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December 19, 2019

BY ELECTRONIC MAIL

Mr. Joshua Lieberman, President
Ortho-Step, Inc.
105 River Ave, Suite 103
Lakewood, New Jersey 08701

Re: Final Audit Report: Ortho-Step, Inc.

Dear Mr. Lieberman:

As part of its oversight of the Medicaid and New Jersey FamilyCare program (Medicaid), the New Jersey Office of the State Comptroller, Medicaid Fraud Division (OSC) conducted an audit of Ortho-Step, Inc.'s (Ortho-Step) claims submitted under National Provider Identification Number [REDACTED] and Medicaid Provider Number [REDACTED] for the period of January 1, 2013 through December 31, 2017 (audit period). OSC hereby provides you with this Final Audit Report.

Executive Summary

OSC conducted an audit of Ortho-Step to determine whether its paid Medicaid claims complied with applicable state and federal law and regulations and Managed Care Organization (MCO) policies. Ortho-Step is a family owned orthopedic shoe store and Durable Medical Equipment (DME) provider located in Lakewood, New Jersey. During the audit period, Ortho-Step submitted 91,161 Medicaid claims resulting in payments totaling \$13,479,024. The audit findings were based on a sample of 68 randomly selected Medicaid beneficiaries for which Ortho-Step submitted and was paid for 914 claims during the audit period.

Both after the preliminary audit findings and the Draft Audit Report, Ortho-Step submitted written arguments and documents challenging OSC's findings, methodology, and its overpayment determination. OSC reviewed these submissions and, as explained in more detail below, modified its preliminary findings to give credit for claims where

Ortho-Step submitted contemporaneous documentation to justify the claims and rejected the remaining arguments/documentation.

In sum, OSC determined that for 673 of the 914 claims in the sample, Ortho-Step violated *N.J.A.C. 10:49-9.8* by not disclosing fully the goods/services (hereafter referred to only as services) provided, and/or by inaccurately billing Healthcare Common Procedure Coding System (HCPCS)/Current Procedural Terminology (CPT) codes. The identified overpayments include claims that were not adequately supported by prescribing practitioner (physician) orders or customer invoices, as well as claims that were overbilled and upcoded. OSC found that these issues extended across every category of DME and related medical supplies reviewed. Specifically, OSC determined that 673 claims totaling \$111,501 lacked adequate supporting documentation and, thus, were paid in error. After extrapolating the findings to the universe of claims, OSC determined that Ortho-Step received overpayments totaling \$7,265,776 that it must repay to the Medicaid program.

Background

Ortho-Step, a family owned orthopedic shoe store and DME provider located in Lakewood, New Jersey, was established in 2004. The facility is licensed by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC).

The New Jersey Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) contracts with five MCOs to administer the provision of health care services to Medicaid beneficiaries in New Jersey. That contract requires MCOs and their network providers to adhere to applicable federal and state laws and regulations. UnitedHealthCare (UHC) is one of five MCOs under contract with the state and the MCO through which Ortho-Step submitted the vast majority (97 percent) of its Medicaid claims. In addition to having to comply with applicable federal and state laws and regulations, as a provider within the UHC MCO network, Ortho-Step must adhere to UHC's policies. According to *N.J.A.C. 10:49-9.8*, providers must "keep such records as are necessary to disclose fully the extent of services provided." In the DME context, providers, at a minimum, must maintain a legible, dated prescription for the item that is signed by the prescribing practitioner and references the item prescribed. *See N.J.A.C. 10:59-1.5* and UHC Coverage Determination Guideline for durable medical equipment, orthotics, ostomy supplies, medical supplies and repairs/replacements (UHC Policy).

DME is defined by *N.J.A.C. 10:59-1.2* as "an item or apparatus, other than hearing aids and certain prosthetic and orthotic devices . . . which . . . is primarily and customarily prescribed to serve a medical purpose and is medically necessary . . . is not useful to a beneficiary in the absence of a disease, illness, injury or disability and is capable of withstanding repeated use" Under a generally accepted definition, an orthotic appliance is a device or a brace used to provide support, increased function, and to overcome physical impairment or defects. Similarly, a prosthetic appliance is a functional replacement, corrective, or supportive device. In general, prosthetics artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.

Pursuant to UHC Policy, DME and orthotics are deemed medically necessary when (i) ordered by a physician, (ii) the item meets UHC’s medical necessity definition, (iii) the item is consistent with the state definition of DME or orthotics, and (iv) the item meets the criteria for DME Medicare Administrative Contracts established by the Centers for Medicare and Medicaid Services (CMS). Similarly, according to *N.J.A.C. 10:59-1.5*, to seek payment for validly dispensed DME, the DME provider must possess a legible, dated prescription or a Certificate of Medical Necessity signed by the prescribing practitioner.

During the audit period, Ortho-Step received \$13,479,024 in Medicaid payments through 91,161 claims. Ortho-Step’s claims were primarily for compression stockings, orthopedic shoes, shoe inserts, and breast pumps. Table I provides a breakdown of Ortho-Step’s claims by item, dollar amount, number of claims, and percentage of claims.

Table I
Total Billings and Claims Paid
for DME/Medical Supplies

Item Description	Dollar Amount	Number of claims	% of the Total
Compression Stockings	3,877,712	14,379	29
Orthopedic Shoes	3,899,733	32,974	29
Shoe Inserts	3,755,027	33,090	28
Breast Pumps	1,517,450	4,133	11
Other	429,102	6,585	3
Total	\$13,479,024	91,161	100%

Prescription compression stockings are custom-made or custom-fitted pressure gradient support stockings that help to reduce edema and control vascular disorders. Compression stockings are available in different pressure gradients (18-30 mmHg, 30-40 mmHg, and 40-50 mmHg) and come in a variety of lengths, which include knee-length, thigh-length, and waist-length. The HCPCS codes billed by Ortho-Step are dependent on the pressure gradient and length. For example, HCPCS codes A6539 and A6540 are both waist-length but have a pressure gradient of 18-30mmHg and 30-40mmHg, respectively. A listing of the HCPCS codes billed by Ortho-Step can be found in Exhibit A.

Orthopedic shoes prevent or correct foot deformities by providing arch support, holding the foot in an upright position, and permitting the addition of assistive devices. The American Medical Association (AMA) lists over 30 HCPCS codes under orthopedic footwear. Ortho-Step primarily billed four codes: L3216, L3221, L3230, and L3250.

Codes L3216 and L3221 cover depth inlay shoes for female and male patients, respectively. These shoes have a full-length heel-to-toe filler that, when removed, provides additional depth used to accommodate custom molded or customized inserts.

Codes L3230 and L3250 are used for custom shoes.¹ Code L3230 covers the supply of a custom-made depth inlay shoe to accommodate a deformed foot. Code L3250 covers the supply of a custom-made prosthetic shoe with a removable inner mold or insert which helps patients with a toe amputation or distal foot amputation.

Shoe inserts are total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot to correct foot function and minimize stress. Ortho-Step primarily billed shoe inserts using the following codes: L3010, L3020, and L3030. Codes L3010 and L3020 cover the supply of a removable foot insert custom fabricated from a model of the patient's foot. L3030 covers the supply of a removable foot insert formed directly against the patient's foot.

Breast pumps are mechanical devices that a lactating mother uses to extract breast milk. Breast pumps can be manual, electric, or hospital grade and are coded as E0602, E0603, or E0604, respectively. Manual breast pumps are powered by the individual user and electric breast pumps are powered by an external electric source. Hospital grade breast pumps are for multi-patient use in a hospital setting.

Objective

The objective of the audit was to determine whether claims submitted by Ortho-Step complied with Medicaid requirements under applicable state and federal laws and regulations.

Audit Scope

The audit scope entailed a review of Ortho-Step's Medicaid claims for medical supplies and DME from January 1, 2013 through December 31, 2017. This audit was conducted pursuant to OSC's authority as set forth in *N.J.S.A. 52:15C-23* and the *Medicaid Program Integrity and Protection Act, N.J.S.A. 30:4D-53 et seq.*

Audit Methodology

To achieve the audit objective, OSC reviewed a statistically valid random sample of 68 Medicaid beneficiaries and the 914 claims associated with these beneficiaries that Ortho-Step billed and received payment for during the audit period.

OSC's methodology consisted of the following:

¹ According to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Quality Standards, a custom fabricated item (including shoes and inserts) is one that individually is made for a specific patient from raw materials based on clinically derived casting, tracing, measurements, and/or other images of body parts. No patient other than the one for whom the item was fabricated would be able to use the item.

- Selecting a sample of 68 Medicaid beneficiaries and the 914 claims associated with these beneficiaries totaling \$176,654 billed by Ortho-Step during the audit period.
- Reviewing Ortho-Step’s records supporting the 914 claims to determine whether the documentation complied with the requirements of *N.J.A.C. 10:49-9.8* and *N.J.A.C. 10:49-5.5*. See also *N.J.A.C. 10:59-1.2, -1.4, -1.5* and UHC policies.

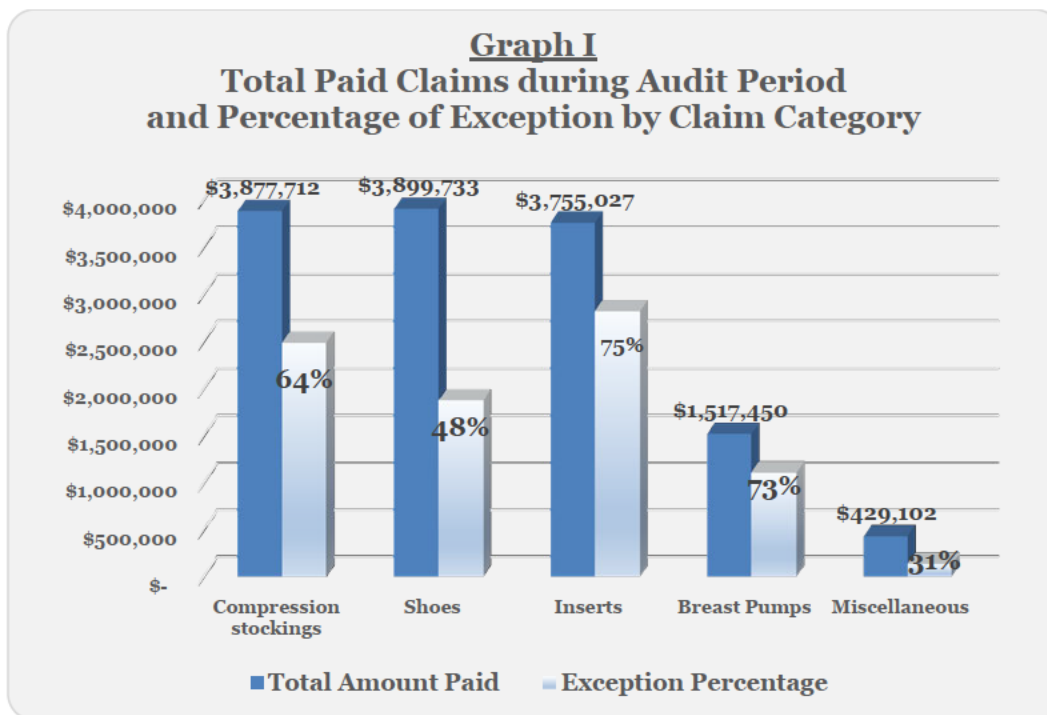
Audit Findings

OSC reviewed 914 Medicaid claims submitted by Ortho-Step between January 1, 2013 and December 31, 2017. The 914 claims were comprised of compression stockings, shoe inserts, orthopedic shoes, breast pumps, and other miscellaneous items. OSC determined that for 673 of the 914 claims, totaling \$111,501 out of a universe of \$176,654, Ortho-Step violated *N.J.A.C. 10:49-9.8* by not fully disclosing the services provided, and/or by inaccurately billing Healthcare Common Procedure Coding System (HCPCS)/Current Procedural Terminology (CPT) codes. See Attachment 8 for the testing results summary and Table II for total exceptions (*i.e.*, claims that failed to meet the audit criteria) by claim category.

**Table II
 Exceptions by Category**

Claim Category	Number of Sampled Claims	Sampled Claim Dollar Amount	Number of Claims with Exceptions	Claim Exception Dollar Amount
Compression Stockings	342	98,237	276	62,688
Shoe Inserts	243	29,255	195	22,042
Orthopedic Shoes	240	30,777	144	14,719
Breast Pumps	38	15,120	33	11,040
Miscellaneous	51	3,265	25	1,012
Total	914	\$176,654	673	\$111,501

OSC extrapolated the sample results to their respective universe of claims to determine the total overpayment amount. Based on this extrapolation, OSC determined that the total overpayment is \$7,265,776. Specific exceptions will be addressed in the following sections. See Graph I below for a representation of error rate (*i.e.*, exceptions) for each claim category and the total dollar amount of Medicaid claims paid for each category.



A. Compression Stockings

OSC reviewed 342 claims for compression stockings. These claims included HCPCS codes A6530, A6533, A6534, A6537, A6539 and A6540. The different HCPCS codes denote various compression levels and stocking designs (*i.e.*, waist, thigh, or knee length). Virtually all (99 percent) of the claims in the sample were for A6539 and A6540, waist-length compression stockings. OSC found that 276 of 342 claims reviewed were in violation of *N.J.A.C.* 10:49-9.8. These exceptions total \$62,688 out of the universe of \$98,237 paid claims sampled. However, due to the reasons explained in further detail below, OSC determined that \$20,874 of the \$62,688 constituted non-monetary findings, leaving \$41,814 of the \$62,688 as monetary findings. See Table III for a breakdown by exception.

Table III
Compression Stockings Exceptions

Exception	Monetary Findings		Non-Monetary Findings	
	Number of Claims	Claim Dollar Amount	Number of Claims	Claim Dollar Amount
No Physician Order	53	14,634		
Inadequate Physician Order	78	23,313		
No Invoice	13	3,868		
Overbilling			129	21,101
Underbilling			3	(228)
Total	144	\$41,814	132	\$20,874

Monetary Findings

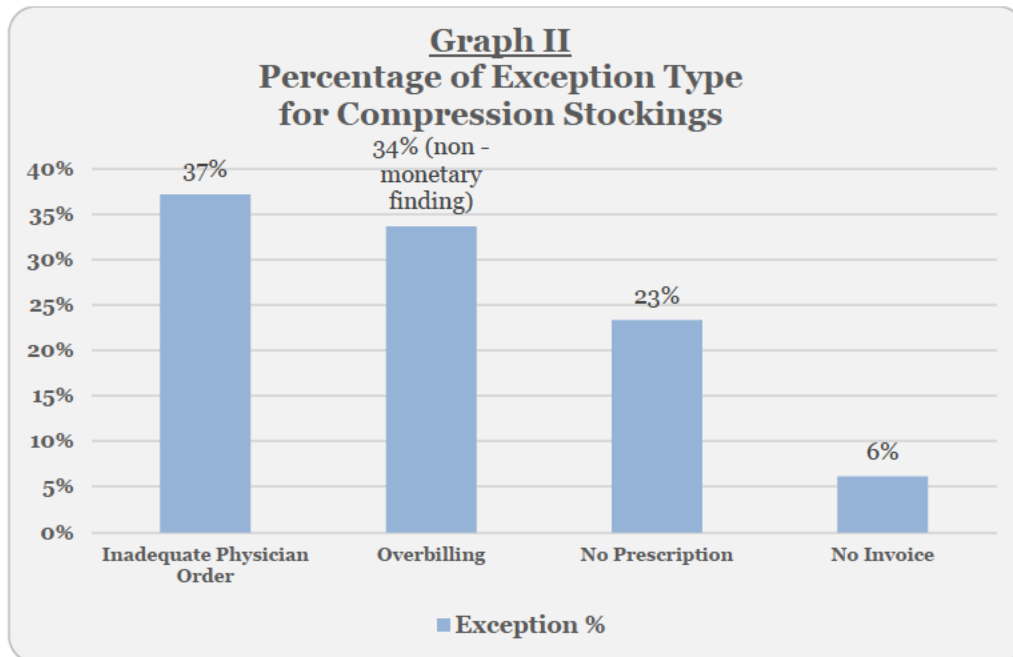
According to *N.J.A.C. 10:49-9.8*, claims must be true, accurate, and complete and the records supporting such claims must disclose fully the extent of services provided. Pursuant to the relevant UHC Policy, DME, related supplies, and orthotics are covered when an item is ordered by a prescribing practitioner.

OSC found that for 53 claims there was no evidence that the compression stockings were ordered by a physician. OSC found that 78 claims were in error because the ordering physician could not be identified, and/or the prescriptions lacked a date, physician signature, or a description of the item prescribed. At a minimum, these elements are needed to ensure that the physician orders are legitimate, correspond to the claim being billed, and meet the record keeping requirement set forth in *N.J.A.C. 10:49-9.8*. OSC identified 13 instances where a claim had a valid physician's order but no customer invoice to indicate that the customer actually received the prescribed item. These claims totaled \$41,814.

As an example of one of the 78 deficient physician orders, Ortho-Step included a physician order form dated April 9, 2014 to support billing six pairs of 30-40mmHg waist-length compression stockings under HCPCS code A6540, totaling \$455.04. While the order form included the Medicaid beneficiary's name, date, diagnosis (varicose veins), and indicated that three pairs of "pantyhose" were to be provided along with three refills, the prescription did not include a physician's name or license number. Therefore, OSC could not rely on the form because it did not indicate who prescribed the item and whether the prescriber was authorized to do so.² Attachment 1.

In addition to the deficient claims noted above, OSC also identified 48 claims totaling \$14,302 that were not supported by customer invoices indicating that the beneficiary received the item prescribed. OSC excluded those claims from its overpayment analysis, however, because these claims were already cited for not having a physician's order or an inadequate physician's order. *See* Graph II below for the error rates for each exception type for the compression stockings category.

² Moreover, Ortho-Step did not provide a customer invoice, but rather provided a cash register receipt. This receipt showed that the Medicaid beneficiary paid \$394 in cash for these items; however, based on the provider agreement, Medicaid providers are prohibited from charging Medicaid beneficiaries and accepting Medicaid reimbursement as payment in full.



Non-Monetary Findings

In addition to the deficiencies relating to a lack of proper documentation, Ortho-Step also overbilled Medicaid by charging for more units than were provided to the beneficiary and/or were ordered by the physician. OSC identified 129 instances where a claim was accompanied by a valid physician order and a customer invoice; however, Ortho-Step billed for more items than prescribed by the physician or dispensed to the beneficiary. Within the audit sample, Ortho-Step overbilled Medicaid for 309 pairs of compression stockings, averaging \$68 per pair. For instance, a physician's prescription dated May 14, 2013 called for two pairs of waist-length compression stockings. Ortho-Step's documentation showed that on that same date the beneficiary picked up six pairs of waist-length compression stockings from Ortho-Step, which is four more than the physician prescribed. Ortho-Step submitted a claim and was paid for six pairs of waist-length compression stockings, resulting in an overpayment of \$303. *See Attachment 2.*

Another example follows a similar fact pattern. The same beneficiary as discussed above obtained an order dated August 13, 2013 for three pairs of compression stockings. As with the example above, despite an order calling for three pairs of compression stockings, Ortho-Step submitted a claim and was paid for six pairs of compression stockings, resulting in an overpayment of \$228. *See Attachment 3.* It should be noted that the next day (August 16, 2013) Ortho-Step billed for an additional two pairs for this same beneficiary with no accompanying records. In sum, between August 15th and 16th Ortho-Step billed for eight pairs of waist-length stockings when its documentation established that a physician had ordered only three pairs.

OSC also identified three instances where Ortho-Step billed for fewer stockings than what was provided and prescribed to the beneficiary. These instances totaled \$228 for which

Ortho-Step would have received credit if these exceptions had resulted in a monetary finding.

After receiving OSC's preliminary audit findings, Ortho-Step provided additional information challenging a number of findings. Ortho-Step maintained that it billed the compression stocking codes based on guidance it had received from UHC. In further support of this position, Ortho-Step provided OSC with a copy of a UHC pre-payment review from August 2017 for A6540 compression stockings. The narrative accompanying the UHC pre-payment review stated that Ortho-Step should treat two pairs of A6540 stockings as four billable units. When OSC requested that UHC clarify its policy regarding claim submissions for A6540 stockings, UHC advised that one pair of these stockings should be treated as one billable unit.

Given the conflicting information provided by UHC, OSC is not seeking a recovery for overbilling exceptions associated with compression stockings. It should be noted, however, that Ortho-Step did not employ a consistent methodology when billing for these items. In thirty percent (30%) of its claims, Ortho-Step correctly billed one unit for one pair of waist-high compression stockings. In another thirty percent (30%) of its claims, Ortho-Step billed in accordance with the UHC prepayment review methodology of two units for one pair of waist-high compression stocking prescribed and/or dispensed. In the remaining forty percent (40%) of its claims, Ortho-Step did not follow either of the two methodologies described above. For example, a beneficiary received a physician order in September 2015 for "compression stocking" and one refill. According to the customer invoice, Ortho-Step provided two pairs of A6540 stockings and one pair A6539 stockings to the patient, but billed for four units. In another instance, Ortho-Step received a physician order dated January 26, 2016 for three pairs of 20-30 mmHg waist-high compression stockings. The invoice shows that Ortho-Step dispensed two compression stockings to the beneficiary and billed Medicaid for four waist-high compression stockings.

In summary, it appears that Ortho-Step inconsistently billed Medicaid for waist-high compression stockings by alternating the quantities of stockings prescribed, invoiced, and billed between units and pairs. As previously stated, OSC is not seeking a monetary recovery for these noted exceptions given UHC's tacit approval of Ortho-Step's billing through its pre-payment review, the conflicting information from UHC, and Ortho-Step's claim that it relied on UHC's guidance.

B. Shoe Inserts

OSC reviewed 243 claims classified as shoe inserts. These claims primarily include inserts covered under HCPCS codes L3010, L3020, and L3030. Codes L3010 and L3020 cover custom-made inserts that are fabricated from a three dimensional model of a patient's foot (*e.g.*, cast, foam impression, or virtual true 3-D digital image). Code L3030 covers inserts that are formed directly to the patient's foot through the use of an external heat source. OSC found that 195 of 243 claims reviewed were in violation of *N.J.A.C.* 10:49-

9.8. These exceptions total \$22,042 out of the universe of \$29,255 paid claims sampled. See Table IV for a breakdown by exception.

Table IV
Shoe Inserts Exceptions

Exception	Number of Claims	Claim Dollar Amount
No Physician Order	169	19,204
Inadequate Physician Order	8	1,067
Upcoding	13	1,107
No Invoice	5	664
Total	195	\$22,042

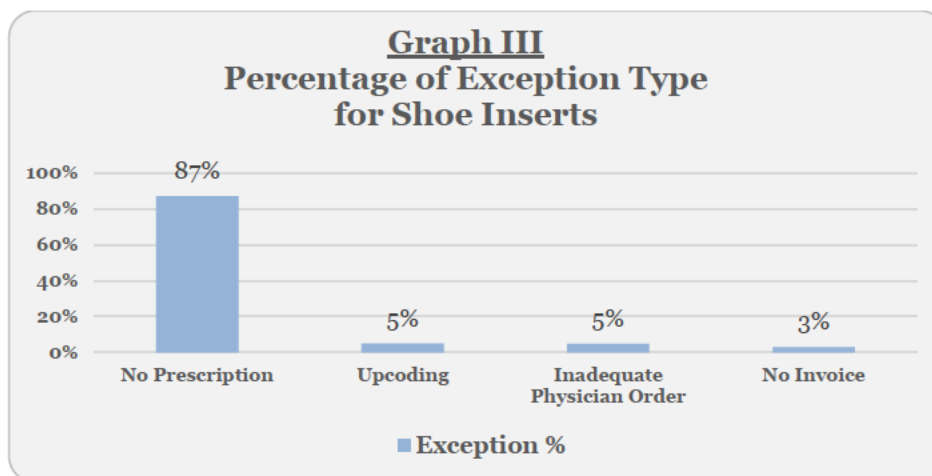
OSC found that there was insufficient documentation to support 169 claims for shoe inserts because there were no physician orders/prescriptions for such product. For almost 93 percent of those 169 claims, Ortho-Step billed and was paid for inserts after being presented with a physician order for only orthopedic shoes. For example, a beneficiary obtained a physician’s order dated August 18, 2014 for shoes with depth and stability due to a heel spur and plantar fasciitis. The physician had the option to prescribe shoe inserts, but did not check off the box on the preprinted physician order form. Subsequently, although there was no prescription for inserts, Ortho-Step dispensed to this beneficiary a pair of shoes with inserts and billed and was paid by Medicaid for both the shoes and inserts. Attachment 4. For an additional eight claims, OSC could not rely on the physician orders because the ordering physician could not be identified, the prescriptions lacked a date, physician signature, or a description of the item prescribed.

OSC identified 13 claims where Ortho-Step billed for L3010 and L3020 custom-made inserts when there was documentation showing that Ortho-Step provided an insert, but no record that the inserts were custom fabricated. Ortho-Step advised that for all custom inserts, it sends foam impressions to orthotics laboratories to be fabricated for Ortho-Step’s customers. OSC independently confirmed through the named orthotics laboratories that they had no record of having fabricated inserts for any of these 13 claims. Accordingly, OSC found Ortho-Step improperly upcoded these claims. To calculate the amount of overpayment attributable to these claims, OSC determined the difference between the amount paid for the custom inserts and the amount that should have been charged for orthotics. OSC determined that this difference amounted to \$1,107.

There were another five instances where claims were supported by valid physicians’ orders but there were no customer invoices associated with these claims documenting that Ortho-Step dispensed inserts to the customers or that the customers received the inserts. In total, Ortho-Step was paid \$664 for these deficient claims.

OSC determined that there were 37 additional claims totaling \$4,913 that were not supported by customer invoices. These claims were not considered for purposes of ascertaining an overpayment amount because these claims were already cited for not

having a physician’s order or for having an inadequate physician’s order. See Graph III below for an error rate representation by exception type for the shoe inserts category.



C. Orthopedic Shoes

OSC reviewed 240 claims for orthopedic shoes comprised of HCPCS codes L3216, L3221, L3230, and L3250. HCPCS codes L3216 and L3221 represent non-customized shoes that provide extra depth and stability for female and male beneficiaries, respectively. HCPCS code L3230 is used to bill for a custom-made depth inlay orthopedic shoe and L3250 is for a custom-made prosthetic shoe with removable inner mold or insert for beneficiaries with a partial foot amputation. OSC found that 144 of the 240 claims violated *N.J.A.C. 10:49-9.8*. These claims total \$14,719 out of the universe of \$30,777 paid claims sampled. See Table V for a breakdown by exception.

Table V
Orthopedic Shoes Exceptions

Exception	Number of Claims	Claim Dollar Amount
Upcoding	106	9,113
No Physician Order	15	2,315
Inadequate Physician Order	18	2,696
No Invoice	5	595
Total	144	14,719

OSC found that for 106 of the 144 exceptions, Ortho-Step billed for custom-made orthopedic shoes (L3230, L3250) when there was no record to support that the shoes provided to beneficiaries were custom-made. Further, the invoices provided by Ortho-Step indicated that these shoes were off-the-shelf, not custom-made. Accordingly, OSC down-coded those 106 L3250 and L3230 claims to either HCPCS codes L3216 or L3221 (depending on the gender of the beneficiary). Average claims payments for L3250 codes were \$218, which OSC then down-coded to an average payment of \$82, resulting in an

average overpayment of \$136 per pair. Similarly, average claims payments for L3230 codes were \$112, which OSC then down-coded to an average payment of \$82, resulting in an average overpayment of \$30 per pair.

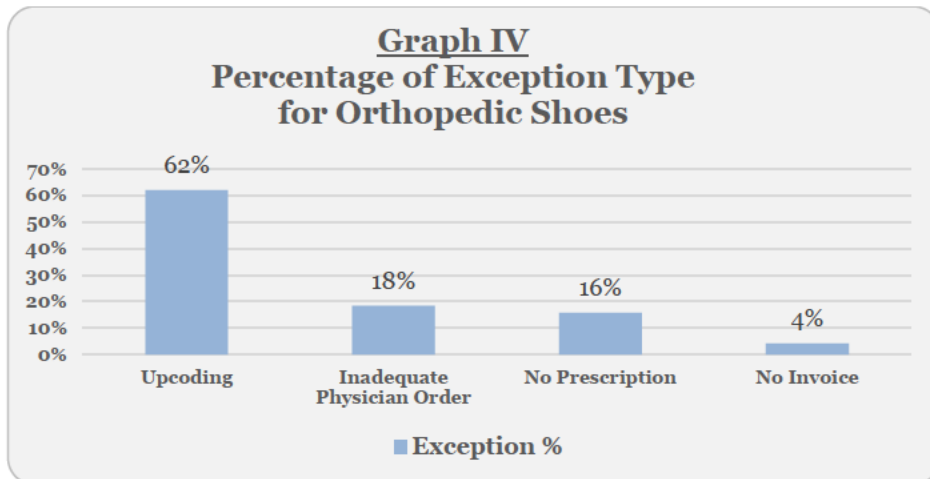
The following are examples of L3250 and L3230 codes that were down-coded. In an order dated July 24, 2014, a physician prescribed shoes with depth and stability to address tibialis tendonitis and tarsal tunnel. Ortho-Step filled this prescription on September 8, 2014, submitted a claim, and was paid for custom-made prosthetic shoes (HCPCS code L3250). The documentation provided by Ortho-Step, however, contained no evidence that Ortho-Step had fabricated a custom-made prosthetic shoe with a removable inner mold. On the contrary, the invoice indicates that Ortho-Step provided the beneficiary a pair of off-the-shelf New Balance 990 sneakers. Consequently, OSC downgraded the L3250 claim to the lower paid claim, L3216. Attachment 5. As previously stated, L3216 codes are used to bill for non-customized orthopedic shoes that provide extra depth for females. At the time, the difference in the amount paid between the two codes was \$141. A pair of L3216 shoes was paid at the rate of \$77 compared with \$218 when code L3250 was used.

The second example involves the same beneficiary and physician. In March 2015, the physician prescribed shoes with depth and stability to address metatarsalgia. Again, the documentation provided by Ortho-Step contained no evidence that Ortho-Step fabricated customized shoes. Rather, just as with the example above, the invoice showed that the beneficiary received a pair of off-the-shelf New Balance 990 sneakers. Ortho-Step submitted a claim and was paid for an orthopedic custom-made depth inlay shoe (HCPCS code L3230). Attachment 6. In this instance, the payment difference between what Ortho-Step was paid and what it should have been paid based on the documentation (the difference between the payment rates for HCPCS codes L3230 and L3216) was \$35.

The third example involves the same beneficiary as the examples above, but a different physician. In October 2015, the beneficiary obtained a physician order to address posterior tibial tendonitis. Again, Ortho-Step provided the beneficiary with a pair of New Balance 990 sneakers, for which Ortho-Step billed code L3230, which is used for orthopedic custom-made depth inlay shoes. Unlike the previous examples, however, the invoice correctly indicated the off-the-shelf shoe (HCPCS code L3216), which was subsequently crossed off and manually changed to the higher priced custom-made depth inlay shoe (L3230 code). Attachment 7.

The remaining exceptions include 33 claims that lacked or were not supported by adequate physician orders and 5 more that were not supported with customer invoices.

As with the previous two findings, OSC excluded from the recovery calculation an additional four claims totaling \$625 that were not supported by customer invoices because the claims already were cited for not having a physician's order or an inadequate physician's order. *See* Graph IV below for the error rate representation by exception type for the orthopedic shoes category.



D. Breast Pumps

HCPCS code E0603 is used to bill for electric breast pumps and E0604 for hospital grade breast pumps. Hospital grade breast pumps are reimbursed at a rate of \$450 per unit, while electric breast pumps are reimbursed at a rate of \$120 per unit, a difference of \$330 per pump. Although hospital grade breast pumps are also electric, they are intended for multi-patient use in hospitals and outpatient facilities. OSC reviewed 38 claims for breast pumps billed under HCPCS codes E0603 and E0604. OSC found that 33 of the 38 claims violated *N.J.A.C. 10:49-9.8*. These exceptions amount to \$11,040 out of \$15,120. See Table VI for a breakdown by exception.

Table VI
Breast Pumps Exceptions

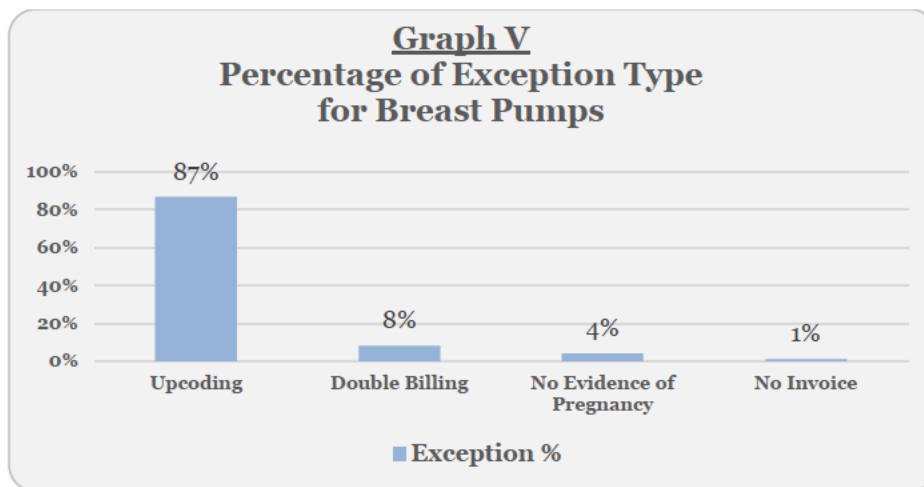
Exception	Number of Claims	Claim Dollar Amount
Upcoding	29	9,570
Double Billing	2	900
No Invoice	1	120
No Evidence of Pregnancy	1	450
Total	33	\$11,040

OSC found that for 29 of the 33 exceptions, Ortho-Step billed for hospital grade breast pumps but, based on customer invoices, Ortho-Step did not provide hospital grade breast pumps. Rather, Ortho-Step provided beneficiaries with electric breast pumps. Specifically, Ortho-Step provided Medela Advanced breast pumps, which are electric and include various accessories but are not hospital grade pumps.

The remaining four exceptions include two instances where Ortho-Step billed for two breast pumps for the same beneficiary for the same pregnancy and one where OSC could

not find evidence of a pregnancy for the Medicaid beneficiary. The remaining one claim was not supported with an invoice.

Three claims totaling \$1,350 were not supported by customer invoices, but OSC excluded these claims from its overpayment calculation because they already were cited either within the “double billing” exception category or the “no evidence of pregnancy” exception category. See Graph V below for an error rate representation by exception type for the breast pumps category.



E. Miscellaneous Billings

In addition to the aforementioned categories, OSC reviewed 51 claims consisting of walking boots, supportive devices, breast shields, and orthotics management and training. OSC found that 25 of the 51 claims violated *N.J.A.C. 10:49-9.8*. These claims total \$1,012 out of \$3,265. There were a total of 20 claims (consisting of 8 claims billed for orthotics management and training and 12 claims for breast shields) that did not have documentation to support the billing. The remaining five claims for supportive devices had inadequate physician orders. See Table VII for a breakdown by exception.

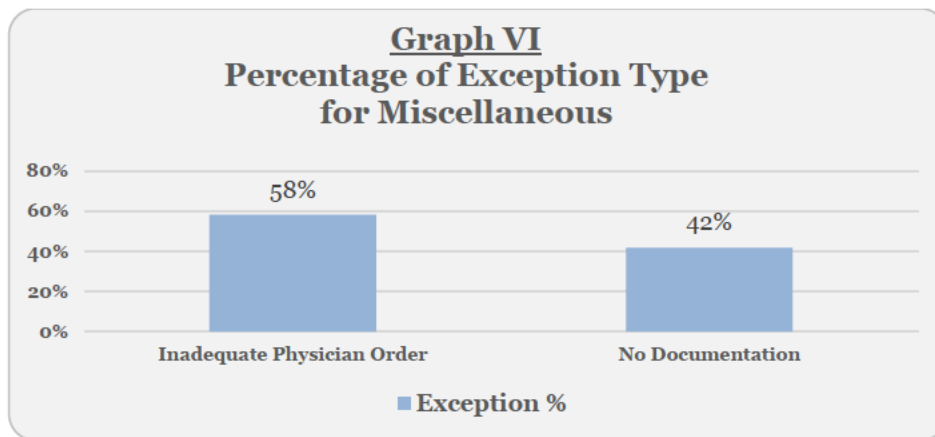
Table VII
Miscellaneous Items Exceptions

Exception	Number of Claims	Claim Dollar Amount
No Documentation	20	423
Inadequate physician order	5	589
Total	25	\$1,012

In eight instances, Ortho-step billed CPT code 97760 in conjunction with codes L3216, L3221, L3230 and L3250. CPT code 97760 is defined as “Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15

minutes.” There was no documentation to support the claim for management and training having been provided. Moreover, the L codes Ortho-Step billed in conjunction with CPT code 97760 already incorporate professional services related to the fitting and adjustment. Therefore, billing the CPT 97760 in addition to L codes should be properly documented in the patient medical record and should describe the services that are above and beyond what is considered customary. In addition, there were 12 claims for breast shields where there was no documentation justifying the need for the items, no invoices indicating what specific items were provided, and no evidence that these items were delivered to the beneficiaries.

Finally, the remaining exceptions include five claims where the prescribing physician could not be identified and the physician order did not include a diagnosis. See Graph VI below for an error rate representation by exception type for the miscellaneous category.



Discussion of Ortho-Step’s Audit Responses

In response to OSC’s preliminary and draft audit findings, Ortho-Step submitted arguments and documentation challenging OSC’s findings. Ortho-Step’s formal response is included as Attachment 13. Ortho-Step’s response includes claim specific objections, an assertion that OSC failed to provide it with the relevant UHC Policy, as well as a challenge to OSC’s use of statistical sampling and extrapolation.

General Objections

OSC applied an independently validated sampling/extrapolation method in this audit. Without providing any specific objections or pointing to any support, Ortho-Step objected to OSC’s use of its sampling/extrapolation method. OSC is confident that its independently validated sampling/extrapolation method meets or exceeds relevant industry standards and that OSC properly applied these validated methods in this audit. Accordingly, OSC stands behind the sampling and extrapolation results. As for Ortho-Step’s claim that OSC failed to provide it with the relevant UHC medical necessity policy,

OSC rejects this assertion because it provided Ortho-Step with a copy of the UHC policy referenced in the audit report on April 18, 2019.

Claim- Specific Objections

Ortho-Step's claim-specific submissions fall into two general categories. Ortho-Step maintained some documents in its business files, contemporaneously prepared with the questioned Medicaid billing and payments that were the subject of the audit. These documents include physician orders, customer invoices, and related documents that Ortho-Step maintained to support its billed Medicaid claims. The remaining documents Ortho-Step acquired from other sources, not its own files. Some of the documents were not contemporaneously prepared with the billed Medicaid claims, but rather were prepared specifically to respond to the audit findings. These documents include prescribing physician attestations, beneficiary attestations, and medical records, including prescriptions that were not originally included in Ortho-Step's records. OSC carefully reviewed all of the documents Ortho-Step provided and, as explained above, found that only some of the information from Ortho-Step's files contained sufficient indicia of reliability to change OSC's audit findings. OSC determined that the remaining documentation did not contain sufficient indicia of reliability for OSC to modify its findings.

In assessing the degree of reliability of a given document, OSC assigned a higher degree of reliability to those documents that Ortho-Step possessed during the audit period and those that Ortho-Step maintained as required by regulation. Accordingly, when provided with physician orders and customer invoices that did not conflict with other information in OSC's possession, OSC adjusted its findings, including the overpayment amount, to reflect the existence of these documents. In contrast, OSC determined that documentation that came from sources other than Ortho-Step, provided specifically in response to OSC's findings (as opposed to being maintained in the usual course of business as required by regulation), lacked a sufficient degree of reliability for OSC to modify its audit findings.

a. Physician Attestations

Ortho-Step submitted 61 physician attestations to support the lack of or inadequate prescriptions. OSC found these documents insufficiently reliable to warrant modifying its findings. Specifically, eighty seven percent (87%) of the attestations lacked signatures, were not on a prescriber's letterhead, did not identify the prescribing physician, and/or failed to disclose important details such as the quantity or the type of shoe, insert or stocking prescribed. *See* Attachment 9 for an example of a deficient attestation. Furthermore, all of the attestations Ortho-Step submitted to support the need for orthopedic inserts conflicted with prescriptions that were on file with Ortho-Step and in OSC's possession as part of this audit. For instance, the prescriptions, which came from Ortho-Step's files during the course of the audit, prescribed only shoes. The physician attestations, however, stated that the provider prescribed shoes and inserts. Given these inconsistencies and shortcomings, OSC relied on the contemporaneous documents that

Ortho-Step maintained as required by regulation, not the physician attestations that Ortho-Step subsequently provided in response to OSC's audit findings.

b. Beneficiary Attestations

Ortho-Step also provided eight beneficiary attestations to support claims lacking invoices. According to Ortho-Step, these attestations "indicate that the beneficiary received a product from Ortho-Step on or around a specified date of service." These virtually identical attestations include a space for the beneficiary to include his/her name, a date, and product by type (*e.g.*, "shoes," "custom shoes"). The information contained in these attestations, including the product descriptions, are vague, as OSC could not verify whether the specific item at issue was, in fact, dispensed to the named beneficiary on the date of service referenced in the source information. Accordingly, these attestations lack sufficient indicia of reliability for OSC to modify its findings.

c. Medical Records

OSC found that the medical records that Ortho-Step provided in response to the preliminary audit lacked sufficient reliability to override other records that OSC previously obtained from Ortho-Step as part of the audit. Ortho-Step submitted medical records from medical providers primarily to justify the necessity for inserts in instances where physician orders only referenced orthopedic shoes. These medical records lack sufficient indicia of reliability to override existing documentation from Ortho-Step's files.

First, for cases where the medical records conflict with prescription or other contemporaneous documentation, OSC questions how Ortho-Step knew to dispense a given item when Ortho-Step did not possess this medical record at the time it received the prescription and without any documentary evidence showing that the prescribing provider communicated this need to Ortho-Step at that time.

Second, OSC found that 17 out of 106 medical records (16 percent) provided by two prescribing providers from the same practice lacked a corresponding Medicaid claim for an office visit submitted by the prescribing provider associated with the medical record service date. In other words, Ortho-Step provided a record showing that a medical provider wrote a prescription for a given DME item for a Medicaid beneficiary on a certain date, but in 17 instances no Medicaid claim existed for an office visit corresponding to that patient and service date. According to the New Jersey Medicaid Management Information System, for 16 of these 17 medical records, the nearest claim service for the provider in question was, on average, over one year from the date of the purported service. This lack of a corresponding Medicaid claim for a medical record service date raises questions as to the reliability of the medical records provided.

Third, there were eight instances comprised of the above mentioned 17 medical records where some or all of the content of the medical records for the same beneficiary appeared identical from one record to the other (*e.g.*, identical signatures and markings), with the only difference being a change of date. It strains credulity that two or more medical

records purportedly created at two different points in time would be virtually identical, including notations, stray marks, and shading. *See Attachment 10* for an example of identical medical records with two different service dates.

d. Physician Orders/Prescriptions

In addition to the submissions noted above, Ortho-Step provided supplemental physician orders/prescriptions that it claimed supported certain billings. For example, Ortho-Step identified a claim in sample #46 (orthotic insert) as one for which it should receive credit. OSC compared the information it originally received for sample claim #46 with the documentation that Ortho-Step later provided in support of this claim. OSC found that the original prescription showed that under the header for “Shoes,” the document indicated a check mark next to the box for “Shoes w/depth/stability,” and lacked any other check marks under any of the other boxes listed, and lacked any information under the “DX” (diagnosis) category. In Ortho-Step’s supplemental submission, however, this same form shows a check mark in the box for “Foot orthotic,” calling for a “Moldable” orthotic and included two diagnoses where previously none existed. *See Attachment 11*. Given the higher degree of reliability that attaches to the original document and the self-serving nature of the subsequent document, OSC does not give credence to the subsequent submission and, thus, declines to modify this finding.

e. UHC Pre-Payment Review

Finally, Ortho-Step maintained that it should be given credit for claims relating to orthopedic shoes (HCPCS codes L3230 and L3250) that Optum/UHC had approved through a pre-payment review process. In support, Ortho-Step pointed to a claim in sample #18 as an example of an Optum/UHC pre-payment approved claim that Ortho-Step relied upon and for which it should receive credit.

OSC reviewed Ortho-Step’s more recent supporting documentation for a claim in sample #18 and compared these records to the files OSC previously obtained from Ortho-Step during the course of the audit. This review revealed that OSC rejected the original invoice for a claim in sample #18 because it referenced an off-the-shelf “Jerrie Black Quilt” woman’s loafer, while Ortho-Step billed and received payment for a custom molded shoe under HCPCS code L3250. The documentation that Ortho-Step provided to Optum/UHC contained an appropriate description of this item as a custom molded shoe to treat a diagnosis for a bunion. Optum/UHC likely approved payment for this item based on the description that Ortho-Step provided to it, which conflicts with the invoice that OSC obtained from Ortho-Step’s records. *See Attachment 12*. Given this conflict, OSC relies on Ortho-Step’s business record, which shows that Ortho-Step dispensed an off-the-shelf loafer but billed and received payment for a custom molded shoe. Accordingly, OSC declines to modify its finding for this claim.

Summary of Overpayments

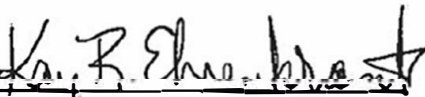
In summary, based on the review of documentation, OSC determined that Ortho-Step improperly billed and received payment for 673 out of the 914 claims sampled for the period of January 1, 2013 through December 31, 2017. The 673 claims paid in error totaled \$111,501, with \$90,627 of this amount identified as monetary findings and \$20,874 as non-monetary findings. The monetary findings were extrapolated to the universe of claims resulting in a total overpayment of \$7,265,776.

Recommendations

1. Ortho-Step shall reimburse the Medicaid program \$7,265,776.
2. Ortho-Step must ensure that it adequately documents the Medicaid services and durable medical equipment and/or medical supplies provided in a comprehensive manner in a patient's record in accordance with N.J.A.C. 10:49-9.8 and N.J.A.C. 10:49-5.5(a)13 before submitting a claim for payment.
3. All claims billed by Ortho-Step should adhere to the AMA, CPT, and HCPCS guidelines.
4. Ortho-Step must provide OSC with a Corrective Action Plan (CAP) indicating the steps it will take to implement procedures to correct the deficiencies identified in this report.

Thank you for your attention to this matter.

Sincerely,

By: 
Kay Ehrenkrantz, Deputy Director
Medicaid Fraud Division

Attachments (Omitted Unless Otherwise Noted):

1. Exhibit A - AMA HCPCS and CPT Code Descriptions
2. Attachment 1 - Compression Stockings - Example 1
3. Attachment 2 - Compression Stockings - Example 2
4. Attachment 3 - Compression Stockings - Example 3
5. Attachment 4 - Shoe Insert - Example 1
6. Attachment 5 - Orthopedic Shoes - Example 1
7. Attachment 6 - Orthopedic Shoes - Example 2

Office of the State Comptroller
Medicaid Fraud Division
Ortho-Step, Inc.

8. Attachment 7 – Orthopedic Shoes – Example 3
9. Attachment 8 – Testing Results Summary
10. Attachment 9 – Attestation Example
11. Attachment 10 – Medical Record Example
12. Attachment 11 – Example of modified documentation submitted to OSC
13. Attachment 12 – Example of documentation submitted to OSC and UHC
14. Attachment 13 - Ortho-Step Response to Draft Audit Report (Included, w/o Appendix A)

Cc: Lourdes Martinez Esq. (Garfunkel Wild, P.C.)
Kay Ehrenkrantz, Deputy Director (OSC – Medicaid Fraud Division)
Don Catinello, Supervising Regulatory Officer (OSC – Medicaid Fraud Division)
Glenn Geib, Recovery Supervisor (OSC – Medicaid Fraud Division)

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FILE NO.: 71416.0003

November 6, 2019

CONFIDENTIAL

[REDACTED]

Auditor-In-Charge - Medicaid Fraud Division
New Jersey Office of the State Comptroller
20 W. State Street, 4th Floor
PO Box 025
Trenton, NJ 08625

Re: Ortho-Step, Inc. ([REDACTED])
Objections to and Submission in Connection with New Jersey Office of the State
Comptroller, Medicaid Fraud Division's Confidential Draft Audit Report Dated
October 8, 2019.

Dear [REDACTED]:

As you know, we represent Ortho-Step, Inc. ("Ortho-Step") in connection with the New Jersey Office of the State Comptroller, Medicaid Fraud Division's (the "OSC's") audit of claims paid by United Healthcare Community Plan of New Jersey ("UHC") for the period of January 1, 2013 through December 31, 2017 (the "Audit Period") (the "Audit").

Ortho-Step's final submission may be accessed using the secure link found in the accompanying e-mail message. You will receive a separate e-mail with the password for the link. This submission includes attestations from eight (8) UHC beneficiaries, which indicate that the beneficiary received a product from Ortho-Step on or around a specified date of service. Attestations have been obtained for certain instances where the OSC had found there had been an adequate physician order, but no invoice.

In addition to the aforementioned documents and records, Ortho-Step objects to all of the OSC's proposed disallowances set forth in the Draft Audit Report, dated October 8, 2019. Below are Ortho-Step's specific objections to certain categories of disallowances, as well as its general objections to the Audit.

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I. Improper Findings Related to HCPCS Codes A6539 and A6540

In the Draft Audit Report, the OSC asserts that for Healthcare Common Procedure Coding System ("HCPCS") codes A6539 and A6540 there was no physician order (53 claims) or an inadequate physician order (78 claims) for compression stockings. We strongly disagree, and specifically request that the OSC reconsider and re-review the documents submitted in response to the Summary of Findings for following sample numbers: 5, 6, 9, 20, 24, 26, 32, 54, and 57.¹

During the course of the Audit, Ortho-Step requested that UHC and the OSC provide the UHC policies, procedures, fee schedules and other relevant and applicable provider communications and guidance related to the coverage and reimbursement of compression stockings that were in effect during the Audit Period. To date, neither the OSC nor UHC has provided Ortho-Step with the requested information or documentation. Ortho-Step has attempted to obtain the applicable archived UHC policies, procedures, guidance, correspondence and/or provider updates that were in effect during the Audit Period, but such information is not readily available online and we were told by UHC it was not available. As a result, Ortho-Step is unable to fully dispute this category of disallowances due to the lack of access to potentially relevant documents.

For the foregoing reasons, Ortho-Step objects to this category of disallowances and respectfully requests that the OSC provide all relevant policies, procedures, fee schedules and/or relevant provider communications in effect during the Audit Period. In addition, Ortho-Step reserves the right to submit additional information following its review of the same. At a minimum, the proposed disallowances in these categories should not be extrapolated.

II. Improper Findings Related to Orthotic Inserts (HCPCS Codes L3010, L3020 and L3030)

The OSC alleges, in connection with the audited claims for HCPCS codes L3010, L3020 and L3030, there was no physician order (169 claims) or an inadequate physician order (8 claims) for the orthotic inserts.

Ortho-Step previously submitted a significant amount of documentation to the OSC including medical records, physician orders, and letters from physicians to provide support that the physician intended to prescribe both an orthopedic shoe and insert(s), as applicable. We request that you reconsider and re-review the documentation previously submitted as well as for Sample Number 46.

Moreover, OSC has alleged that in 5 instances, Ortho-Step had provided an adequate physician order, but there had been no invoice to support that the beneficiary had received the insert. Accordingly, Ortho-Step submits the attached affirmations from these beneficiaries, each indicating that the beneficiary received orthotic inserts on or around the date of service. (See Appendix A)

¹ Ortho-Step submitted documentation to the OSC on April 30, 2019, May 6, 2019 and May 8, 2019.

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For these reasons, Ortho-Step objects to the OSC's Draft Audit Report disallowances. At a minimum, the disallowances should not be extrapolated.

III. Improper Findings Related to Orthopedic Shoes (HCPCS Codes L3230 ad L3250)

A. Reliance on United Healthcare Audits

With respect to orthopedic shoes (HCPCS codes L3230 and L3250), the OSC alleges that, in 106 claims, Ortho-Step incorrectly billed the product that was provided to the patient. However, based on past pre-payment reviews conducted by Optum/UHC, as well as UHC's past payment practices, Ortho-Step believed that it had billed for orthopedic shoes correctly. In fact, during a UHC pre-payment review, UHC reviewed the documentation for Sample Number 18 in the OSC's Audit Findings Summary spreadsheet and approved payment of that specific claim. As a result, Ortho-Step had good reason to believe it was billing appropriately. We request that the OSC reconsider and re-review the documentation from Optum and UnitedHealthcare Community Plan provided for Sample Number 18.

B. The Supplemental Documents Provided by Ortho-Step Clearly and Convincingly Support the Appropriately Billed Claims

Ortho-Step submitted a significant amount of documentation to disprove the OSC's assertions that there were no physician orders (15 claims) and that there were inadequate physician orders (18 claims). We disagree with the OSC's decision not to take into account this additional documentation. We specifically ask that the OSC reconsider and re-review the documents submitted in response to the Summary of Findings for Sample Numbers: 7, 9, 22, 53 and 54.

Moreover, the OSC asserts that in 5 instances, Ortho-Step provided an adequate physician order, but there was no invoice demonstrating that the respective beneficiary had received the orthopedic shoe(s). Therefore, Ortho-Step submits the attached affirmations from these beneficiaries which indicate the orthopedic shoes were received in these specific instances on or around the date of service. Additionally, where Ortho-Step used a receipt to document an invoice because its system was not functioning properly, the beneficiary has indicated there was no payment provided for those products.²

For these reasons, Ortho-Step objects to the OSC's Draft Audit Report disallowances. At a minimum, the disallowances should not be extrapolated.

IV. Improper Findings Related to CPT Code 97760

The OSC disallowed Current Procedural Terminology ("CPT") code 97760 for 8 claims related to training and management services due to an alleged lack of documentation. For the reasons set forth below, Ortho-Step objects to the OSC's Draft Audit Report disallowances.

² Copies of these receipts were previously submitted to the OSC and we request that the OSC reconsider these receipts as proof of delivery.

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CPT code 97760 is a time-based code that is billable for each 15-minute training interval. This code includes training on exercises performed in the orthotic; instruction pertaining to skin care and orthotic wearing time; and time associated with modification of the orthotic due to healing of tissue, change in edema, or interruption in skin integrity.

Ortho-Step's regular practice during the Audit Period was to provide and conduct training to patients for orthotics, and to provide patients with the Ortho-Step Orthotic Guide (the "Guide").³ The training covered the following: instructions, initial use of orthotics, exercises performed in orthotics, skin care, orthotic care, and general information. During part of the Audit Period, while Ortho-Step provided patients with the appropriate training and a copy of the Guide, it did not obtain signed forms from the patients acknowledging that they had received the training and a copy of the Guide. However, it was Ortho-Step's practice to have patients sign the invoice to indicate they received all services. Since 2017, Ortho-Step has required patients to sign an acknowledgement of receipt of training and a copy of the Guide.

For the foregoing reasons, Ortho-Step objects to this category of disallowances. At a minimum, these proposed disallowances should not be extrapolated.

V. Improper Findings Related to HCPCS Codes E0604 and A4284

The OSC disallowed 28 claims for HCPCS code E0604 related to breast pumps provided to patients during the Audit Period. In addition, the OSC denied 12 claims for code A4284 related to "Breast Shield and Splash Protector." For the reasons set forth below, Ortho-Step objects to the OSC's Draft Audit disallowances.

The OSC's Draft Audit Report contradicts Ortho-Step's understanding of UHC's billing policies and procedures. As a result, Ortho-Step requested copies of UHC's policies, procedures, fee schedules and other relevant and applicable provider communications related to the coverage and reimbursement of breast pumps that were in effect during the Audit Period. To date, neither UHC nor the OSC has provided Ortho-Step with the requested documents and information. Moreover, Ortho-Step is unable to access potentially relevant archived policies, procedures and or/provider updates on the UHC website, as these documents are not available online. As a result, Ortho-Step is unable to fully dispute this category of disallowances due to the lack of access to potentially relevant documents. For the foregoing reasons, Ortho-Step objects to this category of disallowances and respectfully requests that the OSC provide all relevant policies, procedures, fee schedules and/or relevant provider communications. In addition, Ortho-Step reserves the right to submit additional information following its review of the same. At a minimum, the proposed disallowances in these categories should not be extrapolated.

³ A copy of the "Guide" was previously submitted to the OSC.

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VI. General Objections to the OSC's Audit, Statistical Sampling and Extrapolation

In addition to the aforementioned objections, Ortho-Step objects to the use of the statistical sampling and extrapolation in the Audit, and expressly reserves the right to challenge the OSC's sampling and extrapolation methodologies, including, but not limited to: the sampling plan (including but not limited to, the sampling frame, sample unit, sample design, sample size and population quantities to estimate); any and all documents describing any and all steps taken to create and verify the reliability of the sample frame; the random seed(s) used to generate the random numbers for the sample; the output(s) of the program used to generate the random numbers for the sample(s); the numbered frame used to pull the statistical sample(s); all file(s) with the overpayment amount for each sample item; all file(s) with the output from the valid statistical software program used to analyze any and all sample results; any and all communications with technical and/or subject matter experts about the sampling frame; all file(s) with overpayment calculations; all documents, information and file(s) related to whether a "probe" or "pilot" sample was performed in connection with Audit, and if not, an explanation of why a probe or pilot sample was not performed; all other documents, information and files relating to the statistical sampling used in connection with the Audit (including, but not limited to, as to the statistical validity of the sample(s) and confidence level(s) used in the Audit); and the calculation of the overpayment demand based on the OSC's Draft Audit Report.

VII. Corrective Action Plan

While Ortho-Step asserts its specific objections to categories of disallowances (as set forth above), and general objections to the Audit, the OSC's statistical sampling and extrapolation methodologies, Ortho-Step has implemented certain corrective action as a result of the OSC's Audit. Specifically:

1. Ortho-Step is in communication with the Legal Department regarding the overpayment amount as set forth in the Draft Audit Report.
2. Ortho-Step personnel reviews all prescriptions/physician orders carefully and sends back any incomplete orders to the ordering practitioner, as appropriate. The personnel who reviews the order initials and dates the top left corner of the order to indicate it was reviewed. These orders will be maintained for 6 years.
3. Ortho-Step keeps electronic invoices for all products dispensed.
4. All billing staff have been re-inserviced on the current and appropriate billing and documentation rules for HCPCS and CPT codes included in the Audit as promulgated by UHC (and other payor[s]).
5. Ortho-Step will conduct quarterly audits of appropriate use of HCPCS/CPT codes, billing and record keeping requirements of the same.

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VIII. Conclusion

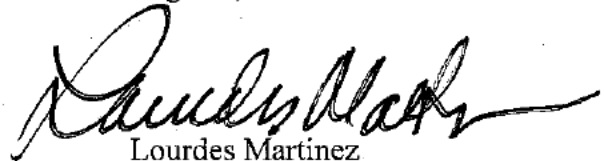
For the foregoing reasons, Ortho-Step objects to the OSC's proposed disallowances and requests that the OSC revise its Draft Audit Report. Ortho-Step welcomes the opportunity to discuss the Audit and the additional documentation submitted herewith.

* * *

The referenced records are confidential and not subject to production under the New Jersey Open Public Records Act, N.J.S.A. 47:1A-1, et seq. Ortho-Step also asserts any other exemption to disclosure under the above law or any similar law, rule or regulation governing protected health information and the confidentiality of patient records.

Please note that to the extent that any document produced herein is protected by any privilege, protection or immunity, its production shall be deemed inadvertent and shall not be deemed a waiver of the applicable privilege, protection or immunity, either as to the document or as to the subject matter of this document. Please note that Ortho-Step expressly reserves all rights, privileges, defenses and protections it has in connection with this matter and that it does not waive any of the foregoing, either in whole or in part.

Regards,



Lourdes Martinez

LM:cj

cc: Baila Lieberman

GARFUNKEL WILD, P.C.