DHS required the provider to maintain—in order to verify the actual provision of services. Section 49.45(3)(f)2., in turn, permits recoupment if the provider's claim cannot be verified using the method described in subd. 1—that is, through an audit of the records that DHS required the provider to maintain. Thus, while Newcap contends DHS cannot recoup payments where *any record* in the provider's possession shows the services in question were actually provided, the statute clearly permits DHS to recoup where the actual provision of services cannot be determined based on the specific records that DHS required the provider to maintain. Newcap's interpretation is therefore at odds with the plain language of the statute.

II. Submission of records at the administrative hearing

¶21 Newcap further contends that, even if WIS. STAT. § 49.45(3)(f) granted DHS authority to recoup based on Newcap's failure to maintain the records DHS requires, DHS's final decision was in error because it failed to acknowledge that Newcap produced some of the required records during the administrative hearing. Specifically, Newcap asserts it “worked with its drug distributors to obtain copies of the missing invoices” following DHS's audit, and

“by the time of the hearing, [it] presented invoices that account[ed] for over \$150,000.00 of the claimed recoupment amount.”

¶22 Newcap is correct that DHS’s final decision did not acknowledge these invoices. We agree with DHS, however, that Newcap could not remedy its failure to provide required records at the time of the audit by subsequently providing them during the administrative hearing. Again, WIS. STAT. § 49.45(3)(f)1. permits DHS to audit the records it required a provider to maintain in order to verify the actual provision of services, as well as the appropriateness and accuracy of claims. If a provider’s claim cannot be verified “under subd. 1.”—that is, during DHS’s audit of the required records—§ 49.45(3)(f)2. grants DHS authority to recoup. When read together, these subdivisions make it clear that a provider has an obligation to make the required records available to DHS at the time of an audit in order to allow DHS to verify the provider’s claims, and DHS may recoup payments already made if the provider fails to do so.

¶23 In addition, it makes sense, as a practical matter, that a provider should not be able to avoid recoupment by submitting the required records for the first time during an administrative hearing. The purpose of the audit discussed in WIS. STAT. § 49.45(3)(f)1. is for DHS to verify that the services billed by a provider were appropriate, that they were actually provided, and that the provider’s claim was accurate. This purpose would be frustrated if a provider could neglect to produce required records during an audit, only to provide them later on during an administrative hearing—a hearing which, in all likelihood, would not have been necessary had the provider submitted the required records during the audit. Stated differently, allowing a provider to avoid recoupment by submitting the required records at an administrative hearing would decrease the provider’s incentive to maintain required records and produce the records during

an audit, thereby reducing the overall efficiency of the auditing process. For these reasons, we reject Newcap's argument that DHS erred by failing to reduce the recoupment amount based on the invoices Newcap submitted during the administrative hearing.⁸

III. Failure to maintain invoices for prescription drugs

¶24 Thus far, we have concluded that DHS has legal authority to recoup payments based on a provider's failure to maintain required records, and that the provider must make the required records available to DHS at the time of an audit. Nevertheless, these conclusions do not end our analysis. Newcap argues, in the alternative, that DHS lacked authority to recoup payments made to Newcap based on Newcap's failure to maintain invoices for prescription drugs because Newcap was not actually required to retain those invoices. In response, DHS cites several administrative code provisions, which it contends required Newcap to retain the invoices in question. We agree with Newcap, however, that none of the provisions DHS relies upon imposed that requirement.⁹

⁸ The Virginia Court of Appeals has reached a similar conclusion, holding a provider's "required documentation must be maintained prior to and at the time of the audit, not through reorganizing and explaining following a failed audit." *1st Stop Health Servs., Inc. v. Department of Med. Assistance Servs.*, 756 S.E.2d 183, 190 (Va. Ct. App. 2014).

⁹ Newcap asserts we should not defer to DHS's interpretations of the relevant administrative code provisions. Again, DHS does not clearly indicate the level of deference it believes we should apply. Once more, however, we need not resolve this issue. DHS's interpretations of the relevant code provisions are unreasonable. Thus, we would reject DHS's interpretations even under great weight deference—the level of deference most favorable to DHS. See *County of Dane*, 315 Wis. 2d 293, ¶16 (under great weight deference, an agency's interpretation will be upheld as long as it is reasonable).

¶25 DHS first cites WIS. ADMIN. CODE § DHS 106.02(9)(d)2. (Jan. 2014),¹⁰ which states, in relevant part, that a provider “shall retain all evidence of claims for reimbursement.” DHS argues “all evidence” supporting a provider’s claims for reimbursement includes invoices documenting the provider’s purchase of prescription drugs that were dispensed to Medicaid patients.

¶26 We are unpersuaded. While WIS. ADMIN. CODE § DHS 106.02(9)(d)2. imposes a *general* requirement that a provider retain “all evidence” necessary to support its claims, that subdivision cannot reasonably be read to impose a *specific* requirement that a provider retain invoices documenting its purchase of prescription drugs. If a provider retained and submitted to DHS patient records showing that the prescription drugs in question were actually dispensed to Medicaid patients, it is not self-evident, based on the text of § DHS 106.02(9)(d)2., that the provider would also be required to retain and submit to DHS invoices documenting its own purchase of the same prescription drugs. The invoices, in and of themselves, would not provide any evidence that the drugs were actually dispensed to Medicaid patients. The patient records, meanwhile, do demonstrate such dispensing. Under these circumstances, the general reference to “all evidence of claims for reimbursement” in § DHS 106.02(9)(d)2. cannot reasonably be interpreted as informing providers of a specific requirement that they retain invoices documenting their purchase of prescription drugs.

¶27 DHS next cites WIS. ADMIN. CODE § DHS 105.02(4), which states in relevant part:

¹⁰ All references to WIS. ADMIN. CODE ch. DHS 106 are to the current, January 2014 version. Once again, the relevant provisions of ch. DHS 106 have not changed since January 2010, the beginning of the audit period at issue in this case.

Providers shall prepare and maintain whatever records are necessary to fully disclose the nature and extent of services provided by the provider under the program. Records to be maintained are those enumerated in subs. (6) and (7). All records shall be retained by providers for a period of not less than 5 years from the date of payment by the department for the services rendered, unless otherwise stated in chs. DHS 101 to 108.

DHS then cites WIS. ADMIN. CODE § DHS 105.02(7)(b), which provides:

Prescribed service providers. The following records shall be kept by pharmacies and other providers of services requiring a prescription:

1. Prescriptions which support MA billings;
2. MA patient profiles;
3. Purchase invoices and receipts for medical supplies and equipment billed to MA; and
4. Receipts for costs associated with services billed to MA.

¶28 DHS contends the prescription drugs at issue in this case constitute “medical supplies,” and Newcap was therefore required to retain invoices for those drugs under WIS. ADMIN. CODE § DHS 105.02(7)(b)3. Chapter DHS 105 does not define the term “medical supplies.” DHS therefore relies upon WIS. ADMIN. CODE § DHS 107.21, which discusses covered family planning services. The various paragraphs of § DHS 107.21(1) describe different categories of family planning services that are covered by Medicaid. As relevant here, paragraph (g), entitled “Supplies,” provides:

The following supplies are covered when prescribed:

1. Oral contraceptives;
2. Diaphragms;
3. Jellies, creams, foam and suppositories;

4. Condoms; and
5. Natural family planning supplies such as charts.

Sec. DHS 107.21(1)(g)1.-5. Because “oral contraceptives” constitute “supplies” under this definition, DHS argues they must also qualify as “medical supplies” under § DHS 105.02(7)(b)3. DHS therefore argues that, pursuant to § DHS 105.02(7)(b)3., Newcap was required to maintain invoices documenting its purchase of oral contraceptives for five years.

¶29 There are two problems with DHS’s argument. First, it relies on the false premise that each prescription drug for which Newcap failed to provide an invoice was an oral contraceptive. To the contrary, the record shows that, in addition to oral contraceptives, DHS sought recoupment based on Newcap’s failure to provide invoices for Zithromax and metronidazole, which are antibiotics,¹¹ and Depo-Provera, an injectable contraceptive.¹² These medications clearly do not fall within the definition of “supplies” set forth in WIS. ADMIN. CODE § DHS 107.21(1)(g). Thus, even if we agreed with DHS that the term “medical supplies” in WIS. ADMIN. CODE § 105.02(7)(b)3. was synonymous with the term “supplies” in § DHS 107.21(1)(g), we would nevertheless conclude DHS exceeded its authority by seeking recoupment based on Newcap’s failure to provide invoices for drugs other than oral contraceptives.

¹¹ See PFIZER, *Patient Summary of Information about Zithromax® (azithromycin for oral suspension)*, <http://labeling.pfizer.com/ShowLabeling.aspx?id=656> (last visited May 23, 2018); MAYO CLINIC, *Metronidazole (Oral Route)*, <https://www.mayoclinic.org/drugs-supplements/metronidazole-oral-route/description/drg-20064745> (last visited May 23, 2018).

¹² See MAYO CLINIC, *Depo-Provera (contraceptive injection)*, <https://www.mayoclinic.org/tests-procedures/depo-provera/about/pac-20392204> (last visited May 23, 2018).

¶30 Second, we do not, in fact, agree with DHS that the term “medical supplies” in WIS. ADMIN. CODE § DHS 105.02(7)(b)3. is synonymous with the term “supplies” in WIS. ADMIN. CODE § DHS 107.21(1)(g). Section DHS 105.02(7)(b)3. requires providers to maintain invoices for “*medical supplies*,” not “supplies.” (Emphasis added.) As Newcap notes, ch. DHS 107 contains a separate definition of “medical supplies,” which provides: “In this chapter, ‘medical supplies’ means disposable, consumable, expendable or nondurable medically necessary supplies which have a very limited life expectancy. Examples are plastic bed pans, catheters, electric pads, hypodermic needles, syringes, continence pads and oxygen administration circuits.” WIS. ADMIN. CODE § DHS 107.24(1).

¶31 We agree with Newcap that, in light of the separate definition of “medical supplies” in WIS. ADMIN. CODE § DHS 107.24(1), it is not reasonable to conclude the term “medical supplies” in WIS. ADMIN. CODE § DHS 105.02(7)(b)3. is synonymous with the term “supplies” in WIS. ADMIN. CODE § DHS 107.21(1)(g).¹³ Under § DHS 107.24(1), the term “medical supplies” encompasses physical supplies that are used in the care of a patient and then discarded, rather than prescription drugs such as oral contraceptives. We therefore

¹³ DHS correctly notes that WIS. ADMIN. CODE § DHS 107.24(1) states the definition of “medical supplies” in that subsection applies “[i]n this chapter,”—i.e., in ch. DHS 107. Be that as it may, that definition informs our understanding, as a general matter, of what DHS understood the term “medical supplies” to mean when it promulgated WIS. ADMIN. CODE § DHS 105.02(7)(b)3., the provision at issue here. Moreover, while § DHS 107.24(1) states its definition of “medical supplies” applies “[i]n this chapter,” it does not expressly state that definition applies *only* in this chapter. Aside from arguing that the definition of “medical supplies” in § DHS 107.24(1) cannot be applied outside of ch. DHS 107, DHS does not develop any argument explaining why that definition should not apply to the term “medical supplies” in § DHS 105.02(7)(b)3. In addition, we observe that the definition of “supplies” that DHS would have us apply to § DHS 105.02(7)(b)3. also hails from ch. DHS 107, rather ch. DHS 105.

agree with Newcap that § DHS 105.02(7)(b)3. did not require Newcap to retain invoices for oral contraceptives—or any other prescription drugs—that it dispensed to Medicaid patients. Instead, Newcap was required under that subdivision to maintain invoices only for its purchases of medical supplies and equipment.¹⁴

¶32 DHS argues, in the alternative, that “federal guidance” pertaining to the 340B Drug Pricing Program required Newcap to maintain the invoices in question. DHS cites a single sentence from a 1994 Federal Register excerpt, which states that all entities participating in the 340B program must “maintain records of purchases of covered outpatient drugs and of any claims for reimbursement submitted for such drugs under title XIX of the Social Security Act.” Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994).

¶33 We do not find DHS’s reliance on this language persuasive. WISCONSIN STAT. § 49.45(3)(f)1. requires Medicaid providers to maintain records “as required by the department for verification of provider claims for reimbursement.” Thus, in order for a provider’s failure to maintain records to form the basis for a recoupment action, the recordkeeping requirement must have been imposed by DHS for the purpose of verifying the provider’s Medicaid reimbursement claim. The Federal Register section DHS cites pertains to audits of

¹⁴ Drawing a distinction between medical supplies and prescription drugs is consistent with the fact that WIS. ADMIN. CODE ch. DHS 107 includes separate sections addressing both “medical supplies,” *see* § DHS 107.24, and “[d]rugs and drug products,” *see* § DHS 107.10(1). The section addressing drugs and drug products expressly refers to oral contraceptives as “drugs,” *see* § DHS 107.10(3)(e)8., which further undercuts DHS’s contention that the term “medical supplies” in WIS. ADMIN. CODE § DHS 105.02(7)(b)3. includes oral contraceptives.

340B providers by drug manufacturers and the United States Department of Health and Human Services to ensure compliance with 340B program requirements. *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, 59 Fed. Reg. at 25,113. It requires 340B providers to maintain records of drug purchases *for the purpose of those audits*.

¶34 Moreover, the Federal Register excerpt that DHS cites expressly states:

The Office of Drug Pricing is developing proposed audit guidelines which will be published in the Federal Register with public comment invited. The notice will address only audits related to purchases as a covered entity; *it does not address other audit requirements related to participation in State Medicaid programs* or receipt of Federal funding.

Id. (emphasis added). This language makes it clear that the cited excerpt was not intended to impose requirements on 340B providers for purposes of state Medicaid audits. We therefore reject DHS’s argument that this “federal guidance” required Newcap to maintain invoices for purposes of § 49.45(3)(f)1.

¶35 For all the foregoing reasons, we conclude, as a matter of law, that Newcap was not required to retain invoices for the prescription drugs at issue in DHS’s audit. DHS therefore erred by seeking recoupment based on Newcap’s failure to retain those invoices.

IV. Submission of claims with missing or invalid NDCs

¶36 Newcap also argues DHS lacked legal authority to recoup payments it made for claims that Newcap submitted with missing or invalid NDCs. We agree that DHS lacked legal authority to recoup on this basis.¹⁵

¶37 As discussed above, WIS. STAT. § 49.45(3)(f)1. requires providers to “maintain *records* as required by the department for verification of provider *claims* for reimbursement.” (Emphasis added.) Section 49.45(3)(f)2., in turn, gives DHS authority to recoup when a provider fails to retain the required records, such that DHS cannot verify the actual provision of services or the appropriateness and accuracy of the provider’s claims. Here, it is undisputed that Newcap submitted claims to DHS with missing or invalid NDCs. However, the plain language of § 49.45(3)(f)1. unambiguously demonstrates that a “claim” is something distinct from the “records” DHS requires a provider to maintain. Specifically, a “claim” is something submitted by the provider, which DHS may then attempt to verify using the required records. Thus, under the statute, Newcap’s submission of claims with missing or incorrect NDCs cannot alone constitute a failure to maintain “records” as required by DHS.¹⁶ Section

¹⁵ Newcap appears to concede that it was required by DHS to include NDCs on some of its claims for reimbursement. However, it argues that it was only required to include NDCs on claims for provider-administered drugs, and that “some of the claims for which [DHS] seeks recoupment ... were for drugs that are not provider-administered.” We need not address this issue, in light of our conclusion that Newcap’s submission of claims with missing or invalid NDCs did not provide a legal basis for DHS to recoup. See *Turner*, 268 Wis. 2d 628, ¶1 n.1. In other words, it ultimately does not matter whether Newcap was required to provide NDCs for only some, as opposed to all, of the claims at issue in this case, because even assuming Newcap was required to provide NDCs for all of those claims, its failure to do so did not provide a legal basis for DHS to recoup payments it had already made.

¹⁶ DHS only argues on appeal that it required Newcap to include correct NDCs on Medicaid claims. It does not develop any argument that it otherwise required Newcap to maintain records containing NDCs for drugs dispensed to Medicaid patients.

49.45(3)(f) therefore provides no authority for DHS to recoup based on Newcap's submission of claims lacking valid NDCs.

¶38 DHS also cites WIS. STAT. § 49.45(2)(a)(10)a., which states in relevant part that DHS shall, “[a]fter reasonable notice and opportunity for hearing, recover money improperly or erroneously paid or overpayments to a provider.” DHS asserts this language grants it authority to recoup monies “if a reimbursement payment was made to a provider when it should have been rejected based on a lack of documentation of the claim.”

¶39 DHS does not, however, develop a convincing argument that payments made on claims submitted without valid NDCs constitute “improper[]” payments, “erroneous[]” payments, or “overpayments” under WIS. STAT. § 49.45(2)(a)10.a. or violate any other statute or regulation. DHS cites WIS. ADMIN. CODE § DHS 106.02(2), but that regulation merely states a provider “shall be reimbursed only for covered services specified in ch. DHS 107.” DHS does not explain why a provider's failure to include a correct NDC on a claim renders the underlying “services” non-covered.

¶40 DHS also cites WIS. ADMIN. CODE § DHS 106.02(9)(a), which requires providers to prepare and maintain truthful, accurate, and complete documentation, according to the requirements set forth in WIS. ADMIN. CODE chs. DHS 105, 106, and 107. However, DHS does not point to any provision *in those chapters* that specifically requires a provider to include NDCs on its claim forms.¹⁷

¹⁷ DHS instead cites 42 U.S.C. § 1396r-8(a)(7), which requires “the State” to “provide for the collection and submission of” NDCs in order for the state to receive reimbursement from the federal government. *See* 42 U.S.C.A. § 1396r-8(a)(7)(A)-(C) (West 2018).

Moreover, DHS does not explain why a provider's failure to comply with the documentation requirements in § DHS 106.02(9)(a) renders any payment made by DHS improper, erroneous, or an "overpayment." See WIS. STAT. § 49.45(2)(a)(10)a.

¶41 DHS next cites WIS. ADMIN. CODE § DHS 107.02(2)(a), which provides:

[DHS] may reject payment for a service which ordinarily would be covered if the service fails to meet program requirements. Non-reimbursable services include:

(a) *Services which fail to comply with program policies or state and federal statutes, rules and regulations, for instance, sterilizations performed without following proper informed consent procedures, or controlled substances prescribed or dispensed illegally.*

(Emphasis added.) This regulation permits DHS to *reject payment* for services that fail to comply with state and federal requirements; it does not provide authority for DHS to recoup payments already made. Moreover, § DHS 107.02(2)(a) defines "[n]on-reimbursable services" to include *services* that fail to comply with program policies or state and federal law. Here, DHS does not contend that the *services* Newcap provided failed to comply with any of those requirements. It argues instead that the *claims* Newcap submitted in order to obtain reimbursement for its services were defective. DHS does not develop any

argument that a provider's submission of a defective claim renders the underlying services "[n]on-reimbursable" under § DHS 107.02(2)(a).¹⁸

¶42 Finally, we observe that DHS issues guidance to providers through both its online handbook and through "Forward Health" updates. In a July 2008 update, entitled "National Drug Codes Required on Claims for Physician-Administered Drugs," DHS informed providers that it would "require that NDCs be indicated on claims for all physician-administered drugs," and "[i]f an NDC is not indicated on a claim ... or if the NDC indicated is invalid, the claim will be denied." DHS reiterated in an August 2010 update that claims submitted with missing or invalid NDCs "will be denied." During the audit period at issue in this case—i.e., January 2010 to December 2011—DHS's provider handbook similarly stated that DHS would deny claims with missing or invalid NDCs. Thus, DHS's stated policy at the time of the audit was to *deny* claims with missing or invalid NDCs. DHS never informed providers that their failure to include that information could result in recoupment of claims DHS had already paid.

¶43 For these reasons, we conclude DHS lacked legal authority to recoup payments made based on Newcap's submission of claims with missing or invalid NDCs. DHS therefore erred by seeking recoupment on that basis.

¹⁸ Moreover, we observe that WIS. ADMIN. CODE § DHS 107.02(2)(a) lists "sterilizations performed without following proper informed consent procedures, or controlled substances prescribed or dispensed illegally" as examples of the types of "services" that are non-reimbursable due to their failure to comply with program policies or state and federal law. These examples show that § DHS 107.02(2)(a) is focused on the type of services rendered, rather than technical defects in a provider's claims.

CONCLUSION

¶44 In summary, we conclude WIS. STAT. § 49.45(3)(f) gives DHS authority to recoup payments made to a Medicaid provider when that provider failed to maintain records as required by DHS for verification of the provider's claims, regardless of whether other records possessed by the provider show that the provider actually rendered the services in question. We further conclude the provider has an obligation to make the required records available to DHS at the time of DHS's audit, and records subsequently submitted during an administrative hearing are insufficient to defeat DHS's recoupment claim.

¶45 We conclude, however, that DHS was not entitled to recoupment under the specific circumstances of this case because: (1) Newcap was not required to maintain invoices for the prescription drugs at issue in this case; and (2) Newcap's submission of claims with missing or invalid NDCs did not grant DHS legal authority to recoup payments already made. We therefore affirm the circuit court's order reversing DHS's final decision.

By the Court.—Order affirmed.

Recommended for publication in the official reports.

