

Audit Report

Infinity Pharmacy Solutions, LLC

A Texas Vendor Drug Program Provider



**Inspector
General**

Texas Health
and Human Services

**June 23, 2020
OIG Report No. AUD-20-012**



HHS OIG

TEXAS HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

June 23, 2020

Audit Report

INFINITY PHARMACY SOLUTIONS, LLC

A Texas Vendor Drug Program Provider

WHY OIG CONDUCTED THIS AUDIT

The Vendor Drug Program helps ensure that fee-for-service Medicaid and Children's Health Insurance Program (CHIP) recipients receive access to prescription medications in an efficient and cost-effective manner. During the audit period of September 1, 2014, through August 31, 2017, Infinity processed 22,009 Medicaid claims for dispensed prescriptions through VDP, for which it received reimbursements of \$6.8 million from Texas Medicaid.

The audit objectives were to determine whether Infinity (a) properly billed Texas Medicaid VDP based on established contract requirements and (b) complied with applicable procedure manuals published by VDP and selected TAC requirements.

WHAT OIG RECOMMENDS

Infinity should ensure that all claims it submits to VDP:

- Include a signature from the prescriber.
- Are supported by the information required by TAC.
- Contain (a) a prescriber identification number associated with the physician who signed the prescription and (b) the correct prescription issuance date.
- Have refills and changes in quantity that are authorized by the prescriber and documented prior to dispensing.

MANAGEMENT RESPONSE

Infinity agreed with the audit results. In its management responses, Infinity stated that, as of May 2020, it had taken appropriate actions to address issues identified in this report.

For more information, contact:

OIGAuditReports@hhsc.state.tx.us

WHAT OIG FOUND

Infinity Pharmacy Solutions, LLC (Infinity) complied with Texas Administrative Code (TAC) and contract provisions related to National Drug Code (NDC) usage, controlled substances, and drug acquisition.

Infinity did not always bill the vendor drug program (VDP) properly or comply with other contractual or TAC requirements related to claims validity, refills, and quantity. Specifically, a total of 22 exceptions were identified associated with 20 of 232 claims tested. Infinity dispensed and billed VDP for:

- 4 prescriptions that were not signed by the prescriber.
- 1 prescription that did not meet the requirements for a transferred prescription.
- 8 prescriptions with a prescriber identification number that was not associated with the prescriber who signed the prescription.
- 2 prescriptions with the incorrect prescription issuance date.
- 2 prescriptions with an unauthorized refill.
- 5 prescriptions with quantities other than prescribed.

Compliance with the above requirements helps ensure recipients receive prescription drugs that have been authorized by a physician and are dispensed and refilled to the recipient in the appropriate strength and quantity.

VDP reimbursed Infinity \$5,186.28 for 20 unsupported claims. The error rates identified in the statistically valid random samples were applied to the appropriate populations. The \$5,186.28 identified as a dollar-for-dollar overpayment resulted in \$7,569.29 when applied to the populations.

Based on the results of this audit, Infinity should return the extrapolated overpayment amount of \$7,569.29 to the State of Texas.

BACKGROUND

Pharmacies participating in VDP dispense prescription medications to clients and are reimbursed for prescription medication costs by the Texas Health and Human Services Commission (HHSC). Reimbursements to these pharmacies are designed to cover (a) the cost of the prescription medication dispensed and (b) a dispensing fee, and must meet the requirements established in its contract and other criteria.

TABLE OF CONTENTS

AUDIT BACKGROUND	1
AUDIT RESULTS	4
CLAIMS VALIDITY	
<i>Issue 1: Prescriptions Not Signed by the Prescriber</i>	<i>5</i>
<i>Issue 2: Incomplete Documentation for Transferred Prescription</i>	<i>6</i>
<i>Issue 3: Incorrect Prescriber Identification Numbers</i>	<i>8</i>
<i>Issue 4: Incorrect Prescription Issuance Date</i>	<i>9</i>
REFILLS	
<i>Issue 5: Unauthorized Refills</i>	<i>11</i>
QUANTITY	
<i>Issue 6: Incorrect Medication Quantities</i>	<i>12</i>
OVERPAYMENTS TO INFINITY	
<i>Extrapolation</i>	<i>14</i>
CONCLUSION	15
APPENDICES	16
A <i>Sampling and Extrapolation Methodology</i>	<i>16</i>
B: <i>Audit Issues Index</i>	<i>18</i>
C: <i>Infinity Management Response Letter</i>	<i>19</i>
C: <i>Report Team and Distribution</i>	<i>21</i>
D: <i>OIG Mission, Leadership, and Contact Information</i>	<i>23</i>

AUDIT BACKGROUND

The Texas Health and Human Services (HHS) Office of Inspector General (OIG) Audit and Inspections Division has completed an audit of Infinity Pharmacy Solutions, LLC (Infinity), a Texas Vendor Drug Program (VDP) provider.

NPI Number: 1962834762

License Number: 28673

Address: 3313 Essex Drive
Suite 200
Richardson, Texas 75082

Infinity processed 22,009 Medicaid claims for dispensed prescriptions through VDP during the audit period, for which it received reimbursements of \$6.8 million.

Objectives and Scope

The audit objectives were to determine whether Infinity (a) properly billed Texas Medicaid VDP based on established VDP contract requirements and (b) complied with applicable procedure manuals published by VDP and selected Texas Administrative Code (TAC) requirements.

The audit scope included both initial fill claims and refill claims for the period from September 1, 2014, through August 31, 2017, as well as a review of relevant activities, internal controls, and information technology (IT) general controls in place through the end of fieldwork in March 2020.

Methodology

The OIG Audit and Inspections Division collected information for this audit through discussions, interviews, and electronic communications with Infinity management and staff and by reviewing:

- Supporting documentation for two samples, one of initial fill claims and one of refill claims, billed to VDP during the audit period.
- Relevant Infinity policies and procedures.
- Relevant IT general controls associated with the systems used by Infinity to process and support pharmacy claims.

For this audit, the OIG Audit and Inspections Division used two populations of paid claims with service dates ranging from September 1, 2014, through August 31, 2017. One population contained initial fill claims, and the second population contained refill claims. Two separate samples were selected for testing. One sample contained 112 initial fill claims, and the second sample contained 120 refill claims, for a total of 232 claims.

For the claims in both samples, the OIG Audit and Inspections Division tested Infinity's compliance in six areas: (a) claims validity, represented by claims documentation maintained by the provider, (b) National Drug Code (NDC) usage, (c) refills, (d) quantity, (e) controlled substances, and (f) drug acquisition. Additionally, any controlled substance (C-II) prescriptions in the selected samples were tested to determine whether written prescriptions were executed on tamper-resistant pads. This report details results, issues, and recommendations in those areas, when applicable, and the results of limited testing of IT general controls.

The OIG Audit and Inspections Division verified sampled claims against corresponding data and documentation maintained by Infinity. Based on the results of this verification, the data was considered sufficiently reliable for the purposes of this audit.

The OIG Audit and Inspections Division issued an engagement letter on September 26, 2019, to Infinity providing information about the upcoming audit, and conducted a site visit at Infinity's Richardson, Texas, facility from October 14, 2019, through October 18, 2019.

The OIG Audit and Inspections Division presented audit results, issues, and recommendations to Infinity in a draft report dated May 5, 2020. Infinity was provided with the opportunity to study and comment on the report.

Infinity agreed with the audit results. In its management responses, Infinity stated that, as of May 2020, it had taken appropriate actions to address issues identified in this report. The Infinity management responses to the audit recommendations contained in the report are included in the report following each recommendation. The full Infinity management response letter is included in Appendix C of the report.

Criteria

- Tex. Hum. Res. Code § 32.039 (2011 and 2015)
- 1 Tex. Admin. Code § 354 Subchapter F (2002 through 2016)
- 22 Tex. Admin. Code § 291 Subchapter B (2012 through 2016)

- Vendor Drug Program Pharmacy Provider Contracts # 146911 (2014) and #148527 (2016)
- Texas Vendor Drug Program Pharmacy Provider Procedure Manual, §§ 5.2 (2014 through 2016), 6.2 (2016), and 8.1 (2016 through 2017); and Chapter 5, § 4.2 (2017)
- Texas Medicaid Provider Procedures Manual, Vol. 1, § 1.1 (2014 through 2017)

Auditing Standards

Generally Accepted Government Accounting Standards

The OIG Audit and Inspections Division conducted this audit in accordance with generally accepted government auditing standards (GAGAS) issued by the Comptroller General of the United States. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the issues and conclusions based on our audit objectives. The OIG Audit and Inspections Division believes the evidence obtained provides a reasonable basis for our issues and conclusions based on our audit objectives.

ISACA (formerly known as the Information Systems Audit and Control Association)

The OIG Audit and Inspections Division performs work in accordance with the IT Standards, Guidelines, and Tools and Techniques for Audit and Assurance and Control Professionals published by ISACA.

AUDIT RESULTS

Infinity complied with TAC requirements and contractual provisions related to NDC usage, controlled substances, and drug acquisition. Selected IT general controls reviewed were in place, and the data used to form audit conclusions was sufficiently reliable for the purposes of this audit.

Infinity did not always comply with requirements related to claims validity, refills, and quantity. Details of these exceptions are included in the sections that follow.

Of the 232 claims selected for testing in statistically valid random samples, 22 total exceptions were identified associated with 20 claims. Two claims were associated with more than one exception and are included in more than one issue in this report.³ The 20 claim exceptions represent overpayments to Infinity. Table 1 summarizes the types of exceptions that are detailed in the issues that follow.

Table 1: Summary of Exceptions

Exception Type	Number of Exceptions	Total for Exceptions
Prescriptions Not Signed by the Prescriber	4 of 112	\$1,191.05
Incomplete Documentation for Transferred Prescription	1 of 112	131.77
Incorrect Prescriber Identification Numbers	8 of 232	520.99 ¹
Incorrect Prescription Issuance Date	2 of 232	15.08 ²
Unauthorized Refills	2 of 120	3,203.93
Incorrect Medication Quantities	5 of 232	200.74
Total	22³	\$5,263.56

Source: *OIG Audit and Inspections Division*

Results indicated an extrapolated overpayment amount of \$7,569.29. When calculating the estimated overpayment amount for this report, the dollar value of the errors was extrapolated across the appropriate sample population, and each claim was only counted as an exception once. Details about the claim exceptions can be found in Appendix B.

¹ This amount includes the dispensing fee of \$68.91 for one claim with two exceptions. For the purposes of this table, the full amount of \$3,184.48 is included in the unauthorized refills total amount for extrapolation.

² This amount includes the dispensing fee of \$8.37 for another claim with two exceptions. For the purposes for this table, this dispensing fee is also included in the incorrect medication quantities total amount for extrapolation.

³ Two of the 22 claims had two exceptions: one had an unauthorized refill and an incorrect prescriber and the other had an incorrect medication quantity and an incorrect prescription issuance date.

CLAIMS VALIDITY

Pharmacies participating in VDP are contractually required to maintain documents to support Medicaid claims. Claims validity is demonstrated by documentation maintained by the pharmacy. In consideration for payment under the VDP contract, participating pharmacies must comply with all applicable laws, rules, and regulations, including Texas State Board of Pharmacy (Pharmacy Board) rules and regulations in effect at the time the prescription is serviced.⁴ According to Pharmacy Board rules, a prescription or a physician order must contain several elements in order to be valid, including the (a) name of the patient, (b) address of the patient, (c) name, address, and telephone number of the practitioner at the practitioner's usual place of business, (d) name and strength of the drug prescribed, (e) quantity prescribed, (f) intended use for the drug unless the practitioner determines the furnishing of this information is not in the best interest of the patient, and (g) date of issuance.⁵

If the pharmacy (a) does not maintain or cannot produce documents to support the dispensing of the medication or (b) if any of the required elements are not documented on the face of the prescription or physician order, then the related claim is invalid and not eligible for reimbursement by VDP.⁶

Issue 1: Prescriptions Not Signed by the Prescriber

For 108 of 112 initial fill claims tested, the prescriber signed the prescriptions. For the remaining four claims, Infinity dispensed and then billed VDP for prescriptions which were not signed by the prescriber.

TAC requires pharmacies to maintain and make available for audit a prescription signed by the prescriber for each paid claim.⁷

Infinity did not follow TAC and contract requirements to maintain a signed prescription. As a result, VDP reimbursed Infinity \$1,191.05 for four unsupported initial fill claims. Details about these claims can be found in Appendix B. The amount of \$1,191.05 for the four claims is subject to extrapolation and recoupment. See the Extrapolation section of this report on page 14 for more information.

⁴ Texas State Board of Pharmacy rules are published in 22 Tex. Admin. Code, Part 15.

⁵ 22 Tex. Admin. Code § 291.34(b)(7)(A) (Sept. 8, 2013, through Dec. 19, 2016).

⁶ 1 Tex. Admin. Code § 354.1863(b) (Sept. 23, 2008, and May 15, 2016).

⁷ 1 Tex. Admin. Code § 354.1863(b) (Sept. 23, 2008, and May 15, 2016).

Recommendation 1

Infinity should ensure that prescriptions are signed by the prescriber prior to dispensing medication and billing VDP.

Management Response

Action Plan

IPS does not dispute this finding and fully agrees with the error. These 4 prescriptions were filled for a skilled nursing facility resident for which the community maintains signed physician orders on monthly basis. Because IPS quit serving this home in 2016, and because the facility has undergone ownership and several management changes since then, we were unable to obtain copies of the signed physician chart order as requested. Staff have been reeducated on process.

Responsible Manager

Chief Executive Officer and President

Target Implementation Date

May 2020

Issue 2: Incomplete Documentation for Transferred Prescription

A total of three prescriptions in the sample of 112 initial fill claims were transfers from other pharmacies. Of these, Infinity dispensed and then billed for one prescription that did not meet the requirements for a transferred prescription. Specifically, the word “transfer” was not written on the face of the prescription, and the prescription record did not indicate it was a transfer. Also, the number of refills authorized on the original prescription, the remaining refills, and the name of the individual transferring the prescription were not recorded on the prescription order or the supporting documentation provided.

For the purpose of initial and refill dispensing, TAC states that the transfer of original prescription drug order information is permissible between pharmacies if the pharmacy receiving the transferred prescription drug order ensures the following occurs:

- The word “transfer” is written on the face of the prescription or the prescription record indicates the prescription was a transfer.
- The following information is reduced to writing: (a) the date of issuance and prescription number, (b) the original number of refills authorized on the original prescription drug order, (c) the date of original dispensing, (d) the number of valid refills remaining, (e) the name and address of the transferring pharmacy, (f) the name of the individual transferring the prescription, and (g) the name and address of the pharmacy that originally dispensed the prescription, if different.⁸

Infinity did not fully document the information required by TAC for a prescription that was transferred from a different pharmacy. As a result, VDP reimbursed Infinity \$6,391.73 for the one claim missing the required information. Details about this claim can be found in Appendix B. The dispensing fee for the claim totaled \$131.77 and is subject to extrapolation and recoupment. See the Extrapolation section of this report on page 14 for more information.

Recommendation 2

Infinity should ensure that all transferred prescriptions are supported by the information required by TAC.

Management Response

Action Plan

IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff. Staff have been reeducated on process.

Responsible Manager

Chief Executive Officer and President

Target Implementation Date

May 2020

⁸ 22 Tex. Admin. Code § 291.34(g) (Sept. 8, 2013, through Dec. 19, 2016).

Issue 3: Incorrect Prescriber Identification Numbers

For 224 of 232 claims tested, the correct prescriber identification number was included when billing VDP for reimbursement. For the other eight claims, Infinity dispensed and then billed VDP for prescriptions with a prescriber identification number that was not associated with the prescriber who signed the prescription. In all eight instances, the prescriber listed on the prescription had a unique national provider identification (NPI) number that Infinity should have included with the claims.

Pharmacies are required to include the prescriber's identification number, as listed with the appropriate medical specialty board, on each claim submitted for payment.⁹

Pharmacies are required to submit claims using the NPI number of the prescribing provider or the supervising prescriber where applicable. For prescriptions written by physician assistants, advance practice registered nurses, or prescribing pharmacists that do not have an NPI number, the supervising prescriber's NPI number will be accepted.¹⁰

Infinity did not follow TAC and program manual requirements, which require VDP claims to be paid only when the prescriber number is associated with the physician who signs a prescription. As a result, VDP reimbursed Infinity \$24,281.53 for eight claims with incorrect prescriber identification numbers. The dispensing fees for seven of the eight claims totaled \$452.08 and are subject to extrapolation and recoupment. The full overpayment amount of \$3,184.48 associated with the remaining claim was identified in Issue 5.¹¹ Details about these claims can be found in Appendix B. See the Extrapolation section of this report on page 14 for more information.

Recommendation 3

Infinity should ensure that all claims it submits to VDP for reimbursement contain a prescriber identification number associated with the physician who signed the prescription.

⁹ 1 Tex. Admin. Code § 354.1835 (Sept. 1, 2001, and May 15, 2016).

¹⁰ Texas Vendor Drug Program Pharmacy Provider Procedure Manual, §§ 5.2 (Feb. 11, 2014, through Mar. 1, 2016), 6.2 (Apr. 1, 2016), and 8.1 (July 1, 2016, through May 1, 2017); and Chapter 5, § 4.2 (June 1, 2017, through Aug. 1, 2017).

¹¹ The overpayment amount is included in the extrapolation amount for Issue 5. As a result, the overpayment amount of \$3,184.48 is not included for extrapolation in Issue 3.

Management Response

Action Plan

IPS does not dispute this finding and fully agrees with the error as the HHSC VDP rules require. IPS does maintain that all prescriptions were fully compliant with Texas State Board of Pharmacy Rules and Regulations, as the prescriptions were filled under the prescriber for which the PA or NP was working. Staff have been reeducated on process.

Responsible Manager

Chief Executive Officer and President

Target Implementation Date

May 2020

Issue 4: Incorrect Prescription Issuance Date

For 230 of the 232 claims tested, the correct prescription issuance date was included when billing VDP for reimbursement. For the other two claims, Infinity dispensed and then billed VDP for prescriptions with an incorrect prescription issuance date.

Claims data submitted by or on behalf of Infinity (a) must be true, complete, and accurate, (b) must be verified by reference to source documentation maintained by Infinity, and (c) are subject to audit in accordance with the Texas Vendor Drug Program Pharmacy Provider Procedure Manual.^{12,13}

Infinity did not follow TAC and contract requirements, which require VDP claims to be paid only when the claim information matches the supporting documentation, including the prescription date. As a result, VDP reimbursed Infinity \$26.06 for two claims with incorrect issuance dates.

The dispensing fee for one of the two claims totaled \$6.71 and is subject to extrapolation and recoupment. The dispensing fee associated with the remaining claim in the amount of \$8.37 was identified in Issue 6 and included in the extrapolation amount for that issue. Details about these claims can be found in

¹² Vendor Drug Program Pharmacy Provider Contract #146911, Part 2(G) (June 9, 2014), and #148527, Part 3(F) (May 5, 2016).

¹³ The Texas Vendor Drug Program Pharmacy Provider Procedure Manual underwent several name changes during the audit scope.

Appendix B and extrapolation information can be found in the Extrapolation section of this report on page 14.

The OIG Audit and Inspections Division verified that the recipients did not receive medication beyond the correct expiration date by reviewing the prescription numbers' claim history.

Recommendation 4

Infinity should ensure that all claims it submits to VDP for reimbursement contain the correct prescription issuance date as written on the prescription by the prescribing physician.

Management Response

Action Plan

IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff. Staff have been reeducated on process.

Responsible Manager

Chief Executive Officer and President

Target Implementation Date

May 2020

REFILLS

TAC requires explicit authorization from the prescribing physician for medication refills.¹⁴ On the original prescription, the physician may authorize no refills or designate the number of refills allowed. Dispensing a refill without authorization or without maintaining documentation is an error and not eligible for reimbursement. Prescription refills must be properly authorized to prevent overmedication of patients, fraud, waste, or abuse.

An individual who fails to maintain documentation to support a claim for payment in accordance with requirements is liable for either the amount paid or an administrative penalty.¹⁵

¹⁴ 1 Tex. Admin. Code § 354.1867 (June 9, 2010).

¹⁵ Tex. Hum. Res. Code §§ 32.039(b)(3) and 32.039(b-1) (Sept. 1, 2011, and Apr. 2, 2015).

All refills are counted when determining compliance with the authorized refill limitation. In the absence of specific refill instructions, the prescription must be interpreted as not refillable. If a prescription notes specific refill instructions, any future prescriptions dispensed must be considered refills of the original prescription unless the prescriber has been contacted for authorization to dispense a new supply of medication. If authorization is granted, a new and separate prescription is prepared.¹⁶

Issue 5: Unauthorized Refills

For 2 of the 120 claims tested for the refill population, Infinity was unable to provide documentation authorizing the refill that was dispensed and then billed.

Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order.¹⁷ Further, the provider must submit claims information that is complete, accurate, and supported.^{18,19}

For these two claims, Infinity did not follow TAC and contract requirements, which require VDP claims to be paid only when refills are authorized on a prescription or authorization is obtained from the prescribing physician and documented prior to dispensing a refill.

As a result, VDP reimbursed Infinity \$3,203.93 for two unauthorized refill claims. The amount of \$3,203.93 for the two claims is subject to extrapolation and recoupment. Details about these unauthorized claims can be found in Appendix B. See the Extrapolation section of this report on page 14 for more information.

Recommendation 5

Infinity should ensure refills are authorized on a prescription or obtain authorization from the prescribing physician prior to dispensing a refill.

Management Response

Action Plan

IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff on documenting the verbal authorization when speaking to clinic. Staff has been reeducated on process.

¹⁶ 1 Tex. Admin. Code § 354.1867 (June 9, 2010).

¹⁷ 22 Tex. Admin. Code § 291.34(b)(8)(A)(i) (Sept. 8, 2013, through Dec. 19, 2016).

¹⁸ Vendor Drug Program Pharmacy Provider Contract #146911, Part 2(G)(1) (June 9, 2014).

¹⁹ Vendor Drug Program Pharmacy Provider Contract #148527, Part 3(F)(1) (May 5, 2016).

Responsible Manager*Chief Executive Officer and President*Target Implementation Date*May 2020***QUANTITY**

Pharmacists may dispense a different quantity of medication than ordered by the prescribing physician as long as the prescribing physician is contacted and authorizes the change, which must be documented by the pharmacy. Quantity changes made to comply with Medicaid limitations for reimbursement purposes do not override the pharmacist's obligation to obtain the prescriber's authorization for quantity changes.

Issue 6: Incorrect Medication Quantities

For 227 of 232 claims tested, the correct medication quantities were dispensed and billed to VDP for reimbursement. For the other five claims tested, Infinity dispensed and then billed VDP for a different quantity of medication than was ordered, without documented authorization from the prescribing physician. The quantity dispensed exceeded the prescribed amount in one of the five claims, while the other four claims involved quantity decreases.

Prescriptions must be dispensed in accordance with the prescriber's authorization as indicated on the original prescription drug order including clarifications to the order given to the pharmacist by the practitioner or the practitioner's agent and recorded on the prescription.²⁰

Infinity did not follow TAC requirements, which require VDP claims to be paid only when changes in quantity are properly authorized by the prescribing physician and documented prior to dispensing. As a result, VDP reimbursed Infinity \$6,931.28 for five claims that were not properly authorized. Details about these unauthorized claims can be found in Appendix B.

The one claim with a quantity increase is subject to extrapolation and recoupment for the full amount of \$36.62. The dispensing fee amount of \$164.12 for the other four unauthorized claims with quantity decreases is subject to extrapolation and recoupment. The total combined amount subject to extrapolation and recoupment

²⁰ 22 Tex. Admin. Code § 291.34(b)(6)(A) (Sept. 8, 2013, through Dec. 19, 2016).

for incorrect medication quantities is \$200.74. See the Extrapolation section of this report on page 14 for more information.

Although TAC requires prescriptions to be dispensed as authorized by the practitioner, in general practice and with approval of the Pharmacy Board, pharmacists only need to obtain the prescriber's authorization when dispensing a quantity greater than the quantity indicated on the face of the prescription, not when dispensing less. According to a letter received from the executive director of the Pharmacy Board dated February 20, 2018,²¹ "the Board will be considering amending its rules to clarify that a pharmacist may dispense less than prescribed at the request of the patient or the patient's agent at a future Board meeting."

Pharmacies are paid a professional dispensing fee as compensation for the administrative effort required to fill a Medicaid prescription. Infinity did not follow TAC or VDP rules when processing identified claims. In recognition of this, the OIG Audit and Inspections Division determined the professional dispensing fees are recoupable for the unauthorized quantity decreases.

Recommendation 6

Infinity should ensure that any changes in the quantity dispensed from the quantity prescribed are both authorized by the prescribing physician and documented prior to dispensing.

Management Response

Action Plan

IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff on documenting the verbal authorization when speaking to clinic. Staff has been reeducated on process. IPS understands the disparity between TAC prescription requirements and State Board of Pharmacy requirements and standards of practice on quantity reductions, and looks forward to the TAC rules being updated to be in alignment.

Responsible Manager

Chief Executive Officer and President

Target Implementation Date

May 2020

²¹ Letter from Texas State Board of Pharmacy Executive Director to HHS Inspector General (Feb. 20, 2018).

OVERPAYMENTS TO INFINITY

Overpayments identified for the sample of claims were used to calculate an error rate, which was applied to the population of all claims using extrapolation. See Appendix A for the sampling and extrapolation methodology.

Extrapolation

The populations included in this audit consisted of 22,009 fee-for-service VDP claims from September 1, 2014, through August 31, 2017, for which HHSC paid Infinity \$6,778,454.80. Two statistically valid samples were selected that included a total of 232 claims for which HHSC paid Infinity \$517,391.45.

The 20 claims with 22 exceptions are detailed in Issues 1 through 6. The dollar value of a claim is only included once in the extrapolation.

Issue 1	\$1,191.05
Issue 2	131.77
Issue 3	452.08
Issue 4	6.71
Issue 5	3,203.93
Issue 6	<u>200.74</u>
Total	\$5,186.28

The estimated overpayment amount was calculated by extrapolating the dollar value of the errors across the appropriate sample population. By extrapolating the results to both populations of claims within the scope of the audit, OIG determined that the exceptions represented an overpayment for the population of \$7,569.29. The overpayment was calculated using the lower limit of a two-sided 80 percent confidence interval.

Therefore, based on the results of this audit, Infinity should return the extrapolated overpayment amount of \$7,569.29 to the State of Texas.

CONCLUSION

Infinity complied with TAC and contract provisions related to NDC usage, controlled substances, and drug acquisition. Selected IT general controls reviewed were in place, and the data used to form audit conclusions was sufficiently reliable for the purposes of this audit.

The OIG Audit and Inspections Division noted 22 exceptions related to claims validity, refills, and quantity. For those claims, Infinity did not bill VDP properly or comply with TAC requirements, contractual provisions, and program manuals. The 20 claims with 22 exceptions resulted in overpayments of \$5,186.28 subject to extrapolation and recoupment. The total amount due to the State of Texas is \$7,569.29.

The OIG Audit and Inspections Division offered recommendations to Infinity, which, if implemented, will correct deficiencies in compliance with TAC requirements, contractual provisions, and program manuals. In its management response, Infinity Pharmacy Solutions, LLC indicated corrective actions had been implemented by May 2020.

The OIG Audit and Inspections Division thanks management and staff at Infinity for their cooperation and assistance during this audit.

Appendix A Sampling and Extrapolation Methodology

Statistical Sampling

The OIG Data and Technology Division provided data for testing. It was administratively infeasible to review every claim in the population; therefore, the OIG Audit and Inspections Division selected a sample of 112 initial fill claims and a sample of 120 refill claims to test for a total of 232 claims. The following query parameters are provided for replication purposes.

Two item detailed queries were run in the Xerox Pharmacy Claims Data Warehouse using the Texas VDP PBM Universe table. The data sets included only fee-for-service paid claims for the audit scope. One data set included only initial fill paid claims and the second data set included only refill paid claims.

Query Result Objects field names included:

Prescription Number	Last Name (client)
First Name (client)	Participant ID
Drug Name	Drug Strength
Quantity	Days Supply
Nbr of Refills Authorized	Refill Number
Date of Service	Date Prescribed
Date Paid	Total Reimbursed Amount
DAW Code	NDC
Drug Class Code	Client Mailing Address Line 1
Birth Date (client)	Compound Code
DEA Code	Basis of Cost Determination
Basis of Reimbursement	Basis of Reimbursement Descr.
Prescriber ID	NPI (prescriber)
Prescriber Name	Batch Doc. Type Code
Group ID (client)	Tx Status Code
TPL Amt	Pharmacy ID
TCN	Pharmacy Name
Claim Line Number	Unlimited Drug Indicator
Allowed Ingredient Amount	Dispensing Fee Amount

Query Filters Included:

- Date of Service (between 09/01/2014, to 08/31/2017)
- TX Status Code (equal to PD)
- Batch Doc. Type Code (equal to A;C)
- Group ID (equal to V)

- Pharmacy ID (equal to [REDACTED])
- TPL Amt Less than or Equal to (0)

Extrapolation

OIG provided Infinity with an extrapolation detail file at the same time as the draft audit report. The extrapolation detail file contains information about the data and methods used to determine the overpayment in sufficient detail, so the extrapolation results may be demonstrated to be statistically valid and are fully reproducible.

The extrapolation detail file contains the (a) population of claims, (b) sample frame, including sample size determination, (c) seed value for random number generation, (d) extrapolation validation, and (e) results printout from the RAT-STATS software. The populations used for extrapolation included in this audit consisted of initial fill and refill claims with dispensing dates between September 1, 2014, and August 31, 2017. The estimated overpayment amount of \$7,569.29 was calculated by extrapolating the dollar value of the errors as identified in Appendix B across the appropriate population for initial fills or refills for this audit at the time of the final report. The overpayment was calculated using the lower limit of a two-sided 80 percent confidence interval.

Infinity was kept apprised of all aspects of the audit process and, in order to ensure audit findings were accurate, was offered multiple opportunities to provide relevant documentation and information.

Opportunities to provide relevant documentation extended to the draft audit report stage. After receiving the draft report, Infinity did provide additional relevant documentation or other sufficient evidence that would support the removal of some identified errors on which the overpayment in the draft report was based. Errors were removed based on sufficient additional evidence being provided at the draft report stage, the overpayment amount was recalculated, and a new extrapolation amount is provided with the final report.

The Texas Legislature has recognized HHS OIG's authority to utilize a peer-reviewed sampling and extrapolation process. HHS OIG has formally adopted RAT-STATS software as the statistical software to be utilized for the extrapolation process to be consistent with the Office of Inspector General for the United States Department of Health and Human Services. The Association of Inspectors General concluded a peer review of this process on January 7, 2016, and opined that OIG met all relevant policies, procedures, and AIG standards for the period under review.

Appendix B: Audit Issues Index

The table below provides details about the claims filed and paid in error for the following issues discussed in the report.

Issue 1:	Prescription Not Signed
Issue 2:	Improper Transfer of Prescription
Issue 3:	Incorrect Prescriber Identification Numbers
Issue 4:	Incorrect Prescription Issuance Date
Issue 5:	Unauthorized Refill
Issue 6:	Incorrect Medication Quantities

Sample Number	Prescription Number	Fill Date	Issue Number	Claim Amount
IF-4	██████	██████/2014	1	\$1,155.81
IF-7	██████	██████/2014	1	12.60
IF-8	██████	██████/2015	1	11.13
IF-12	██████	██████/2015	1	11.51
IF-77	██████	██████/2016	2	131.77
IF-1	██████	██████/2014	3	7.35
IF-95	██████	██████/2016	3	0.00 ²²
RF-3	██████	██████/2014	3	7.12
RF-6	██████	██████/2015	3	156.26
RF-23	██████	██████/2015	3	20.26
RF-65	██████	██████/2016	3,5	3,184.48
RF-69	██████	██████/2016	3	131.77
RF-78	██████	██████/2016	3	129.32
IF-79	██████	██████/2016	4	6.71
IF-110	██████	██████/2017	4,6	8.37
RF-82	██████	██████/2016	5	19.45
IF-71	██████	██████/2016	6	131.20
IF-96	██████	██████/2016	6	36.62
RF-57	██████	██████/2015	6	14.68
RF-120	██████	██████/2016	6	9.87
Total	—	—	—	\$5,186.28

Source: OIG Audit and Inspections Division

²² The cost of the medication dispensed was \$19.76; however, for Issue 3, the extrapolation amount was based on the dispensing fee. For this prescription, a dispensing fee was not paid to Infinity; therefore, the claim amount was \$0.00.

Appendix C: Infinity Pharmacy Management Response Letter



Infinity Pharmacy Solutions
3313 Essex Drive, Suite 200
Richardson, Texas 75082
214-765-5456

Management Response to Audit Results and Action Plan.

June 4, 2020

Steve E. Sizemore, CIA, CISA, CGAP
Audit Director
Texas Health and Human Services Commission (HHSC)
Office of Inspector General, Audit Division
P.O. Box 85200
Austin, Texas 78708-5200

Dear Mr. Sizemore:

The following responses are presented in connection with your audit of Infinity Pharmacy Solutions, LLC (IPS) for specifically, the period of September 1, 2014 through August 31, 2017.

All Action Plans have been completed and staff reeducated on required processes and procedures for compliance.

1. Prescriptions Not Signed by Prescriber

- a.* IPS does not dispute this finding and fully agrees with the error. These 4 prescriptions were filled for a skilled nursing facility resident for which the community maintains signed physician orders on monthly basis. Because IPS quit serving this home in 2016, and because the facility has undergone ownership and several management changes since then, we were unable to obtain copies of the signed physician chart order as requested. Staff have been reeducated on process.

2. Incomplete Documentation for Transferred Prescription

- a.* IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff. Staff have been reeducated on process.

3. Incorrect Prescriber Identification Numbers

- a.* IPS does not dispute this finding and fully agrees with the error as the HHSC VDP rules require. IPS does maintain that all prescriptions were fully compliant with Texas State Board of Pharmacy Rules and Regulations, as the prescriptions were filled under the prescriber for which the PA or NP was working. Staff have been reeducated on process.

4. Incorrect Prescription Issuance Date

- a.* IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff. Staff have been reeducated on process.

5. Unauthorized Refills

- a.* IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff on documenting the verbal authorization when speaking to clinic. Staff has been reeducated on process.

6. Incorrect Medication Quantities

- a.* IPS does not dispute this finding and fully agrees with the error. It was a lack of proper documentation from our staff on documenting the verbal authorization when speaking to clinic. Staff has been reeducated on process. IPS understands the disparity between TAC prescription requirements and State Board of Pharmacy requirements and standards of practice on quantity reductions, and looks forward to the TAC rules being updated to be in alignment.



06/04/2020

Signature (owner or pharmacist in charge)

Date signed

Appendix C: Report Team and Distribution

Report Team

The OIG staff members who contributed to this audit report include:

- Audrey O’Neill, CIA, CFE, CGAP, Chief of Audit and Inspections
- Kacy J. VerColen, CPA, Assistant Deputy Inspector General of Audit and Inspections
- Steve Sizemore, CIA, CISA, CGAP, Audit Director
- Lisa Kanette Blomberg, CPA, CIGA, Audit Manager
- Maria M. Johnson, CFE, Audit Project Manager
- Carol Barnes, CIGA, Staff Auditor
- Emery Hizon, CIGA, Staff Auditor
- Ashley Rains, CFE, Senior Audit Operations Analyst

Report Distribution

Health and Human Services

- Phil Wilson, Acting Executive Commissioner
- Victoria Ford, Acting Chief Operating Officer and Chief Policy and Regulatory Officer
- Karen Ray, Chief Counsel
- Michelle Alletto, Chief Program and Services Officer
- Nicole Guerrero, Director, System Internal Audit
- Stephanie Stephens, State Medicaid Director, Medicaid and CHIP Services
- Katherine Scheib, Deputy Associate Commissioner, Medicaid and CHIP Services
- Gina Marie Muniz, Director, Vendor Drug Program, Medicaid and CHIP Services

Infinity Pharmacy Solutions, LLC

- Doug Smock, Chief Executive Officer and President
- Joshua Keller, Pharmacist in Charge

Appendix D: OIG Mission, Leadership, and Contact Information

The mission of OIG is to prevent, detect, and deter fraud, waste, and abuse through the audit, investigation, and inspection of federal and state taxpayer dollars used in the provision and delivery of health and human services in Texas. The senior leadership guiding the fulfillment of OIG's mission and statutory responsibility includes:

- Sylvia Hernandez Kauffman, Inspector General
- Susan Biles, Chief of Staff
- Dirk Johnson, Chief Counsel
- Christine Maldonado, Chief of Operations and Workforce Leadership
- Juliet Charron, Chief of Strategy
- Mike Thomas, Interim Chief of Investigations
- Steve Johnson, Chief of Medicaid Program Integrity

To Obtain Copies of OIG Reports

- OIG website: <https://oig.hhsc.texas.gov>

To Report Fraud, Waste, and Abuse in Texas HHS Programs

- Online: <https://ReportTexasFraud.com>
- Phone: 1-800-436-6184

To Contact OIG

- Email: OIGCommunications@hhsc.state.tx.us
- Mail: Texas Health and Human Services
Office of Inspector General
P.O. Box 85200
Austin, Texas 78708-5200
- Phone: 512-491-2000