

Revised AU6.1 Attachment 1



Employee Health Benefits Fraud Involving a Medical Spa

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Auditor General

**AUDITOR
GENERAL**

TORONTO

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Executive Summary

City paid \$150M in 2019 for employee benefits

In 2019, the City of Toronto, and by extension, Toronto taxpayers, paid \$150 million to provide health and dental benefits to its employees. These benefits are important to City employees as it allows them to be covered for a comprehensive list of health costs.

City switched benefits plan administrators in 2017

Green Shield Canada (GSC) became the City's new benefits plan administrator in 2017. Prior to this change, the City adopted a recommendation from the Auditor General that made it a requirement that its new benefit administrator have a robust system to monitor claims for inconsistencies, and spot and address fraudulent claims more efficiently. It is our view, that because of those mechanisms, more cases of fraud may be identified.

Report provides details on investigation of alleged benefits fraud by 3 employees

This report summarizes an investigation into allegations of health benefits fraud involving three City of Toronto employees. It is our view that health benefits fraud against the City occurred on several occasions in this case.

We bring this matter to the attention of City Council, City management and City employees for three reasons:

1. To communicate that by implementing past Auditor General recommendations, the City now has a more robust claims monitoring regime and audit system in place that will catch more fraud. Fraud detection and prevention helps improve the sustainability of benefit plans.
 2. To report that management is taking appropriate actions to address all concerns raised in this case, including referring some matters to other regulatory bodies for further consideration.
 3. To make City employees aware that the frequency and sophistication of health benefit monitoring has increased, and it is important to not become involved in schemes like the ones identified in this report.
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This matter helps us to:

1. Better understand how and why employees become involved in fraudulent schemes and how they operate so that we can better educate City of Toronto employees about the various forms of health benefits fraud,
2. Provide recommendations so that the City can continue to improve its controls and make any required changes in order to further identify and stop potential health benefits fraud, and
3. Highlight to other benefit plans and regulatory oversight organizations that the risks presented in this case are potentially not isolated to the City of Toronto benefit's plan.

This is an investigation, not an audit

The work performed in relation to this investigation report does not constitute an audit conducted in accordance with Generally Accepted Government Auditing Standards (GAGAS). However, we believe we have performed sufficient work and gathered sufficient appropriate evidence to provide for a reasonable basis for our findings, conclusions and concerns.

Those submitting claims must ensure they are accurate

It is the employee's responsibility to ensure the claims they submit for reimbursement are legitimate.

GSC is the plan administrator but it is the City that pays to reimburse employees

GSC is the City's benefits plan administrator. They are a gatekeeper of sorts, ensuring that employees are only refunded for treatments approved by the City. It is the City, however who actually pays for claims that are submitted.

Benefits fraud impacts City budget

Research shows that benefits fraud can affect the sustainability of health benefit plans. Frauds have a direct impact on the City of Toronto's budget. At a time when the City's resources are stretched, every dollar counts.

Identifying providers participating or supporting fraud is important to reduce the impact on all plans

When employees are getting away with submitting fraudulent claims, there is a high risk that those claims will continue if they are not caught. When providers are involved, and the fraud is part of a broader scheme supporting multiple employees to defraud one or many plans, such as the orthotics fraud case at Toronto Transit Commission (TTC)¹, it is vital to identify the fraud early and to expose the fraud so that others do not fall victim to it.

¹ TTC Health Benefits Investigation mentioned on p15 of the 2016 Annual Fraud and Waste Hotline Report <https://www.toronto.ca/legdocs/mmis/2017/au/bgrd/backgroundfile-101812.pdf>

Health benefits fraud consequences can be impactful

There are serious consequences for employees who submit fraudulent health benefits claims.

The Canadian Life and Health Insurance Association (CLHIA) says that benefits fraud is becoming more widespread, partly because many people don't understand that it is a crime.

"Most people think, if you are caught, you would just repay the money. In fact, the consequences are bigger than that and can include the loss of your job and in some cases, ending up with a criminal record and jail time."

The investigation

Employees attended medical spa for treatment

This investigation involves three City of Toronto employees who claimed reimbursement for services received at a medical spa. All three claimants, and two of their spouses, attended the spa to receive treatment for various conditions.

The spa states on its website that it offers cosmetic procedures, including Botox injections, laser hair removal, facials, and laser vein treatments.

Invoices said they were treated with Levulan Kerastick for actinic keratosis

Each claimant received and used invoices from the spa to seek reimbursements for their treatments from the City's health benefit plan. The invoices state that they were all treated with the drug Levulan Kerastick (Levulan) for the skin condition actinic keratosis and other conditions, including toenail fungus and rosacea.

All were reimbursed for their treatments.

We found:

- Employee A: had a Drug Special Authorization Form signed by a physician, saying the drug Levulan was to be used to treat actinic keratosis.
- Employee B and spouse: both had Drug Special Authorization Forms signed by the same physician as Employee A, saying the drug Levulan was to be used to treat actinic keratosis. Both also had prescription notes on file at the spa for Levulan from that physician.
- Employee C and spouse: both had prescription notes on file at the spa for Levulan from the same physician as Employee A and B. They did not have Drug Special Authorization Forms. They had been reimbursed for Levulan from the City's previous benefits administrator, so when the City switched to a new administrator, their coverage for Levulan continued.

Spa had employees' Levulan prescriptions on file

By the signature on the Drug Special Authorization Forms, through a separate confirmation to GSC, the physician is listed as diagnosing Employee A and Employee B and their spouse with actinic keratosis, that they were prescribed Levulan, and that this physician was providing treatment to each of them. There was a prescription on file for Levulan from the physician for Employee C and their spouse from the physician for Levulan.

Employees A, B and C, who were not aware that we are investigating others for the same allegations. Each independently confirmed that they never met, spoke to or were actually examined by the physician whether in person, over the phone, or via web conferencing. The physician is an obstetrician and gynecologist (OB/GYN), which is a physician who specializes in female reproductive health.

Average number of Levulan treatments for actinic keratosis: 2-6 per person

Actinic keratosis is a pre-cancerous spot that usually appears on parts of the body that have long been exposed to the sun, such as the face, upper body and hands. Most people who are treated with Levulan for this condition require two to six treatments of Levulan in total.

According to the invoices they submitted to GSC for reimbursement from 2017 to 2019:

2 employees claimed more than 20 Levulan treatments each

- Employee A was treated with Levulan 3 times
- Employee B was treated with Levulan 26 times
- Employee B's spouse was treated with Levulan 5 times
- Employee C was treated with Levulan 28 times
- Employee C's spouse was treated with Levulan 34 times

In total, the employees were reimbursed about \$38,000 in spa services that were not covered by the City's health benefit plan.

For Employee C and her spouse, the services increased from 2017 to 2018: she submitted \$23,165 in 2018 alone.

We know two employees but possibly all three did not actually receive Levulan for actinic keratosis

The information listed on the spa invoices and submitted to GSC was misleading: they claimed that Levulan was used to treat actinic keratosis, and sometimes other conditions.

Two of the three employees (Employee A and B) confirmed to us that they were not receiving treatment for actinic keratosis of the face and/or shoulders, despite the physician's diagnosis, and despite the information on their spa invoices. They were not even treated on that area of the body.

The third employee (Employee C) told us that she does believe she was being treated for another condition on the face with that drug. However, after analyzing the services provided, per the treatment records and how the drug is used and applied, we are concerned her and her spouse's claims are not legitimate.

In the small chance that two of these employees (Employee B and C) were actually treated with Levulan, they were treated with Levulan for other conditions, or on other parts of their body for other conditions, and that treatment is not consistent with the drug product monograph² on Health Canada's website. In the Levulan drug monograph, listed on the drug product database, the only condition mentioned for which Levulan is an effective treatment is actinic keratosis of the face and scalp. No other conditions are named. GSC reimburses employees who use Levulan for actinic keratosis of the face and scalp, which is consistent with Health Canada.

What happened

It appears that the employees used either false and / or misleading prescriptions, diagnoses, treatment records, drug authorization forms or invoices to obtain reimbursement for treatments they did not receive.

One employee admitted this. Another, after much investigation, confirmed that he was aware that the diagnosis on his drug authorization form was not reflective of the area being treated, but this employee submitted it anyway. He then continued, and submitted over 20 claims showing conditions he was not treated for.

Diagnosing and prescribing physician is an OB/GYN

The physician who provided the diagnoses and prescriptions for the employees in this file is registered in Ontario as OB/GYN. While it is not against the rules for a physician to treat patients outside of their usual scope of practice, it does seem unusual for an OB/GYN to be treating male patients for skin conditions.

Attempts to get supporting documents from spa were unsuccessful

We also attempted to verify the information from the claims with the spa. The spa was either unable or unwilling to provide complete documentation, including a great number of treatment records identifying who administered the Levulan prescription for all services for which reimbursement is claimed. Despite the large amount of missing treatment records and/or missing information on the treatment records, both the spa and the physician have confirmed that all records have been provided.

² A drug product monograph lists factual, scientific information about a particular drug, including properties, claims and conditions of use of the drug, and any other information that may be required for the optimal, safe and effective use of the drug.

The scope of our investigation was broad

Our investigation included a review of GSC's work to verify the claims, as well as an examination of the internal work performed by the Pension, Payroll and Employee Benefits Division (PPEB) and the divisions in which each employee works.

In addition, our Office conducted interviews with the three employees involved, reviewed claims, receipts, invoices, treatment notes and other documentation related to the claims. We sought information from subject matter experts, including handwriting, dermatology, and pharmacology experts, analyzed health claim data, and conducted research including about the drug Levulan Kerastick and how it is dispensed, the condition actinic keratosis, and the rules for physicians in Ontario.

We also interviewed the spa owner, the spa COO, and three spa employees³ whose names appeared on some of the records we obtained.

For clarity, we are not investigating the physician, the spa, the spa employees, or the spouses of the employees for which claims were submitted. We are reviewing the claims made to the benefit plan by the employees to verify if they are legitimate, and as part of that we needed to confirm their diagnoses, the treatments provided and the prescriptions written to ensure they are legitimate and eligible for reimbursement under the plan.

Several red flags of healthcare benefits fraud

Red flags of benefits fraud were evident in this investigation:

- Billing for services not rendered
- Issuing receipts for services not received in place of services that are not covered
- Dating invoices differently than the treatment dates
- Claiming treatment took place at one location in the GTA, or being unclear about that, when it took place elsewhere
- Misrepresenting the person treating the employee and/or not keeping records to identify the provider or health professional providing treatment
- Misreporting of diagnoses and procedures
- Issuing unnecessary prescriptions for conditions patients admittedly did not have and were not being treated for

GSC's Claim Watch Team brought the case to the City of Toronto's attention, including some of the red flags above. GSC uses the team specifically for detecting and shutting down fraudulent benefits claims. The team uses a variety of methods to catch, but also stop benefits fraud before it starts.

³ These employees worked at the spa between 2017 and 2019.

Overall conclusion

It is our view that health benefits fraud occurred on several occasions against the City in relation to this file.

We cannot be absolutely sure of the full extent and depth of the role or the exact knowledge of each person or organization (the spa, the doctor, City employees, the treating spa employees and/or registered practical nurse) played in these events because the very nature of a fraud often involves information that is concealed, altered and/or fabricated. Those involved are not always truthful or forthright.

However, based on all of the information that we could obtain from interviews, emails, reviews of documents, and more, and our analysis of the evidence we have reviewed, we make the following conclusions:

- Employee A admitted to the fraud and has made restitution to the City. The cooperation we received from this employee and the information they provided to us was very helpful in our investigation.
- Employee B claimed that he did not know the invoices were not valid. However, he was aware that the diagnosis on the Drug Special Authorization Form that he submitted to GSC to obtain reimbursement showed that another area of his body was being treated. It is our view that this employee committed health benefits fraud. We recommend this employee repay the amount they had been reimbursed (almost \$10,000).
- Employee C also informed us that she thought the invoices were legitimate. We have concerns about the credibility of the statements provided by this employee. In our view, the employee knew or ought to have known that the majority of invoices had services on them that she says she never received. It is our view that, on a balance of probabilities, benefit fraud was committed. We recommend this employee repay the amount they had been reimbursed (over \$26,000) since 2017⁴.

⁴ This employee and her spouse also had about \$8,000 in Levulan claims from 2014 to 2016 when the City had a different health benefits provider.

Auditor General does not determine repercussions of benefits fraud

It is not the Auditor General's role to determine the consequences for employees found to have committed benefits fraud – that is up to City management. However, the repercussions of benefits fraud can include the loss of benefits, termination of employment, or criminal charges.

We recommended that all monies reimbursed to these employees be recovered by the City. We have also recommended that appropriate referrals be made to address the myriad of issues that come under the jurisdiction of other regulatory bodies.

Thank you

We would like to thank the PPEB Division, GSC and their Claim Watch team, and the City Divisions where the employees work for their cooperation with our work. We would also like to thank the experts who supported us during this investigation.

The Complaint

In 2019, the director of the City's Pension, Payroll and Employee Benefits division (PPEB) brought three files to the Auditor General's attention. These files included information on health benefit claims for three employees and two of their spouses.

Green Shield Canada (GSC) had detected the unusual claim patterns while performing reviews of the claims it had paid to City of Toronto employees and passed their concerns to the City.

3 employee files showed potentially unusual claims for drug 'Levulan'

GSC has specialized tools that identified an unusual claiming pattern that showed the employees and the spouses of two of the employees claimed high quantities of the drug called 'Levulan Kerastick 20% aminolevulinic acid-ALA' (Levulan).

Levulan is used to treat actinic keratosis. Actinic keratosis lesions form after prolonged exposure to the sun, and can be pre-cancerous. More information on this drug is available in the background section of this report.

Levulan Kerastick is applied to a lesion by using a pen-like applicator. According to the Levulan Product Monograph, as authorized for sale by Health Canada, Levulan Kerastick is used:

1. To treat actinic keratosis lesions
2. For lesions on the face and scalp
3. When applied by a qualified health professional.

Generally, GSC will only allow this benefit to be reimbursed under these conditions. The City's employment agreements highlight that drugs must be prescribed by a physician and dispensed by a pharmacist.

Investigation Results

A. City of Toronto employees

A. 1. Employee A

1st visit to the spa

Employee A wanted hair loss treatment and had done some research online about potential treatment. He found that a branch of the spa was advertising hair loss treatments. He visited the spa for the first time in 2018 for a consultation.

Sought treatment for hair loss

He said a nurse at the spa, recommended treating his hair with Glofinn PRP injections. Spa staff told him it cost \$500 per treatment.

Glofinn PRP is a blood separation kit that extracts Platelet Rich Plasma (PRP) from the patient's blood and reinjects it into their skin. This is used for various treatments, including skin rejuvenation, hair growth and pain treatment.

The spa's client intake form shows that Employee A listed hair loss and veins as his concerns. A nurse signed the intake form.

Employee had concerns about treatment cost

Employee A had concerns about the cost of the treatment – he told us he didn't feel comfortable paying for it.

Employee told he could get coverage for his treatment by claiming for a drug called Levulan

According to Employee A, he raised his concerns about the cost of the Glofinn PRP hair loss treatment with the nurse and a second employee at the clinic.

"You could have this condition, this condition...you can get a prescription..."

"I was not sure about going through [with the treatment]. They mentioned, 'well, you could have this condition, this condition, and you can get a prescription and then give it to us and we'll take care of the form and a doctor will sign it that you have this condition'."

He told us during an interview that the nurse who was treating him, and another employee of the spa, suggested that he call his benefits provider and ask about whether it was covered.

Employee says spa suggested to call GSC to see if he could be covered

"They suggested to call [GSC]. They mentioned both [Levulan and actinic keratosis]... But I didn't understand what they were saying, that this could be covered. So I called ... the lady said you could just call right now and you could see that they'll just send you the form and you could give it to us and we'll fill it out and we'll take care of filling it out and the doctor will fill it out."

They said they would help with the form

Employee called about two different conditions

Notes from GSC show that Employee A called GSC several times when he was at his first appointment, inquiring about PRP, Glofinn, Levulan and actinic keratosis.

The first condition was not covered by the health benefits plan

Employee A's first call to GSC was at 11:21 am while at his spa appointment. GSC notes state that Employee A was:

"Inquiring about PRP by Physiotherapist - [GSC] advised PLATELET RICH PLASMA (PRP) - MD's and ND's are able to perform this service as part of their scope: Only eligible when performed by MD or ND & use appropriate code based on provider of service. Natural remedies are NAB"

Essentially GSC was informing Employee A that PRP and Glofinn were not covered under the benefits plan unless it met the conditions above.

We interviewed three spa employees. All said these forms are filled out and sent to the doctor for signing.

Employee said he was informed to submit forms for a condition that was covered, and the reimbursement pays for treatment that is not covered

Employee A said that spa staff explained the following to him:

1. The spa would have a doctor sign that Employee A was receiving Levulan for actinic keratosis, even though Employee A was not receiving the drug and did not have that condition.
2. He could submit his receipt for the drug to GSC. The receipt would show he purchased Levulan, and he would be reimbursed.
3. The reimbursement from GSC would cover the costs of the hair loss treatment.

Prior to attending spa, he had never heard of the medication or condition he submitted false documents for

He told us that he had never heard of Levulan or actinic keratosis before that first visit to the spa.

Multiple calls to GSC to see if Levulan Kerastick was covered

About an hour after first calling GSC, GSC records show that Employee A called GSC back again to see if the City's benefit plan would cover the drug Levulan Kerastick. GSC notes indicate he was informed that it was covered, but that he needed to complete a Drug Special Authorization Form.

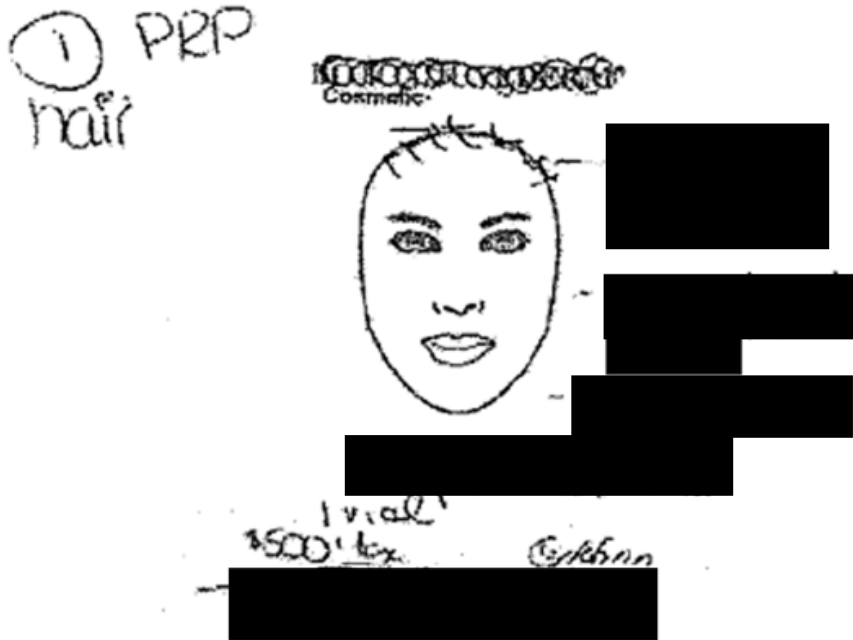
Received forms from GSC

The form requires the doctor's diagnosis, the name of the drug that will be used as part of the treatment and the doctor's signature. GSC emailed him the blank form at 12:27 pm that day.

Employee A receives hair loss treatment – he was not treated for condition put on the form

Employee A proceeded to have his hair loss treatment using Glofinn PRP that same day. He was not treated with Levulan Kerastick for actinic keratosis.

Figure 1: Spa notes from Employee A's first treatment



The notes include the following:

- PRP hair
- 1 Vial Glofinn
- \$500 + tax
- Signed by [Registered Practical Nurse - name redacted by AG's Office]

"...they said that it's not a problem, they do this all the time... She was a nurse"


When we asked him what the spa staff told him about the form. He said:

"They just said that I have to provide them (the spa) with the prescription form [Drug Special Authorization Form] and that I would send it to them (the spa) and that they would fill it out, they'd give it to the doctor to fill it out and then they would take care of anything that needed to be provided."

" ... they said that it's not a problem, they do this all the time... I was taking advice from the spa. She was a nurse."

GSC form forwarded to the nurse right away

Employee A forwarded the Drug Special Authorization Form to the nurse at the spa a little over an hour after speaking with GSC. In his email he says:

On Tue, [REDACTED] 2018 at 1:49 PM [REDACTED] wrote:
Hi [REDACTED]
Here's the form. 
It was a pleasure meeting you today. Thank you,

It was sent to a generic spa email. The nurse told us she did not receive the email but said another spa employee would have been receiving and answering client emails. It is clear, however, that Employee A was dealing with the nurse about this form.

Someone at the spa replied:

On [REDACTED] 2018, at 14:43, "[REDACTED]" <[REDACTED]@gmail.com> wrote:
Hi Employee A
Can you just give me your patient information from the sheet and i will fill it out for you, and will get the doctor to fill out the rest!
Thanks:)

Employee A calls GSC 4th time that day

That same day, he called GSC a fourth time at 5:23pm to discuss the City's benefit coverage for Levulan Kerastick, including inquiring as to how to submit a claim. He told us he wanted to get information on how to submit claims to GSC.

Employee A works with spa to submit claim

At 5:36pm he then replied to the spa's email with his information, which included his address, date of birth, and GSC ID.

Never spoke to the doctor

Employee A told us that he never saw the doctor for a diagnosis or treatment, nor did he see the completed Drug Special Authorization Form until after his third visit.

In an interview with our office, we asked Employee A the following questions:

AG's Office: *Did you ever meet [the doctor who diagnosed you and prescribed the Levulan]?*

Employee A: *No, I didn't.*

AG's Office: *OK. Have you ever spoken to [the doctor] on the phone or interacted with [the doctor]?*

Employee A: *No.*

[Emphasis added]

Submitting receipts

Employee A agreed to go through with the PRP hair loss treatment, at a cost of \$565. Employee A told us that spa staff said if he paid cash, he could get a discount of \$65. He paid cash and received cash receipts showing he paid \$500 for his first visit.

Figure 2: Receipt for 1st visit to spa



Receipt for PRP is a different treatment than the Levulan treatment which is on the invoice submitted to GSC for reimbursement

Receipt for a treatment that is not covered – an invoice submitted to GSC for a false condition and a treatment not given

When Employee A later requested reimbursement from GSC, Employee A submitted the invoice prepared by the spa showing that he paid \$565 for Levulan Kerastick (20% aminolevulinic acid-ALA). This does not match with the cash receipt (shown above) for the same date which shows Employee A paid \$500 in cash for PRP, the hair loss treatment.

Employee submits for a higher amount than the amount paid

When we asked Employee A why he submitted for the higher amount, rather than the amount actually paid, he said:

"To submit a claim, I only had to upload the documents that the Spa provided to me, which I did. The online system didn't ask me to write down the total amount that I was claiming. At the time, I didn't add up the totals on the various forms that the Spa gave me, so I wasn't aware of the exact total they came to. I just scanned in the papers the spa handed to me and submitted them.

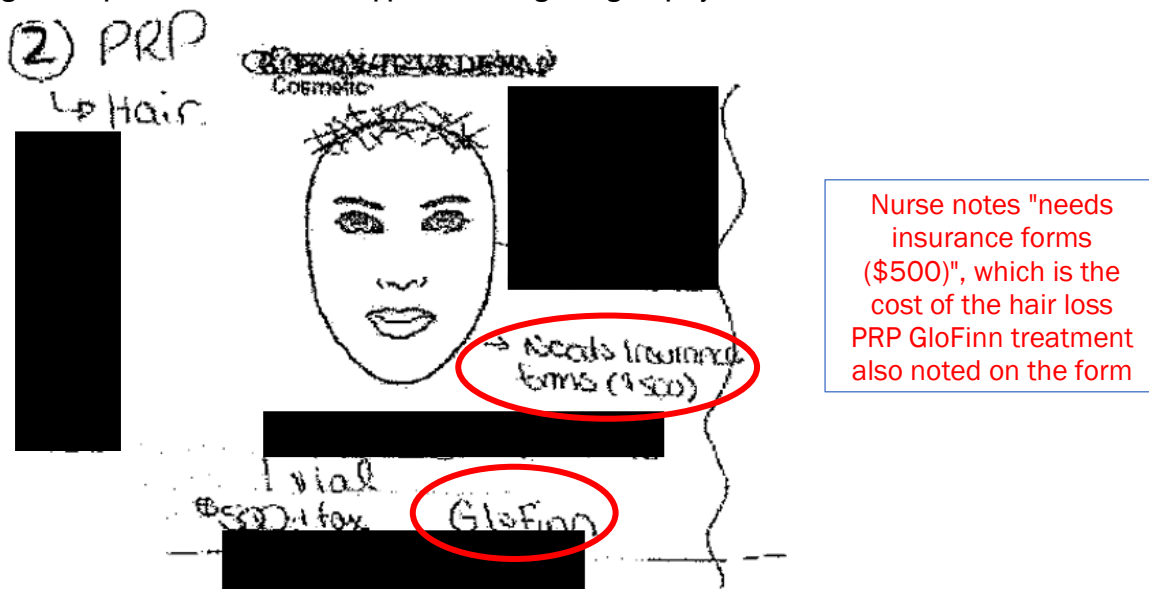
At the time, I believed that I would be getting reimbursement for \$1,500 – the amount I paid to the spa. I didn't think about what the total amount on the paperwork could come out to, because I thought that Green Shield would be reimbursing me for my actual costs. I understand now that the "claim" was for \$1,695.00, but that wasn't what I thought I was claiming when I submitted the documents.

I remember that, three days before [identifying information redacted], I got reimbursed for \$1,491.03, which made sense to me. I was expecting \$1,500, and assumed that the missing nine dollars was for taxes or some kind of administration fee."

2nd visit to the spa for hair loss treatment

Employee A attended the spa for a second appointment a month later. Once again, Employee A did not receive Levulan Kerastick to treat actinic keratosis. He received the Glofinn PRP procedure for hair loss.

Figure 3: Spa notes from second appointment regarding Employee A's treatment



Treatment notes show PRP hair treatment provided

The notes say:

- 2. PRP → hair
- **needs insurance forms (\$500)**
- 1 Vial Glofinn
- \$500 + tax
- Signed by [nurse's name redacted by AG's Office]

[Emphasis added]

Employee A again paid cash, but this time also paid for their upcoming third visit, for a total of \$1,000, and received a discount for paying cash.

Drug Special Authorization Form says the doctor treated Employee A

A Drug Special Authorization Form dated Oct. 29, 2018, from the doctor indicates that:

There were two different diagnoses on the form

- Employee A was the doctor's patient
- The doctor was an obstetrician and gynecologist
- Employee A had two different diagnoses on their drug authorization form: rosacea and treatment for actinic keratosis on the face

Prescription does not match treatment

- Employee A was prescribed 1.5 mL vial of Levulan Kerastick drug DIN 02243933

Location says doctor's office – not the spa where the treatment was given

- The directions on the Drug Special Authorization Form were "Repeat as required"
- Employee A was treated at the doctor's office in Toronto

Figure 4: Portion of Drug Special Authorization Form for Employee A, signed by the doctor, showing Levulan being prescribed "for Actinic Keratosis of face"

[If under 18 years of age, the signature of the parent / guardian is required.]

SECTION 2 – PHYSICIAN INFORMATION

Specialty: Obs & Gyn. Date (Y/M/D): 10/29/18
Telephone Number: [Redacted]
Fax Number: [Redacted]

SECTION 3 – DRUG REQUESTED FOR EVALUATION

Product Name/Strength/Dose/Duration of Treatment: Levulan Kerastick (20% Aminolevulinic acid -AA) Diagnosis: Rosacea
Injectable-location of administration (CHECK ONE):
 HOME
 PHYSICIAN'S OFFICE
 HOSPITAL (IN-PATIENT)
 HOSPITAL (OUT-PATIENT)
 LONG TERM CARE FACILITY

Previous Therapeutic History for above condition (Please include relevant lab results):
Product name/dose/duration and results of prior treatment:
Levulan Kerastick 1.5ml Vial for treatment of Actinic keratosis of face. Repeat as required. DIN # 02243933

Never went to the doctor's office

Never met the doctor

Never received the prescription

3rd visit to spa for hair loss

In the interview with us, Employee A told us that he:

- never attended at the physician's office in downtown Toronto for treatment – he only went to the spa
- never met the doctor who signed the form
- did not go to the spa for treatment for actinic keratosis of the face. Employee A went in for hair loss treatments
- never received a prescription for the drug Levulan

About a month and a half after his first visit, Employee A attended the spa for a third and final time and again underwent the Glofinn PRP procedure for hair loss. Employee A had already paid cash in advance for this visit.

Figure 5: Spa notes from Employee A's third treatment date



"Doctor signed insurance form"

The notes say:

- 3
- Doctor signed insurance form
- 1 vial
- Signed by [nurse's name redacted by AG's Office]

[Emphasis added]

Insurance form lists two different conditions

We confirmed with the doctor who signed the form, and the doctor also confirmed to GSC that the insurance form was in fact signed by him. That form diagnoses Employee A with rosacea, but on the same form, the doctor prescribed Levulan Kerastick for a different condition, actinic keratosis.

The nurse did not treat Employee A for the conditions listed by the doctor

The nurse who wrote these notes did not treat Employee A for either of the conditions on the insurance form that the nurse was referencing in her treatment notes, and the nurse did not use the drug Levulan Kerastick, which was the treatment identified on the insurance form and the spa invoice.

Per the nurse's signature, the nurse treated Employee A with PRP for hair loss, something different than the conditions identified in the insurance form.

Spa provided 3 invoices for Levulan Kerastick

It was during this third visit that the clinic returned the Drug Special Authorization Form to Employee A that was apparently signed by the physician.

Nurse said she did not need to verify with the doctor before administering PRP

We considered how the nurse could be treating a patient for something other than what has been directed by the doctor. We asked the nurse about PRP and whether she was working under the doctor's delegation or instructions to diagnose or treat someone with PRP.

AG's Office: In this case, did you go to him for like for PRP, would you go to him for PRP?

Nurse: No.

Nurse tells us PRP is not a drug

AG's Office: And that is because...? I just want to make sure I'm understanding. That is because...?

Nurse: PRP is not a drug.

AG's Office: Ok. It's an injectable?

Nurse: Yep.

Health Canada says PRP meets the definition of a drug

On Health Canada's *Recalls and Safety Alert* website, it clearly states that PRP meets the definition of a drug:

"PRP meets the definition of a "drug" under the Food and Drugs Act. The preparation of PRP falls under the scope of the practice of medicine and dentistry and is regulated provincially and territorially when it is a) conducted by "practitioners," including physicians and dentists; b) obtained from a patient; and c) administered back to the same patient in a single procedure. Anyone who wishes to sell PRP outside of these conditions must receive authorization from Health Canada, either through a clinical trial or drug authorization.

A “practitioner” is a person who is entitled under the laws of a province or territory to treat patients with prescription drugs in that province or territory. These are the only practitioners that are permitted to prepare and administer PRP.”⁵

Nurse claims the forms were for some other condition, however she did the intake, assisted with the forms, and noted them in her chart

We also specifically asked the nurse about her chart notation “*doctor signed insurance form*”. This note was on the chart for Employee A's third visit. Specifically, we asked the nurse why she was treating someone for something different than what was on the insurance form that the doctor signed. She said she thought the forms were for some other condition that the client was being treated for, and that her notation had nothing to do with the PRP treatment.

We also later noticed a notation on the employee's second visit that said, “*needs insurance form for \$500*”.

The primary reason Employee A went to the spa was for hair treatment, and the nurse was the only person treating him at the spa for those three hair treatments.

Invoices show different conditions and treatments

The spa also provided Employee A with three letters/invoices stating that Employee A was treated with Levulan for actinic keratosis/rosacea, although he was never treated with Levulan and did not have either of these conditions, according to him.

Nurse prepared invoices for a different condition

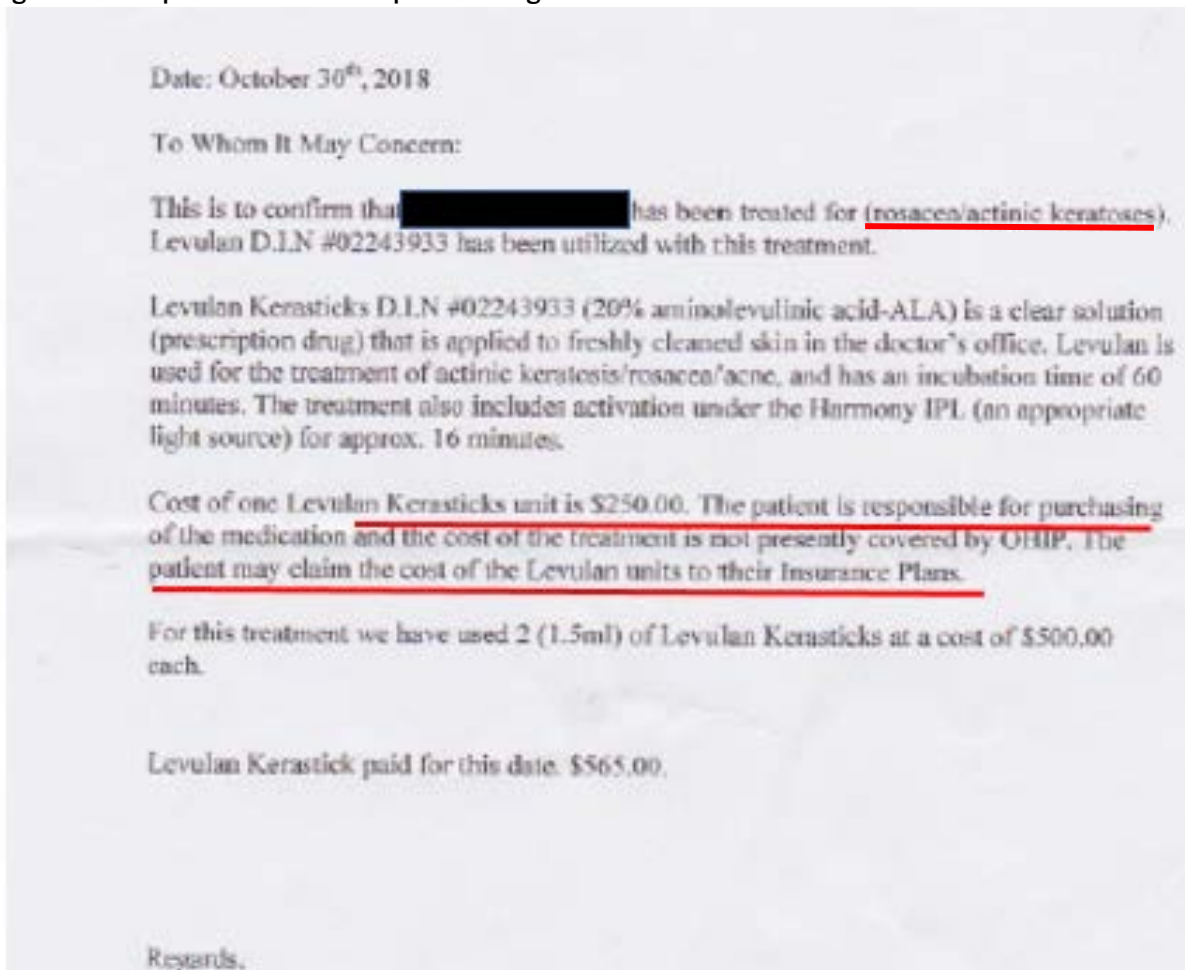
Employee A noted the nurse who did the treatments (for PRP) issued the invoices:

“The person ...who provided the treatments was [nurse's name], a Registered Practical Nurse. It was [spa name] and [nurse's name] who had prepared the letters addressed “To Whom It May Concern.”⁶

⁵ We are unsure whether a Registered Practical Nurse (RPN) is authorized to unilaterally diagnose conditions and administer PRP treatments. Our research shown in Appendix 2 seems to indicate that a doctor needs to be involved. Out of an abundance of caution and for the public's safety, the City has made a report to the College of Nurses of Ontario to look into this matter further.

⁶ The treatment dates written on the letters/invoices were correct except for the third appointment date. The third date did not correspond with the date that Employee A said he attended the spa. The first two dates correspond to the dates he received hair treatments.

Figure 6: Example of invoice from spa indicating use of Levulan Kerastick to treat actinic keratosis



Nurse denied issuing the invoices, but her signature and/or initials appeared in the signature block on all three invoices

The nurse told us she was not involved with issuing the invoice where it states that Employee A was treated with Levulan for Actinic keratosis, but her signature appeared at the bottom of one of the invoices, and her initials appeared at the bottom of the remaining two invoices.

Handwriting expert was used to confirm nurse's writing

When we showed her the signature and initials, she said it was "questionable" whether they were hers. We had it analyzed by a handwriting expert. That expert said that in her opinion, the signature and initials on the spa invoices for Employee A were from the nurse.

Interactions show the spa was not concerned about accuracy of invoices

The invoice indicates that the employee may claim the cost of Levulan on their benefit insurance plan, but Employee A never received the drug, so would not have been eligible for reimbursement from the benefit insurance plan.

Employee A did notice that the date of the last appointment was incorrect on the spa invoice. He told us he informed the spa, but that the spa assured him it was not an issue to be concerned about, and they did not adjust the invoice. Employee A told us:

"... the date for one of the invoices was wrong, because I received it [date of last treatment]. They said don't worry about that."

Claims submitted

**\$1,695.00
reimbursement requested**

On the date of his last treatment, Employee A submitted the claims to GSC requesting reimbursement for three treatments of Levulan Kerastick for actinic keratosis using the spa invoices that indicated that the employee paid \$565 per visit instead of the \$500 he actually paid. Employee A also submitted the Drug Special Authorization Form with the claims. The total amount Employee A requested for reimbursement was \$1,695.00.

Insurance form for Employee A (a male) signed by an OB/GYN

In our interview with Employee A, we asked if he thought it was strange that the Drug Special Authorization Form was signed by an OB/GYN, and one that Employee A had never met. Employee A replied:

"I skimmed through the authorization form. I didn't even know that the doctor was a OB."

Employee A further said the nurse and staff at the spa made him feel as though the whole process was completely normal.

"They said that you don't have to meet with [the doctor] ... they just was always like, you know, don't worry, you don't have to worry, we do this all the time. Like, you will get - you fill it out; [the doctor] just fills it out. So I, yeah, they were nurses and I just, I don't know. The facilitation of this, in a sense, was something that - if they've done this it lessens the guilt, thinking that is what is done."

Employee A told us that he knew the forms were not accurate, but that he trusted the nurse and others at the spa and went along with their suggestions.

He told us that at the time, he didn't grasp the seriousness of what he was doing.

GSC reimbursed \$1,491 Employee A

Several weeks after submitting his claim, GSC processed Employee A's claims. GSC reimbursed Employee A for \$1,491.03 (GSC does not reimburse for 100 per cent of a Levulan claim, which is why the amount reimbursed is slightly less than the amount claimed).

GSC Opens Investigation

March 16, 2019: GSC opens case file

GSC was proactively spot-checking claims when the irregular claims were identified. On March 16, 2019, GSC opened a case file regarding Employee A's claims, noting:

"Stemmed from Case #60453 Spot checking manual pay plan member claims and sketchy claims for Levulan naming [name of spa] are being submitted. Total paid since 2017 is \$1,500.00..."

March 28, 2019: GSC requests more information to support claims

GSC requested that Employee A provide further documentation related to the claim, including:

- A summary of treatment dates,
- A copy of spa records to support each treatment date, and
- The name and credentials of the treating Health Care Professional for each treatment date.

March 28, 2019: GSC requests further information from the doctor

On March 28, 2019, GSC also wrote to the doctor who signed the Drug Special Authorization Form requesting information related to the drug prescribed (Levulan Kerastick), the diagnosis and treatment provided to Employee A:

"We are in receipt of forms requesting the prescription drug product, LEVULAN KERASTICK, to be considered under the benefit plans of the plan members listed above. In order to ensure the accuracy and validity of the information, we require you to please review the following 3 pages and answer the following yes or no questions. Please feel free to include any comments you wish and attach with your response."

GSC made inquiries to the doctor

The letter from GSC asked the doctor to confirm whether Employee A was the doctor's patient, whether the doctor rendered the diagnoses of rosacea and actinic keratosis, whether the doctor prescribed Levulan to Employee A, and whether the doctor administered the three treatments to Employee A. GSC also asked the doctor to verify their signature.

Doctor confirms rosacea/actinic keratosis diagnosis, Levulan prescription and signature

On April 1, 2019, the doctor confirmed to GSC in writing that:

- Employee A was the doctor's patient;
- The doctor diagnosed Employee A with rosacea/actinic keratosis;
- The doctor prescribed and treated Employee A with three treatments of Levulan Kerastick.

Figure 7: Returned letter from doctor to GSC

We are in receipt of forms requesting the prescription drug product, LEVULAN KERASTICK, to be considered under the benefit plans of the plan members listed above. In order to ensure the accuracy and validity of the information, we require you to please review the following 3 pages and answer the following yes or no questions. Please feel free to include any comments you wish and attach with your response.

- Is Employee A your patient? Yes No
- Did you render the diagnosis Rosacea/Actinic Keratosis? Yes No
- Did you prescribe Levulan Kerastick for Employee A? Yes No
- Did you administer (3) treatments to Employee A? Yes No
- Does attached document (page A) contain your original signature? Yes No

Contrary to doctor's statements, Employee A did not have the conditions diagnosed by the doctor

The employee did not seek treatment at the spa for rosacea or actinic keratosis, and there is no treatment record showing he received Levulan. He went to the spa for hair loss treatments.

How can a doctor diagnose and administer treatments without seeing the patient?

We asked the spa's Chief Operating Officer of the spa how Levulan Kerastick can be administered to the employees if the doctor is not on site; the employee told us he never met the doctor.

Spa says doctor delegated, but no delegation documents provided, and treatment on invoices was not given

The spa COO said the treatments are applied by either the nurse or a medical aesthetician "under delegation" from the doctor. The employees in this review gave us consent to request their treatment information. We asked the spa and the doctor for the delegation documents. Despite numerous requests, none were provided. In addition, the treatments rendered were for conditions that differed greatly from the doctor's diagnosis.

Nurse confirmed she was not working under a doctor's directive

The nurse said she was not working under a directive from the doctor to provide PRP treatments.

April 18, 2019: Employee A responds to GSC request and provides documentation

On April 18, 2019, Employee A emailed GSC responding to their March 28, 2019 request and noted:

"In your letter dated March 28, 2019, you asked me to contact my health care provider to obtain the following information:

- Summary of dates of treatments administered from January 1, 2018 to present;
- Copy of the professional clinical notes/patient records to support each treatment date; and
- The name and credentials of the treating Regulated Health Care Professional for each treatment date/chart entry

Employee A confirms the nurse provided treatment then invoices to claim a different drug for a different condition

I went directly to [spa name] and asked for the information you required. The person there who provided the treatments was [nurse's name], a Registered Practical Nurse. It was [spa name] and [nurse's name] who had prepared the letters addressed "To Whom It May Concern." Dated [treatment dates with third date incorrect] which were provided to GSC earlier. I can send them again if you need me to.

Employee A confirms he received the treatment shown in the nurse's notes

[Spa name] gave me [nurse's name]'s notes for my visits on [treatment dates]. I am attaching them to this email. [Nurse's name] is an RPN – I checked and [their] registration number with the Ontario College of Nurses is [number redacted]. I did receive treatments as indicated in [nurse's name]'s notes. I don't know why one of the letters that [the nurse] prepared and was given to GSC earlier was dated [incorrect date] – that is clearly a mistake as I had my treatment on [corrected date].

Please let me know if there is anything else I can help you with."

[Emphasis added]

Employee A provided the following documents to GSC:

- Three letters from the spa regarding his treatment with Levulan Kerastick for rosacea/actinic keratosis, for his treatment dates listed on the invoices;
- Drug Special Authorization Form, signed by the doctor;
- Treatment notes from the nurse.

We questioned Employee A about his response to GSC

When asked why Employee A did not clarify that he did not receive the treatment indicated on the invoice, he pointed to the email which said he received the treatment indicated in the nurse's notes.

Employee A clarifies what he told GSC

Employee A's email response read, in part:

"I did receive the treatments as indicated in [nurse's name]'s notes....

[Nurse's name]'s notes, which I attached to that email, showed that I was receiving PRP at the spa for my hair. When I said that I did receive the treatments "as indicated" in the notes, I was telling Green Shield that I was getting PRP as the note indicated."

GSC determines there is no support for Levulan claims

Upon reviewing this further documentation, GSC determined that the treatment Employee A received at the spa was for Glofinn PRP. Except for the invoice and the Drug Special Authorization Form, there was no information in the treatment record to support the use of Levulan Kerastick.

GSC requests repayment on April 24, 2019

On April 24, 2019, GSC sent Employee A a letter requesting repayment, noting that the treatment notes:

"...documented the use of Glofinn Platelet Rich Plasma (PRP) for hair growth on [treatment dates]. There was not one clinical chart entry for any treatment date that would support the administration of Levulan to you:

- *for the medical condition AK*
- *administered by a qualified health care practitioner*
- *according to manufacturer's direction for use, which encompasses a process requiring two appointment dates per treatment.*

Our payment to you, administered through the contractual terms of your benefit plans, is rendered on the premise of good faith and the presumption that all submitted information/documentation is valid and accurate. Since these claim submissions do not accurately reflect the delivery of eligible products/services, the claims are considered invalid and are not eligible for reimbursement.

Repayment of \$1,491 due May 23, 2019

You are hereby requested to remit the payment amount of \$1,491.03 directly to GSC, no later than May 23, 2019. Please make the certified cheque payable to Green Shield Canada and mail it in the enclosed return envelope ..."

Employee A repays GSC

Employee A submitted a certified cheque dated April 30, 2019 for \$1,491.03 to GSC. GSC thanked Employee A for the repayment and closed the file. GSC informed the City of Toronto of the matter.

Division Investigation

The Division also opened an investigation after being informed about the case.

Their investigation was thorough. Investigators reviewed all documentation about definitions of wrongdoing, conflict of interest, and core values.

Employee A admitted wrongdoing, apologized for their actions

Employee A apologized for his actions, saying he knew what he did was wrong and recognized the seriousness of it. Employee A took full responsibility for his actions.

The Division concludes Employee A committed benefits fraud

The Division investigators concluded that, on a balance of probabilities, Employee A committed benefits fraud. The Division concluded that he violated the following:

- *The Toronto Municipal Code*, Chapter 192, Definition of Wrongdoing
- *The Public Service By-Law*, Chapter 192, Conflict of Interest
- Several of the Division's internal codes.

In addition, staff are required to conduct themselves in a manner which will not bring discredit to the Division.

Employee A was fully cooperative with the Auditor General's investigation

In addition to being fully cooperative with the Auditor General and repaying the funds to GSC, Employee A said he took the following steps to make additional restitution:

- Donated several hundred dollars to six non-profit organizations in the Greater Toronto Area as a form of restitution;
- Underwent training to better understand what benefits fraud is and how to spot it;
- Volunteered at a charitable organization.

Summary of Employee A's case

Through our Office's investigative work, we have confirmed that Employee A:

1. Visited the spa three times for hair loss treatments and received invoices for services totalling \$1,695.00, of which Employee A was reimbursed \$1,491.03.
2. Informed us that he was told by two staff members at the spa that he could call GSC and see if he could receive coverage for other conditions. Once having made those calls to GSC, the forms were returned to the spa for completion, indicating that Employee A was being treated for actinic keratosis with Levulan.
3. Knew that he was receiving hair treatment and would be billing for receiving another treatment because the hair treatment was not covered.
4. Relied on the information from the spa staff, which included a nurse. The form was signed by a doctor.
5. Never met the doctor who signed the Drug Special Authorization Form, which was arranged by the spa.

6. Submitted the invoices and requested repayment from GSC for treatments he did not receive – and was reimbursed \$1,491.03. GSC later realized there could be something wrong with the invoices. After their investigation, they determined there was no support to show that Employee A received the treatment claimed for, so GSC requested repayment.
7. Repaid GSC.
8. Was put on administrative leave and benefits were suspended.
9. Donated several hundred dollars to various non-profit organizations in the GTA, volunteered at a charitable organization and took an anti-fraud course as a form of restitution for his actions.
10. Was upfront with the Auditor General during the investigation by openly and fully cooperating with this investigation.

A. 2. Employee B

Employee B went to a different location

Employee B attended the same spa franchise, but attended a different location (location 2) and claimed reimbursement for Levulan Kerastick to treat actinic keratosis on his face and shoulders, a condition he did not have, and the same physician identified as treating Employee A is on file as the prescribing doctor.

GSC initiated a review of the claims

GSC initiated a review into Employee B's claims in March 2019 as a result of a spot checking program for plan members. GSC requested documents from Employee B to support his treatment and initiated an investigation. They sent their initial findings to the City to conduct their own investigation.

In addition to the City's investigation, the Auditor General's office also initiated an investigation. This section of the report summarizes the findings.

Almost \$10,000 in claims

From May 19, 2018 to March 29, 2019, Employee B submitted 26 claims for Levulan Kerastick. The total amount he was reimbursed by GSC was \$9,952.16.

Spouse had \$2,500 in claims

From February 16, 2019 to April 4, 2019, Employee B's spouse submitted five claims for Levulan to treat actinic keratosis, at the same spa, totalling \$2,542.50.

Their son also attended the spa and, while the family never submitted claims for him to GSC for his treatment at the spa, he also had a prescription for Levulan Kerastick from the doctor.

Drug Authorization forms were needed

Similar to the previous case with Employee A, GSC requires a Drug Special Authorization Form in order to accept a Levulan claim. For reimbursement purposes, generally, GSC only accepts the claim if the drug is used to treat actinic keratosis on the face or scalp. This is consistent with Health Canada's approval for use of the drug.

According to diagnoses, Employee B, his spouse and son suffering with actinic keratosis

All three family members were, according to the diagnoses listed on the Drug Special Authorization Forms, apparently suffering from the exact same conditions (actinic keratosis) on the exact same parts of their bodies, the face, at the same time.

Our interviews confirmed Employee B did not have the diagnosis filled in by the doctor on the insurance forms – he had toenail fungus

Employee B was, however, not being treated for actinic keratosis of the face and shoulders. He told us he was being treated for toenail fungus. He had struggled with toenail fungus for many years. He was reluctant to use prescription medication for this condition. His naturopath told him of a spa that could treat his toenail fungus with a laser.

Spa employee diagnosed toenail fungus

A spa employee noted that she first met Employee B at spa location 2 for the original consultation:

"I saw them myself...I've never seen such a bad case of toenail fungus on a whole family."

"...they come in, I take a look at the situation, which was toe nail fungus. They definitely had it. I explained to them the costs, what they'd have to do, how many times they'd have to come in because they had it really bad, and then after I would give them a prerequisite form if they had insurance and from there they would get back to me to let me know if it was covered or not. They left after the consultation, I spoke to the doctor and told him this [name of Employee B] came through, that they definitely have toe nail fungus and he says ok, that's approved and then they went over to [spa location 3] and then I received a call that they were there and the consultation document went over there. After that I never saw them again."

When Employee B visited the spa at location 2 in May 2018 for a consultation, he told us that they confirmed that they could treat his toenail fungus with a laser. Employee B set up an appointment, and ended up going to the spa location 3 for all of his appointments after that initial consultation.

Employee B has his toenails treated

During our interview with him, Employee B described his first appointment, which took place on May 19, 2018, according to the invoice he received from the spa:

"When I went in for my first treatment ... I sit down in there and take off my socks and she gave me like I guess three courses of the laser to my toenails. And when they're done, she would put this cooling agent on my toes."

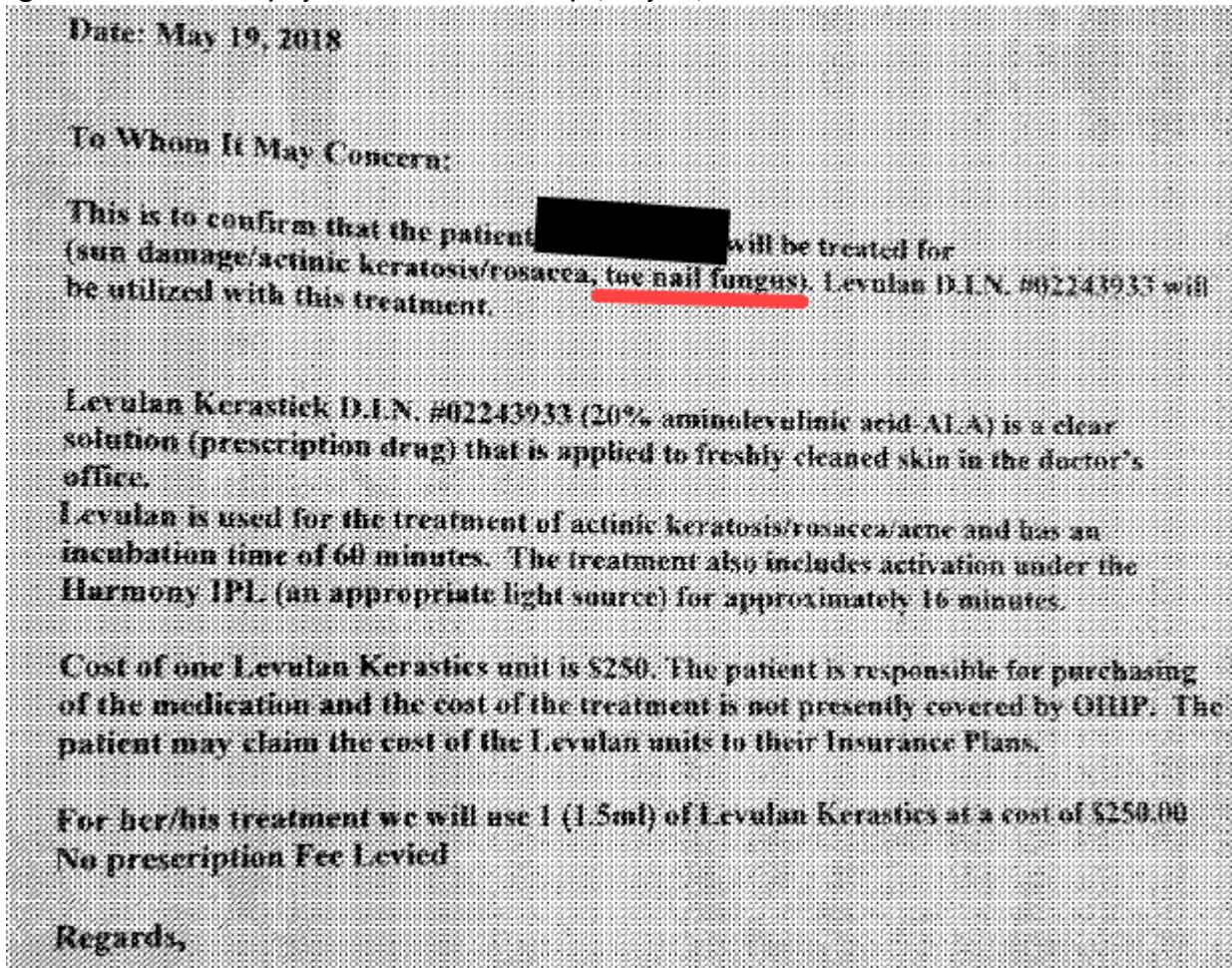
After the treatment, he told us that he paid at the front desk. He said that the spa provided him with letters describing the treatment he received.

Treatment for "sun damage/actinic keratosis/rosacea, toe nail fungus".

The figure below, his spa invoice, indicates he was treated with Levulan Kerastick (20% aminolevulinic acid-ALA) for multiple different conditions: "sun damage/actinic keratosis/rosacea, toe nail fungus".

The invoice also states that in addition to Levulan, he was treated with "Harmony IPL (an appropriate light source) for approximately 16 minutes."

Figure 8: Invoice for Employee B's 1st visit to the spa, May 19, 2018



The invoice lists the cost of one unit of Levulan as \$250. It also says:

"The patient is responsible for purchasing of the medication and the cost of the treatment is not presently covered by OHIP. The patient may claim the cost of the Levulan units to their Insurance Plans."

Almost \$10,000 spent on toenail fungus treatment in span of 10 months

It is important to note that, according to his invoices for treatment from the spa, Employee B spent almost \$10,000 over a span of about 10 months at the spa to receive 26 treatments.

During our interview, Employee B told us that no one at the spa ever mentioned Levulan or actinic keratosis, despite his invoices from the spa saying otherwise.

"That [actinic keratosis and Levulan] was just put on the receipt. I just thought that was part of the laser. I had no idea. I didn't know Levulan was something separate."

Drug Special Authorization Forms

GSC asked that a Drug Special Authorization Form be submitted

On May 22, 2018, Employee B sent the invoice for his first treatment at the spa to GSC for reimbursement.

Doctor writes prescription for Levulan

May 27, 2018: a prescription for Levulan Kerastick was prepared by the doctor from a downtown clinic – not the spa Employee B was attending.

Prescription dated after first treatment date

To note, Employee B's first invoice, which states he was treated with Levulan, is dated May 19, 2018 (see Figure 8). Normally, a person would have a prescription before the drug is administered.

Figure 9: Levulan prescription for Employee B

Doctor's name
OBSTETRICS & GYNAECOLOGY
Downtown Toronto
Clinic
Consultation by Appointment

R
Name: Employee B
Address:
Date: May 27 / 18

Levulan Kerastick
As directed

GSC followed up on May 28, 2018, and requested that Employee B submit a completed Drug Special Authorization Form.

On June 2, 2018, the spa issued Employee B an invoice for the treatment of actinic keratosis.

Drug form issued for nail fungus

Employee B proceeded to get the Drug Special Authorization Form completed.

According to Employee B, the form shown below was filled out by the spa and provided to him. The form shows that the treatment was for "*fungus toes/feet*". It appears that the doctor signed the form on June 6, 2018. Employee B then gave this form to his wife to fax to GSC.

Figure 10: Letter from GSC requesting further information from Employee B regarding his claims – filled out by spa

May 28, 2018

Re: Aminolevulinic Acid (ie. Levulan[®])

Green Shield Number: [REDACTED]

Dear Plan Member,

Your request has been reviewed. Our Drug Special Authorization Department requires additional information in order to evaluate your request. The following is required before a decision can be made:

- A) A diagnosis is required.
- B) The location of the area being treated is required.
- C) The physician's name and signature is required.
- D) Location of administration (i.e. at home, in hospital, in physician's office etc.) is required.

Your physician may provide additional information directly on this sheet if warranted. Once completed, please re-submit to Green Shield Canada for re-assessment.

_____ GOS _____ Toenails

Physician Name: _____ M.D. _____
Print Signature

Office Address: _____

Office Phone: _____ Date 6/6/18

Any original paid receipts submitted with your authorization form have been processed and are now on our system. Should you have any further questions, please call our Customer Service Centre at 1-888-711-1119.

Drug Special Authorization Department
GREEN SHIELD CANADA
drugspecial.auth@greenshield.ca
Fax Number: 1-519-739-6483 or Toll Free: 1-866-797-6483

Another invoice issued for nail fungus treatment

An invoice was issued to Employee B for "Nail fungus" treatment, dated June 9, 2018.

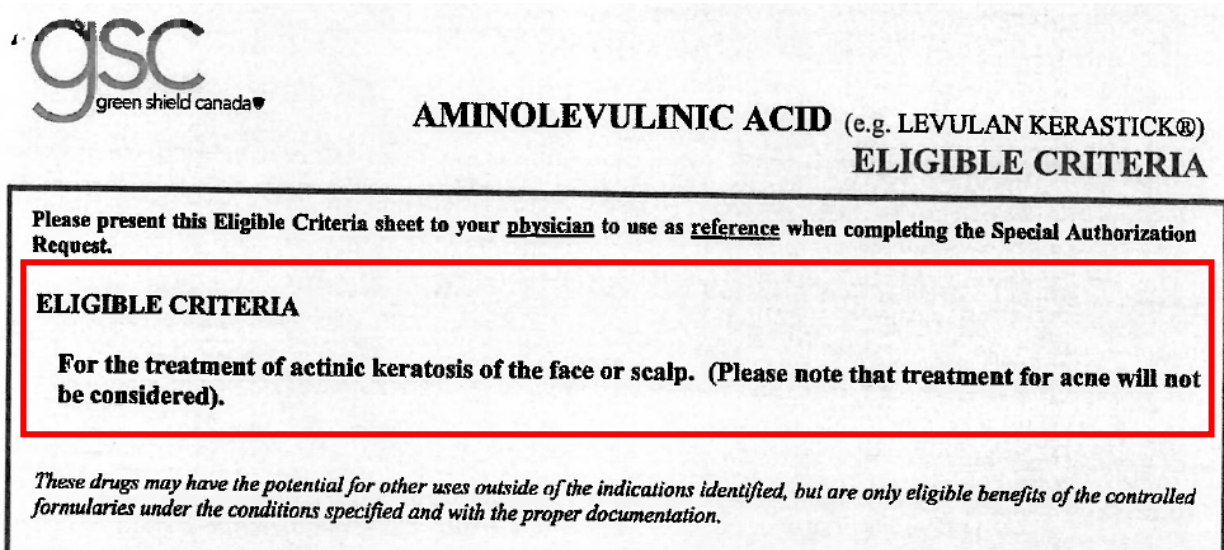
City's health plan does not cover the drug for nail fungus, so GSC returned the form

Since GSC does not cover Levulan for anything but actinic keratosis of the face and scalp, GSC returned the form to the employee, outlining that the eligible criteria that had to be met in order to be reimbursed was that the drug needed to be used for actinic keratosis of the face or scalp. This limitation is consistent with Health Canada guidelines.

Toenail fungus not listed as an eligible condition

GSC's Eligible Criteria for the Levulan drug was written on an information sheet attached to the returned form showing the drug Levulan Kerastick can be reimbursed if used in the treatment of actinic keratosis for the face or scalp.

Figure 11: GSC's Eligible Criteria for Levulan was written on an information sheet attached to the returned form



Employee brought the form back to the spa

In our interview with him, Employee B said he didn't understand what GSC's issue was. He said he then brought the form back to the spa.

"...give me the paperwork. I'll handle this."

He said the staff member at the spa that was giving him the treatments told him that this sort of thing happened all the time, and that they would sort it out for him so that he could get his treatment covered. He told us:

"I went back there, to [the spa], and she said, "Oh, give me the paperwork. I'll handle this. These companies always do this" or something, she said to me... 'They're always fighting with us about whatever.'"

Diagnosis changed on the Drug Special Authorization Form

He told us that he gave the Drug Special Authorization Form, which had been refused by GSC, to a spa employee. He said she took the form from him. He said he thinks either she filled it out, or she got the doctor to fill it out. In any case, the staff member then returned the form to him.

Revised form resubmitted on July 18, 2018. Invoices no longer show toenail fungus

Employee B told us that he gave the form that had the diagnosis changed to his spouse to re-submit to GSC by fax on July 18, 2018. After that date, the invoices no longer show toenail fungus as the condition being treated.

Diagnosis on Drug Special Authorization Form was altered with what appears to be whiteout

"It refers to your face and shoulders – but you only had your toes done"

"I submitted only the paperwork completed by the doctor"

Spa employee says she changed the diagnosis and location of the condition on Employee B's body at the instruction of the physician

Handwriting analysis confirms the spa employee changed the diagnosis

We noticed that the form was altered. The diagnosis appears to have been 'whited out' and changed from "fungus toes/feet" to "actinic keratosis", as shown in Figure 12.

Employee B told us that he saw that the form had been changed but he still submitted it to GSC in support of his claim:

AG's Office: *Did you ever see this change [to the form]?*

It refers to face and shoulders – but you only had toes done. How do you explain submitting this?

Employee B: *"Yes I saw the change made. I submitted only the paperwork completed by the doctor and believed the doctor was submitting forms that were legitimate and would enable me to get treatment for an infection I had since I was a child. [The spa] was the only service I could find that would treat my infection externally without oral drugs."*

[Emphasis added]

We spoke to the spa employee who Employee B said treated him, and to whom Employee B provided the form. This spa employee confirmed that she did treat Employee B. She told us that he had fungus all over his body, including his toes.

She said she changed the diagnosis on the form at the instructions of the physician.

We confirmed her writing with a handwriting specialist – she indeed changed the form. This same employee also confirmed to us that she filled out the top of Employee B's treatment records.

To summarize up to this point:

- Employee B tried to submit an invoice and Drug Special Authorization Form to GSC to be reimbursed for Levulan for fungus of the toes and feet.
- GSC denied that because they only cover Levulan for actinic keratosis of the face and scalp.
- He brought the rejected form to the spa. The spa employee took the form from him and returned it with a new diagnosis that said he had actinic keratosis of the face and shoulders. She said she was instructed by the doctor to change the diagnosis. She also wrote in the top of Employee B's treatment record.
- He was aware he was not being treated at the spa for any condition but toenail fungus.
- He gave the form to his spouse, who submitted the altered form to GSC.

Figure 12: Altered Drug Special Authorization Form

May 28, 2018

Re: Amphetamine/Levodopa Acid (ie. Levlan®)

Green Shield Number: [REDACTED]

Dear Plan Member,

Your request has been reviewed. Our Drug Special Authorization Department requires additional information in order to evaluate your request. The following is required before a decision can be made:

A) A diagnosis is required.

B) The location of the area being treated is required.

C) The physician's name and signature is required.

D) Location of administration (i.e. at home, in hospital, in physician's office etc.) is required.

Your physician may provide additional information directly on this sheet if warranted. Once completed, please re-submit to Green Shield Canada for re-assessment.

on the face and shoulders. actinic keratosis

Physician Name: [REDACTED] M.D. [REDACTED] Signature

Office Address: [REDACTED]

Office Phone: [REDACTED] Date 6/6/18

Any original paid receipts submitted with your authorization form have been processed and are now on our system. Should you have any further questions, please call our Customer Service Centre at 1-888-711-1119.

Drug Special Authorization Department
GREEN SHIELD CANADA

Actinic keratosis spelled incorrectly on altered form

Original toenail fungus diagnosis appears to have been whited out and replaced with actinic keratosis

Several things are noteworthy about this altered form:

- The original document has been altered from "Fungus toes/feet" to a replacement diagnosis of "actinic keratosis on the face and shoulders" in handwriting.
- "actinic keratosis" is spelled incorrectly and is shown as "actinic keratosis".
- Everything else about the form appears exactly the same as the first time it was submitted to GSC.

She says she changed the form because the doctor diagnosed the Employee B with a different condition

We asked the spa employee about how Employee B was originally diagnosed and the changed form with her writing on it. She indicated that the condition changed because the doctor diagnosed Employee B with a different condition.

However, it was odd to us that a doctor would have someone else white out a diagnosis on a form without resigning it, and have the form resubmitted several days later.

We asked her whether the doctor saw Employee B to diagnose him in the first place. She explained to us the following:

Spa employee: First, they just come in the clinic... And then depending on the severity of the need, we direct them to the doctor, which is always, which is the prerequisite at the clinic. You have to chat with the doctor and then the doctor identifies the need of the client and the medical plan.... And then the doctor and the client, and myself – we arrange a mutual meeting time. If the doctor is able to come in physically, great. If not, then we arrange pretty much like, what you and I are doing, a video thing. So then the doctor is able to see the areas of concern and the severity of the situation. And then we decide on the medical plan. So it's like a process of two or three meetings.

AG's Office: Ok so did that happen with [Employee B] where there was a video meeting with the doctor?

Spa employee: Oh yes, it happens with all our clients. Yes.... He actually had to come in physically for [Employee B] and his family. There were quite a few meetings with the doctor⁷.

The spa employee said the doctor identified a severe fungus for Employee B. She said sometimes the doctor and the client do not agree on what the condition to be treated is.

⁷ The spa owner and the spa COO had different descriptions of how the doctor diagnoses their clients. That is described in further detail in section C.

"The doctor has to be satisfied with his diagnosis because it's his name that's going on the paper. The preauthorization is very, very important, and if the doctor does not reauthorize, and it's legal, it is legal, it must be, right, so he has to decide he has to be completely satisfied with his diagnosis, and if he gives the diagnosis based on whatever...and then he rethinks it, the client is still there and he would give his informed consent to that."

The employee who treated Employee B also said that once she was done treating his face, she would provide complimentary treatments to his toes and feet, also with the Levulan, if there was any of the medication left over.

Employee never met the doctor

When we asked Employee B about the Drug Special Authorization Form, and about the doctor. He said the following:

- He never met the doctor;
- He doesn't know what actinic keratosis is;
- He never picked up a prescription for Levulan.

"None of my family ever met that doctor in person or by phone"

We asked him the following questions:

AG's Office:

Were you or any of your family members under your coverage ever examined by the doctor – so this could be either in person or even by phone – who prescribed the Levulan, so this The doctor?

Employee B:

We never met. None of my family ever met that doctor in person or by phone.

[Emphasis added]

"Actinic keratosis?"

We asked further:

"I don't even know what that is really"

AG's Office:

Have you ever been diagnosed by a doctor that you've seen with actinic keratosis?

Employee B:

Not whatever that is. No, I never ... I don't even know what that is really.

GSC accepts the altered form

On August 2, 2018, GSC accepted the altered form, allowing the medication to be covered under Employee B's benefits coverage.

3-month approval period

One thing that is important to note is that on Employee B's Drug Special Authorization Form, there was wording that read:

"Approval period: 3 months"

When we inquired with GSC about this, they said that this means the drug will be paid for three months. After that period of time, if the treatment does not work, then the employee should discuss an alternate form of treatment with a physician, or the physician can provide other information to GSC for consideration of having the approval period extended.

GSC did not follow up after the three-month period as required in this case. GSC says this has been updated and *"all claims will have the 3 month criteria applied."*

Employee says his feet were treated; spa records indicate he was treated on his face and shoulders

Employee B described that all of his treatments were for toenail fungus. He described the treatment: a spa employee would put gel on his feet and would then go over his feet with a laser.

Employee B confirmed that all he received was treatment for toenail fungus on his toes

However, for the treatment records we could find, all treatment records show that he was treated for actinic keratosis of the face and shoulders. There were no entries for toenail fungus treatments – the actual condition he went to the spa for and that Employee B says he was treated for. Employee B told us he was only ever treated at the spa for toenail fungus.

Spa employee prepared records showing a different treatment was given

Handwriting analysis confirms that the spa employee treating Employee B – the same one that changed the diagnosis on the Drug Special Authorization Form – prepared the treatment record below.

Figure 13: Treatment dates for Employee B from the spa

TREATMENT RECORD
(office use only)

Client Name: [REDACTED] Date: [REDACTED] 2018

Fitzpatrick Skin Type: I II III IV V (V circled)

Areas to be treated: Actinic keratosis of face & shoulder.
(treatments to use (2) units Lev. Ker. per session).

1.	[REDACTED]	2018	IPL Pigment Damage	15ms	5KJ
2.	[REDACTED]	2018	"	"	"
3.	[REDACTED]	2018	Pixel, long pulse, 2Hz,	700	KJ
4.	[REDACTED]	2018	"	"	"
5.	[REDACTED]	2018	"	"	"
6.	[REDACTED]	2018	"	"	"
7.	[REDACTED]	2018	"	"	"
8.	[REDACTED]	2018	IPL Pig. Damage	15ms	5KJ
9.	[REDACTED]	2019	Pixel, long pulse, 2Hz,	700	KJ
10.	[REDACTED]	2019	"	"	"
11.	[REDACTED]	2019	IPL Pig. damage	15ms	5KJ
12.	[REDACTED]	2019	"	"	"

RPN: [REDACTED] Name of nurse we interviewed

Spa booking system shows all treatments were for toenail fungus

The spa booking system shows that all of his appointments were for toe fungus.

Figure 14: Clinic Booking System Records showing all visits were for toe fungus for Employee B

Date	Time	Description	Therapist	Room	Status	Payment Info	Created by	Created on
/2019 Friday	7:15 pm - 7:30 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 0		2019 at 3:18:26 pm
/2019 Friday	7:30 pm - 8:00 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 0		2019 at 12:42:43 pm
/2019 Friday	7:30 pm - 8:00 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 2		2019 at 12:42:29 pm
/2019 Friday	7:15 pm - 8:00 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 0		2019 at 12:41:55 pm
/2019 Saturday	4:30 pm - 5:00 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 0		2019 at 3:50:42 pm
/2019 Saturday	4:15 pm - 4:30 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 1		2019 at 3:48:39 pm
/2018 Saturday	2:30 pm - 3:00 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 1		2018 at 5:32:48 pm
/2018 Wednesday	12:30 pm - 1:00 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 1		2018 at 2:13 pm
/2018 Friday	7:00 pm - 7:15 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 1		2018 at 12:07:29 pm
/2018 Saturday	10:30 am - 11:00 am	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 1		2018 at 3:02:23 pm
/2018 Wednesday	7:30 pm - 8:00 pm	Consultations / Laser Toe Fungus			Completed	Laser Toe Fungus on 0		2018 at 1:25:14 pm
/2018 Tuesday	5:00 pm - 5:30 pm	Laser Skin Care / Laser Toe Fungus			Completed	Laser Toe Fungus on 2		2018 at 10:58:58 am

Total visits: 12 Total hours: 5.50

Spa employee indicates Employee B may not know what he is booking his appointments for

The spa employee told us that the booking was done at head office, and that when Employee B calls in, he says "this is what it is, and he'll book in for whatever."

Interesting that the statement that Employee B is booking "in for whatever" happens to be the same reason he attended the spa in the first place.

Almost \$10,000 reimbursed for appointments

The invoices indicate that Employee B continued going to the spa weekly for 10 months, and GSC continued to reimburse him for his appointments for a total of almost \$10,000, or 26 visits.

Invoices appear similar – signatures appear similar

Almost all of his invoices from the spa were identical except for the dates. The signatures often appear similar, and some had what appeared to be similar photocopy marks.

Spa owner not able to identify signatures on majority of the spa invoices

In an interview with the spa owner (which is a different person than the spa COO), the owner could not identify the signatures on Employee B's invoices. She also could not identify most of the signatures on the invoices for Employees A and C.

It is concerning that for these three employees and the spouses of two of the employees, 96 invoices have been issued since 2017, and the owner cannot identify most of the signatures on the invoices except some of her own signatures.

Invoices are mainly for actinic keratosis

For all of Employee B's invoices from the spa, only two mention that he was treated for toenail fungus. The rest say he was treated for actinic keratosis with Levulan and some invoices show treatment for acne and rosacea.

No support showing spa employee a "qualified healthcare professional"

Since the drug monograph, as listed on Health Canada's drug product database, requires that Levulan be administered by a qualified healthcare professional, we asked the spa employee who confirmed that she treated Employee B what her medical qualifications were.

She said she was trained at the spa and received a certification from the doctor. We asked her to provide this documentation – she has not provided it.

Nurse did not write her name on the treatment record

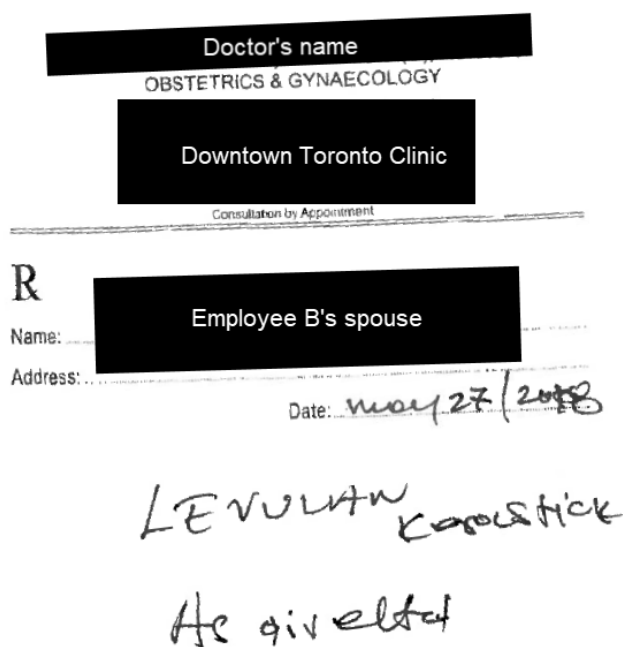
We could not confirm if the nurse was on duty as written on the treatment record. There was no sign-off by the nurse on duty. The nurse confirmed that her name at the bottom of the treatment record was not written by her.

Employee B's spouse

Prescription on file at the spa dated before the spa intake form

The doctor also issued a prescription for Employee B's spouse on the same day Employee B received his prescription, May 27, 2018. However, it was not until June 9, 2018 that the spouse completed the spa's intake form. Given that Employee B said, "None of my family ever met that doctor in person or by phone," we wonder how this patient was examined to have a prescription written.

Figure 15: Prescription for Employee B's spouse, dated before her spa intake form



Employee B's spouse also had fungus

Similar to her husband, she too indicated on that spa's intake form on June 9, 2018 that she was suffering with 'fungus' and, like her husband, that she was referred by a naturopath for treatment.

Employee B's spouse now purportedly being treated for same condition 'actinic keratosis', just like her husband

On December 10, 2018, Employee B's spouse submitted a Drug Special Authorization Form to GSC for the use of Levulan Kerastick for the treatment of *her* actinic keratosis of the face – the same condition her husband was receiving reimbursement for – and the same location on the body.

Doctor's name misspelled on the drug authorization form

Her form was also signed by the doctor. We noted that the spelling of the doctor's name was incorrect.

The handwriting expert said the signature on Employee B's spouse's Drug Special Authorization Form deviates from what the doctor confirmed his signature to be to GSC.

On January 24, 2019, GSC approved it, informing Employee B's spouse that this medication would be covered under her benefits plan as an exception.

From February 16, 2019 to April 4, 2019, Employee B's spouse attended the spa five times, and her invoices show it was also for Levulan, totalling \$2,542.50.

She did not submit her claims until a later date. By the time she submitted her claims, GSC was already investigating the Levulan claims from the spa and so GSC did not reimburse her for those five invoices.

Invoice says spouse treated for "actinic keratosis for the face and upper body"

Her invoices from the spa, which she submitted to GSC, say she was treated with Levulan "for actinic keratosis for the face and upper body."

In an interview with us, Employee B told us that his spouse visited the spa for treatments on her hand and wrist:

"She was getting some laser treatments for something on her hand and her wrist."

Booking system shows spouse booked for toenail fungus treatment

Similar to her spouse, the clinic booking system shows that her visits were for toe fungus.

Figure 16: Employee B's spouse's spa booking system showing appointments were for toe fungus

Date	Time	Therapist	Room	Status	Created by	Created on
2019 Saturday	2:00 pm - 2:30 pm	Consultations / Laser Toe Fungus		Complete		2019 at 5:03:07 pm
2019 Saturday	9:00 am - 9:30 am	Consultations / Laser Toe Fungus		Complete		2019 at 10:44:05 am
2018 Thursday	4:30 pm - 5:30 pm	Consultations / Laser Toe Fungus		Complete		2018 at 2:19:20 pm
2018 Saturday	9:00 am - 9:45 am	Consultations / Laser Toe Fungus		Complete		2018 at 2:10:55 pm
2018 Wednesday	1:30 pm - 1:45 pm	Consultations / Laser Toe Fungus		Complete		2018 at 1:08:42 pm
2018 Friday	7:45 pm - 8:00 pm	Consultations / Laser Toe Fungus		Complete		2018 at 7:39:35 pm
2018 Friday	1:45 pm - 2:30 pm	Consultations / Laser Toe Fungus		Complete		2018 at 1:39:15 pm
2018 Tuesday	12:15 pm - 1:00 pm	Consultations / Laser Toe Fungus		Complete		2018 at 10:16:21 am
2018 Saturday	2:15 pm - 3:00 pm	Consultations / Laser Toe Fungus		Complete		2018 at 2:49:18 pm
2018 Saturday	4:45 pm - 5:00 pm	Consultations / Laser Toe Fungus		Complete		2018 at 4:40:29 pm
2018 Saturday	3:00 pm - 4:00 pm	Laser Skin Care / Laser Toe Fungus		Complete		2018 at 1:48:28 pm
2018 Saturday	11:00 am - 12:00 pm	Consultations / Laser Toe Fungus		Complete		2018 at 4:56:19 pm
2018 Saturday	4:00 pm - 4:45 pm	Consultations / Laser Toe Fungus		Complete		2018 at 4:45:36 pm
2018 Saturday	4:30 pm - 5:00 pm	Laser Skin Care / Laser Toe Fungus		Complete		2018 at 12:21:47 pm
2018 Friday	6:00 pm - 6:30 pm	Consultations / Laser Toe Fungus		Complete		2018 at 12:35:48 pm
2018 Saturday	4:00 pm - 5:00 pm	Laser Skin Care / Laser Toe Fungus		Complete		2018 at 12:11:20 pm
2018 Saturday	4:00 pm - 5:00 pm	Consultations / Laser Toe Fungus		Complete		2018 at 10:13:33 am
2018 Saturday	9:00 am - 10:15 am	Consultations / Laser Toe Fungus		Complete		2018 at 11:20:15 am
2018 Saturday	9:00 am - 9:30 am	Consultations / Laser Toe Fungus		Complete		2018 at 10:10:16 am

Total visits: 19 Total hours: 13.25

Spa claims "toe nail fungus" entries are "generic" bookings instead of an accurate reason for visit

We asked the spa employee who treated Employee B and his spouse, as well as the spa owner, about the discrepancy between the spa invoices showing the visit was for actinic keratosis, and the spa booking system, which shows they visited for toe fungus.

Both said that sometimes, a "*generic reason*" for a visit is added in the booking system, instead of the accurate reason for the visit.

Booking matches reason the spouse went to the spa

It is interesting to note that the generic reason matches the exact reason the spouse attended the clinic – toe fungus.

GSC attempts to obtain supporting documentation for claims

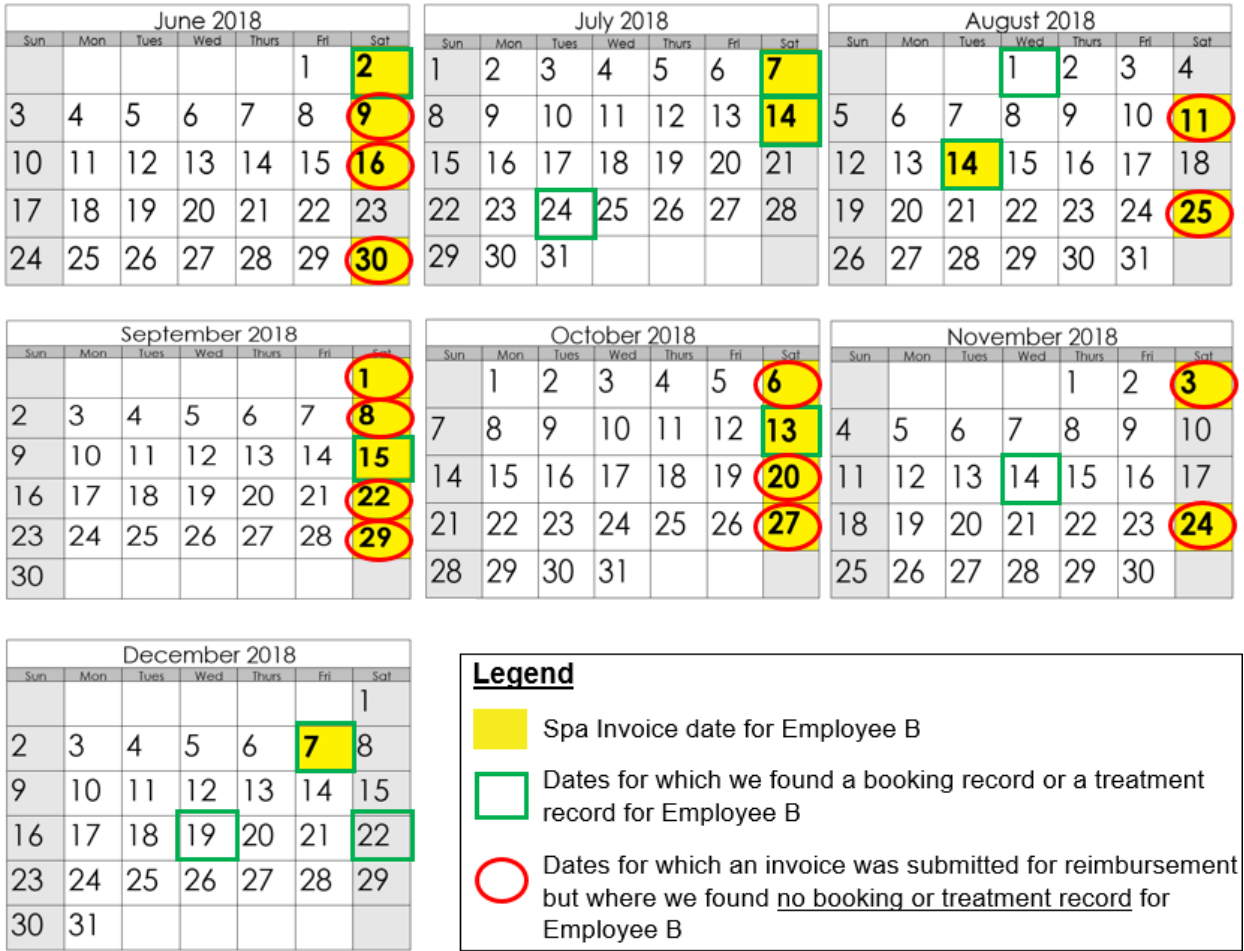
On March 28, 2019, GSC sent a registered letter to Employee B asking him to contact the spa and obtain supporting documentation for Employee B's claims and submit it to them. They requested:

- Summary of dates for treatments,
- Clinical notes and patient records for each treatment date,
- Name and credentials for the treating health care professional.

We found many treatment records missing

We found many treatment records were missing. For example, for Employee B, for the days where there is an invoice, shown in yellow below, we could only find a treatment record for the items boxed in green. The red circles show we could not find a treatment record matching the invoice.

Figure 17: Calendar showing inconsistencies with Employee B's appointment dates and invoices



GSC also sent the same letter to the doctor that they had sent in the case of Employee A. They asked the following:

*Is Employee B your patient?
 Did you render the diagnosis Actinic Keratosis?
 Did you prescribe Levulan Kerastick for Employee B?
 Did you administer (21) treatments to Employee B?
 Does the attached document (page B) contain your original signature?*

*Is Employee B's spouse your patient?
 Did you render the diagnosis Actinic Keratosis?
 Did you prescribe Levulan Kerastick for [Employee B's spouse]?
 Does the attached document (page C) contain your original signature? ..."*

Doctor confirms he diagnosed Employee B and his spouse, and prescribed Levulan for them

Like in the case of Employee A, the doctor responded in writing on April 1, 2019, answering 'Yes' to all of the questions. He also confirmed his signature to GSC and to us.

The handwriting specialist told us the doctor's name on Employee B's spouse's Drug Special Authorization Form looked suspicious because the name was spelled wrong. And the signature on the form deviates from the signature the doctor confirmed to GSC and to us.

GSC asks Employee B to pay back \$9,952

On April 18, 2019, according to GSC, GSC received a response for Employee B and the spa. GSC determined that there was not sufficient documentation to support any of Employee B's Levulan claims. On April 24, 2019, GSC sent Employee B a letter asking him to remit payment for his Levulan claims, totalling \$9,952.16 by May 23, 2019.

Employee B did not respond; benefits suspended

Employee B did not respond with payment by May 23, 2019, and so his benefits were automatically suspended.

Spouse complains

On June 4, 2019, GSC received a hand-written, eight-page letter from Employee B's spouse dated May 28, 2019 detailing how GSC's questions and suspension of their benefits have negatively impacted their family.

She attached a second set of the same treatment records. She said she was provided these by the spa's COO. She also attached the prescriptions from the doctor.

Spouse issues invoice for over \$5,000 for taking up her time providing records

She also included an invoice for GSC to reimburse her for the personal time she spent responding to the GSC review. The invoice was for \$5,650.00.

She references the spa several times, and the COO once. She said the treatment her family received from the spa helped them greatly. At no point does she mention what kind of treatment they were receiving, for what condition, or the doctor who diagnosed them.

Summary of issues found with Employee B and spouse's claims

Our investigation also reviewed all 26 claims for Employee B and all five claims for his spouse.

We reviewed the following documents:

- Invoices for Employee B from the spa
- Invoices for Employee B's spouse from the spa
- Spa booking system showing appointment dates for Employee B
- Spa booking system showing appointment dates for Employee B's spouse
- Spa treatment notes for Employee B
- Spa treatment notes for Employee B's spouse
- Credit card statements from Employee B and Employee B's spouse showing payments made to the spa

Invoices and payment receipts could not be matched

We could only partially reconcile information in two instances:

- Only two of Employee B's 26 invoices from the spa for \$500 each have matching credit card statements showing that his spouse paid the spa \$500 that day.
- A third spa invoice for Employee B for \$500 has a matching credit card statement for that date, but it shows that his spouse paid the spa \$100 that day, not \$500.

Employee B could not match up his own records

We asked Employee B if he could match the amounts claimed to the receipts. He could not.

Invoice detail was not reflected in the treatment records

The other issues we found with their claims were:

- Even though Employee B said that he only ever received treatment for toenail fungus, his spa treatment notes say he was treated for actinic keratosis *and* IPL pigment damage. None of his invoices from the spa mention IPL pigment damage.
- Only two of Employee B's invoices say he was treated for toenail fungus. These were early on in the claims submissions process around the time the drug authorization form was being processed.
- Some of the spa invoices for Employee B were for dates that he did not even have an appointment, as per the spa booking system and the spa treatment notes.

Dates didn't match

- Some of the spa invoices for Employee B were for dates where his spouse had an appointment, not him, as per the spa booking system and the spa treatment notes.
- Some credit card statements show dates where Employee B or his spouse paid for treatment at the spa, but there is no spa treatment record, spa booking system date, or invoice to support that treatment date or the amount paid.
- Few if any of Employee B's spouse's spa invoices match with dates that she had an appointment, according to the spa booking system.
- No credit card statements that we were provided with match with the dates or amounts claimed on the spa invoices for Employee B's spouse.

Employee B said he didn't know records were not matching

We asked Employee B what he thought of all these discrepancies. He told us that he did not realize there was any problem with his invoices until GSC asked him to reimburse them for \$9,952.16.

He told us:

"Well I didn't know they weren't legitimate. I didn't know they weren't matching. No, I didn't know that."

Employee B was not being treated on his face and shoulders

When pressed further about whether he thought it was strange that the drug Levulan and the condition of actinic keratosis was mentioned in his invoices, he said the following:

"I was just happy to be getting treatment for my toes"

"To be honest, I never thought about it. I was just happy to be getting treatment for my toes."

It was later that we confirmed that Employee B was aware that he was not being treated on his face and shoulders – per the diagnosis. He submitted the supporting documentation to GSC for reimbursement anyway.

Health Canada Notes Laser Toenail Fungus Treatments Not Effective to Cure Condition

The spa's website claims about eradicating toenail fungus in 1-2 visits

As part of our research, we needed to understand toenail fungus treatments. While doing this research, we noted that the spa's current website and Facebook page advertises that it can use lasers to *"eliminate and eradicate"* toenail fungus in as little as one or two laser treatments.

Spa employee treating people for toenail fungus says it could take 40-50 treatments

We asked one of the spa employees how many times someone would need to be treated for toenail fungus. She said:

“It could be up to 40 to 50 times depending how bad the toe nail fungus is. If you don't treat toe nail fungus then you end up with fungus like flesh eating disease which will grow up your feet and then we have to treat the fungus that's growing on your feet. Every client is different.”

Lasers not effective to cure toenail fungus, says Health Canada

Our research found a Health Canada Recall and Safety Alert issued an information update in 2019 notes that:

“laser-based medical devices are not licensed in Canada to cure fungal nail infections”

“while some laser-based medical devices are licensed in Canada to temporarily increase the clarity of the nail in patients with a fungal nail infection, none have been licensed to cure these infections

“A fungal nail infection may cause pain, damage to or loss of nails, and skin infections. Some patients, such as those with diabetes or weakened immune systems, may be at greater risk of developing serious complications, including bacterial skin infections and conditions that threaten the limbs.”

and that

“Canadians who have received laser treatments for their condition from anyone other than a health care professional, or who have been told that laser-based medical devices would cure their fungal nail infection, should contact their health care professional in case further treatment is required”⁸

[Emphasis added]

Treatment of toenail fungus to temporarily increase clarity of nail is not covered by the employee healthcare plan

Claims by the spa regarding their ability to eradicate toenail fungus are not consistent with Health Canada's *Recall and Safety* website, and according to the bulletin shown above, appear to be misleading. Laser temporarily increases the clarity of the nail. The treatment of toenail fungus for cosmetic purposes is not covered by the City's healthcare plan.

⁸ <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/70553a-eng.php>

Summary of Employee B's case

The following is a brief summary of the case:

1. Employee B submitted 26 invoices for the treatment at the spa and was reimbursed \$9,952.16 from GSC.
2. There was a prescription on file for Employee B from the doctor for Levulan.
3. According to the Drug Special Authorization Form provided to GSC, signed by the doctor, Employee B was diagnosed with actinic keratosis of the face and shoulders. The spa employee told us she filled in the diagnosis under directions from the doctor.
4. Employee B never met the doctor.
5. Employee B was never treated by the doctor with Levulan for actinic keratosis.
6. Employee B went to the spa to be treated for toenail fungus.
7. At the spa, staff gave him invoices for a different condition and said the treatment could be covered by his health benefits plan.
8. Employee B initially submitted a Drug Special Authorization Form requesting to be treated with Levulan for toenail fungus. This form was denied by GSC. He brought the form back to the spa.
9. Employee B said he gave the Drug Special Authorization Form to a staff member at the spa and the form was returned to him by the spa, after the diagnosis was changed from "fungus toes/feet" to "actinic keratosis on the face and shoulders". The spa employee confirmed that she made the change. Employee B was aware of the change and he was not receiving treatment for a condition on his face and shoulders, but rather his toes. The form was re-submitted successfully to GSC for reimbursement.

10. Employee B told us he did not look closely at the invoices, even though the vast majority of his invoices did not say anything about treating his toenail fungus, and listed conditions he did not have. He was notified by GSC prior to receiving treatments that only actinic keratosis of the face and scalp were eligible for reimbursement. He proceeded to obtain treatment on his toes.
11. The spa records sometimes show no treatment record for Employee B for the date claimed, but there are treatment records for other family members who attended on that day – however, all invoices were in the name of Employee B.
12. Employee B's spouse also went to the spa for treatment, possibly for something on her hand / wrist, according to Employee B.
13. Employee B's spouse submitted five invoices for five separate visits to GSC, and the amount totalled \$2,542.50. These were never reimbursed because they were submitted to GSC after they had already opened an investigation into the claims.
14. Her invoices from the spa say she was treated with Levulan for actinic keratosis.

A. 3. Employee C

Employee C had been attending the spa since 2014, and her spouse attended the spa since 2015. They were each reimbursed about \$4,000 from the City's previous health benefits plan administrator for 30 Levulan claims from the spa from 2014 to 2016.

Reimbursed almost \$30,000 from 2017-2019

Between 2017 and 2019, they were reimbursed a total of \$26,392.60 from GSC for 62 Levulan claims (28 claims for Employee C, 34 claims for Employee C's spouse).

AG interview with Employee C

In our interview with Employee C, the main items we wanted to ascertain were:

- Why she went to the spa
- Her understanding of the treatment she and her spouse claimed for
- Her understanding of Levulan and actinic keratosis

Employee said she noticed the spa when walking by it; record shows she had online coupon for spa

How she heard about the spa

Employee C told us that she noticed the spa when walking by it. While at that first appointment, she filled out a form that detailed her medical history.

The intake form for Employee C, which she filled out and signed on July 16, 2014, shows she heard about the spa from an online coupon company that is used by the spa.

Initially went to spa for facial

What Employee C said she was being treated for

Employee C told us that she initially went to the spa for a facial – the spa employee who treated her also separately told us this.

Staff at spa told her she had rosacea and that they could treat her for that

Employee C told us that staff at the spa diagnosed her with rosacea, and told her they could treat that condition. She told us that she agreed to get treatment for rosacea from the spa.

She went through with this treatment, even though her family doctor never formally diagnosed her with that condition – her family doctor only said she *might* have rosacea.

"It was just actually ... a conversation that we had and she [Employee C's family doctor] gave me some medication to try and said that if that didn't clear up then we should look further into it. And that's when I'd gone to [the spa] and I started enquiring about what their treatments were."

Intake form says she was concerned about fine lines, wrinkles

In addition, the information she gave us about her skin concerns differs from the information on her intake form. Rosacea is not selected. Her intake form shows she was concerned about fine lines, wrinkles, sagging and elasticity.

Figure 18: Employee C's 2014 intake form showing skin concerns were "fine lines & wrinkles"

skin care concerns

These are areas of concern for me: (check all that apply)

<input checked="" type="checkbox"/> Fine lines & wrinkles	<input type="checkbox"/> Excess Underarm Sweating	<input type="checkbox"/> Rosacea/facial redness	<input type="checkbox"/> Sagging Skin
<input type="checkbox"/> Crows Feet	<input type="checkbox"/> Skincare	<input type="checkbox"/> Leg Veins	<input type="checkbox"/> Large Pores
<input type="checkbox"/> Laugh lines/folds around mouth	<input type="checkbox"/> Age spots/Freckles	<input type="checkbox"/> Spider Veins	<input type="checkbox"/> Other _____
<input type="checkbox"/> Excess Hair	<input type="checkbox"/> Acne	<input type="checkbox"/> Broken Capillaries on face or body	

Please prioritize your top 5 concerns:

(1) Fine lines (2) Sagging (3) _____ (4) _____ (5) _____

If you could change one thing about your skin, what would it be? Sagging & elasticity

Discussion about cancer

She explained that spa staff told her rosacea could eventually turn into skin cancer:

"... it's rosacea that they feel would eventually turn into a skin cancer... That's what I was told by the technicians ... There was a nurse there as well. And you know, that's the only people that I had contact with."

We asked her to clarify why she thought she needed treatment for rosacea:

AG's Office: So if I understand correctly, one of the nurses said that rosacea could turn into skin cancer?"

Employee C: Yes that's what I was told. And I've been told that through my family doctor also.

She told us that she was concerned her rosacea could turn into skin cancer:

"My [family member] had been having some trouble with skin cancer, and when I filled out their forms, you know, history, you know, family history, that sort of thing, they asked me about, you know, my [family member]'s skin cancer and told me that they had a treatment for it and said that it was – some of it was covered – it was a medication that they applied to your face that was covered by some benefit plans."

Further, her intake form does not mention any concerns about cancer, which also differs from what she told us.

Figure 19: Employee C's 2014 intake form says no family member has had skin cancer

Have you or any member of your family had skin cancer? Y N If yes, who? _____

Employee C later told us that she only filled out an intake form once. This suggests that at least in 2014 when she first attended the spa, she was not initially concerned about skin cancer or rosacea.

Spa invoices

Invoice dated six days after receiving her facial

Her first 2014 invoice, dated six days after the date on her intake form was signed, shows that she was receiving treatment for "sun damage/actinic keratosis/rosacea" with Levulan. Those conditions are very different and they have different causes. Several months later, her husband started attending the spa to have the same conditions treated with the same drug, Levulan.

The invoices show that the treatments with Levulan continued for both of them over several years.

Previous Levulan claims

From 2014 to 2016 Employee C and her husband claimed about \$8,000 for treatments. The invoices all note the conditions actinic keratosis and rosacea were being treated with Levulan.

From 2017 to 2019, Employee C submitted 28 claims for Levulan Kerastick totalling \$13,842.40, and she was reimbursed \$12,257.33. The amounts on each claim were either for one vial of Levulan at a cost of \$250 (282.50 with tax), or for two vials at a cost of \$500 (\$565 with tax).

In the same timeframe, 34 claims for Levulan Kerastick were submitted for her spouse, totalling \$17,232.50, and he was reimbursed \$14,135.27. The costs for Levulan were also the same as Employee C's claims – either \$282.50 for one vial or \$565 for two vials.

Total amount claimed: \$30,000
The total amount claimed for Levulan from 2017 to 2019 for Employee C and her spouse is about \$30,000, and they were reimbursed \$26,392.60.

Figure 20: Example of invoice supporting a claim from Employee C and her spouse for Levulan Kerastick
Date: July 31, 2018

To Whom It May Concern:

This is to confirm that the patient [REDACTED] has been treated for (sun damage/actinic keratosis/rosacea, toe nail fungus). Levulan D.I.N. #02243933 has been utilized with this treatment.

Levulan Kerastick D.I.N. #02243933 (20% aminolevulinic acid-ALA) is a clear solution (prescription drug) that is applied to freshly cleaned skin in the doctor's office.

Levulan is used for the treatment of actinic keratosis/rosacea/acne and has an incubation time of 60 minutes. The treatment also includes activation under the Harmony IPL (an appropriate light source) for approximately 16 minutes.

Cost of one Levulan Kerastics unit is \$250. The patient is responsible for purchasing of the medication and the cost of the treatment is not presently covered by OHIP. The patient may claim the cost of the Levulan units to their Insurance Plans.

For her/his treatment we have used 1 (1.5ml) of Levulan Kerastics at a cost of \$250.00 each. No prescription fee has been levied

Payment in full this date:

Levulan Kerastick Component- \$282.50

Harmony IPL Component- \$169.50

Regards,

She claims she did not know about the medical condition 'actinic keratosis' or the drug Levulan Kerastick

For every invoice since 2014, she claimed she and her husband were treated for actinic keratosis with Levulan. There were 62 occasions between 2017 and 2019 that she and her husband were treated, and another 30 between 2014 and 2016. Employee C is a medical professional. She says she never looked up what actinic keratosis is, or the drug that was being applied to her.

We asked:

Interviewer: Could you tell us what is actinic keratosis?

Employee C: No, I've never really – I've never looked into that sort of thing. It's just not my field and I just got the receipt and sent it in. I've never looked up what they've written on there, keratosis, that sort of thing. I've never delved into that.

Interviewer So what do you know about the drug Levulan Kerastick?

Employee C: Again, I've never even looked that drug up. I just knew that that was the medication that they would put on me before my treatment.

[Emphasis added]

She claimed she had protective eyewear on while undergoing the treatment and therefore did not see what was happening. However, she also told us the gel used on her skin was clear. These two statements are contradictory.

Invoice states treatment takes 76 minutes

The treatment description on the spa invoices (example seen above) note that Levulan has "*an incubation time of 60 minutes*" and that after, the client is treated with light for "*approximately 16 minutes*".

Employee C says treatment would last about 30 minutes

Employee C said that from start to finish, her treatment would last about 20 minutes to a half hour. She further explained that the application of the Levulan would take 15 to 20 minutes, and then "*the laser may be another 10 minutes or so.*"

City switched benefits plan administrators in 2017

Pre-2017 coverage for Levulan

As mentioned in the Background (Appendix 1), the City of Toronto changed its benefits plan administrator in 2017 from the previous benefits plan administrator to GSC.

Levulan coverage grandfathered in

Unlike the other two employees in this file, Employee C and her spouse had been claiming receipts for Levulan from the spa prior to 2017, and had received coverage when the City benefits were being administered under the previous health benefits program administrator.

When the switch to GSC was made in 2017, Employee C and her spouse's authorization for treatment with Levulan were grandfathered in under the new benefits plan administrator. For this reason, neither Employee C nor her spouse had Drug Special Authorization Forms for their Levulan coverage on file with GSC.

2019: GSC opens file

In 2019, GSC conducted a standard review of claiming patterns and, noticing unusual patterns, opened an investigation into the claims.

GSC noted that the frequency of appointments for Employee C and her spouse were much higher than for anyone else claiming for Levulan.

Request for records

GSC noted immediate concerns with spa response

GSC called the spa to confirm the spa treatment date of January 19, 2019 for Employee C. The GSC operator spoke to a staff member at the spa. The GSC operator noted many concerns, including:

- The spa staff member verified the treatment dates for January 19, 2019 *"in a moment's notice without needing to refer to any appointment records"*.
- The spa staff member told the GSC operator that the doctor administered the treatment, which struck the GSC operator as strange since the doctor is an obstetrician and gynecologist (OB/GYN).

On March 28, 2019, GSC sent registered correspondence to the spa requesting supporting documentation for both Employee C and Employee C's spouse from July 1, 2017 to present.

GSC also sent letters to Employee C and Employee C's spouse advising that GSC requested information from the spa, and for them to follow up with the spa to ensure that information is sent to GSC.

On April 8, 2019, a person who identified himself as the COO of the spa responded to GSC's request by email.

Spa COO confirms 2017 treatment dates for Employee C and Employee C's spouse

He confirmed several treatment dates for Employee C and Employee C's spouse and provided:

- *“Original physician’s referral/ prescriptions for Levulan Kerastick”*

Both of the prescriptions for Employee C and Employee C's spouse were dated June 6, 2017.

Spa COO says spa employee administered treatment "under written Medical Directive"

- Confirmation that:
 - Employee C attended the spa on July 27, 2017, August 14, 2017 and September 21, 2017 and, that
 - Employee C's spouse attended the spa on July 1, 2017, July 28, 2017 and August 15, 2017.
- Professional clinical notes for each patient
- *“The name and credentials of the treating Regulate Health Care Professional for each treatment date /chart entry: [spa employee, spa location], under written Medical Directive”.*

[Emphasis added]

Records say she was treated for "bacterial fungus & AK (toes & feet)" and "rosacea treatments – AK"

Spa Treatment records

Treatment records for Employee C show that she had 36 separate treatments. Four of her 2017 spa treatment notes say Employee C was treated for acne and veins with Levulan. The remainder of her spa treatment notes (listing 32 treatment dates in 2017, 2018 and 2019) list that she was treated for "bacterial fungus & AK (toes & feet)" and "rosacea treatments – AK".

Employee C's spouse has spa treatment notes listing a total of 31 treatments, the majority of which (22) list that he was treated for bacterial fungus on the toes and feet. The rest say he was treated for rosacea and 'pixel long pulse' (no condition listed) with Levulan, and on these notes, the name of the employee is listed beside some of his treatment dates. Seven dates on his invoices do not have a matching treatment record.

Claims that spa employees are acting under medical directives

Employee says she was never diagnosed with actinic keratosis directly from a physician

Levulan Kerastick, the medication noted on Employee C's invoices, is only approved for actinic keratosis by Health Canada and only certain medical professionals (e.g. doctors) can diagnose conditions and prescribe medication.

Medication prescribed

We tried to obtain clarity from Employee C as to who diagnosed her with actinic keratosis and prescribed Levulan as the treatment.

We asked her if she was ever diagnosed with actinic keratosis, a condition noted on her invoices since 2014. She confirmed that she has never been diagnosed with actinic keratosis directly from a physician.

"I'm not sure what the diagnosis was formally, but as I said, it was never ... I was never - I didn't ever sit down with a physician. It was always the staff at [the spa]."

[Emphasis added]

According to Health Canada, Levulan needs to be applied by a qualified healthcare professional. When GSC inquired about treatments, the COO informed GSC that spa staff were operating under written medical directives. In his April 8, 2019 email to GSC, the COO referred to a spa employee as *"the treating Regulated Health Care Professional for each treatment date /chart entry... under written Medical Directive"*.

GSC notes that spa COO's response "very ambiguous and did not give me a verification that Levulan was used"

On April 9, 2019, GSC responded to the spa COO that they were missing treatment records. GSC notes indicate that the spa COO did not appear to provide clear answers to GSC's questions. GSC staff wrote:

"I advised we have more claim receipts for treatment dates supplied. Had a conversation with [the spa COO], he was very ambiguous and did not give me a verification that Levulan was used for treatment and who the medical doctor was. He said they use qualified individuals under medical directive and the physicians will review notes and sign off. I explained regulation and dispensing, applying a Schedule I drug and he didn't seem to understand." [Emphasis added]

Spa says "... doctor has a delegation to our nurses..."

The spa COO confirmed in writing to us something similar when we were trying to understand how clients were diagnosed and who was applying the medication.

"The doctor has a delegation to our nurses at the locations to conduct the medical consultation which gets reviewed by him before we proceed."

The spa COO also wrote:

"Additionally, he [the doctor] conducted many, many telemedicine interviews himself in addition to this."

Spa employee who treated Employee C has no medical credentials

Inconsistencies about diagnosing and interactions with doctor

We spoke to the spa employee that was identified by the COO as the "regulated healthcare professional" having treated Employee C and her spouse "under written medical directive".

The spa employee has no medical credentials. She told us that she has been trained to use the laser machines. When pressed further on her medical qualifications, she told us that she had emergency training from having worked as a lifeguard when she was a teenager, and that she later almost completed training to become a paramedic.

We asked the spa employee who treated Employee C whether she had documented her consultation with the doctor. She said:

"All my documents for [Employee C] and [Employee C's spouse] were given to the owners and then after that I never saw them again. My best way of saying it."

Spa employee who treated Employee C said she would speak to doctor about her consultation with the client, and receive approval on "what I thought was good for [Employee C]"

She said that she would consult with the client, and then speak to the doctor afterwards and receive verbal approval from him about the treatment.

"I would do a consultation and from that we have a doctor that represents the med spa. I would speak to him about my consultation and receive his approval towards what I thought was good for [Employee C]... I'm seeing the patient and I report what I found."

The spa employee who treated Employee C says she diagnoses the client and informs the doctor of what she saw and "he would indicate to me if my diagnosis was appropriate and for me to act forward towards the treatment". She further stated, "you just had to have verbal approval on the diagnosis."

Spa owner said doctor and client have "telemedicine conference"

We also spoke to the spa owner about this. The owner said that when a client comes in, they have a consultation. The spa employee identified by the COO as the regulated healthcare professional who treated Employee C, separately confirmed to us that she does not have medical training.

Another spa employee said doctor would verbally approve diagnosis to spa employee, not client

According to the owner, this employee, which she also called a medical consultant, takes their history and examines their condition. This consultant then phones the doctor or has what she called a "telemedicine conference", and describes the client's condition. Then the doctor would confirm the diagnosis and suggest treatment.

The spa owner and spa employee (medical consultant) said the doctor would come in to the spa about once a month to review paperwork.

We did not see the doctor's signature or initials on any treatment record, with the exception of the blank treatment notes for Employee A, which are discussed in section C.1.

So, in addition to the confirmation from Employee A and B that they never met the doctor in person or by telemedicine, Employee C was asked the following and confirmed that she also never met the doctor.

Employee C never met the doctor

AG's Office: Were you or any of your family members under your coverage examined by the doctor, and this could be in person—

Employee C: No.

AG's Office: - or virtually.

Employee C: No.

[Emphasis added]

Concerns about telemedicine rules not being followed

Even if the doctor saw the patients via telemedicine (via telephone, email, video, etc.), it is our understanding that the rules around delegation of their treatment still apply: there must be a pre-existing relationship between the physician and the patient, the patient must consent to their care being delegated, the physician must follow up on the patient's treatment, and keep medical records.

We wanted to confirm the diagnosis and treatment to compare it to the services on the invoices submitted to GSC. When asked to provide the records that would indicate that a physician delegated care for these clients, the spa COO would not provide it. He said, via his lawyer:

"The spa does not wish to provide its delegation of duties document"

"The spa does not wish to provide its delegation of duties document as that is an internal document and this is not a review of the care received or of the way duties are assigned."

He told us that all records have been provided.

Employee C diagnosed by the spa

We spoke to the spa employee/medical consultant who 'diagnosed' Employee C.

She describes that she essentially diagnoses the clients and describes over the phone to the doctor what she is seeing. She then explains to the client what the diagnosis is. The client does not speak with the doctor.

AG's Office: What was your first diagnosis?

Spa employee: Originally? Honestly I can't remember exactly what it was. She did have sun damage because she works outside which is cancer lesions ... She did have really bad rosacea. From what I could see, she had enlarged pores, redness of the face, and a great deal of bacteria under the skin, skin swelling in her cheek area and under the chin. She had spider veins also from working out in the sun and the heat.

This is consistent with the owner's description of what happens.

She told us that she also diagnosed Employee C with toenail fungus.

Spa employee says acne and veins listed on treatment record refer to laser head used, not condition of client

We asked her why it said veins and acne on the treatment record if Employee C was being treated for actinic keratosis.

The spa employee said the words 'acne' and 'veins' do not refer to the condition the client has, but rather refer to the type of laser head to use for the treatment. Acne appears on two invoices as a condition that was treated.

Figure 21: 2017 Spa notes for Employee C

Office Use Only

Treatment Record

Client Name: [REDACTED] Date: June 27/17.

Fitzpatrick Skin Type: I II III IV V

Areas to be treated: face.

(1 levulan) June 27/17.	- IPL - Acne treatment	30ms + 10 J's	250.00 +tax	Ⓢ
(1 levulan) July 7/17	- IPL - Acne "	30ms + 10 J's	250.00	
(1 levulan) August 14/17	Veins	210 J's + 10ms	250.00 +tax	Ⓢ
(1 levulan) August 14/17	- IPL - Acne treatment	30ms + 10 J's	250.00 +tax	Ⓢ
(1 levulan) Sept 21/17.	Veins	210 J's + 10ms	250.00 +tax	Ⓢ
(1 levulan) Sept 21/17.	- IPL - Acne treatment	30ms + 9 J's	250.00 +tax	Ⓢ
(1 levulan) 1/levulan)	Veins	210 J's + 10ms	250.00 +tax	Ⓢ

Spa employee who gave the treatment only trained as a laser technician

Spa employees' lack of medical training

According to Health Canada, Levulan is to be administered by "qualified healthcare professionals". The spa COO informed GSC of the name of the spa employee who was the "regulated healthcare professional" administering the drug under "written medical directives."

As mentioned earlier in this section, this spa employee could not provide evidence of any medical credentials or qualifications. She appears to only be trained as a laser technician on the equipment in the spa.

Spa employees who treated Employee B and C (and their spouses) do not appear to have medical training

To note again, we have not seen any documentation to support that any of these spa employees who treated Employee B and C (and their respective spouses) have any medical training. One employee told us that she received training at the spa, and that she received a certification of some kind from the doctor. We asked her to provide this certification to us – she has not.

Only the nurse mentioned in some of the records has medical training, and to the best of our knowledge, she only administered the treatment for Employee A.

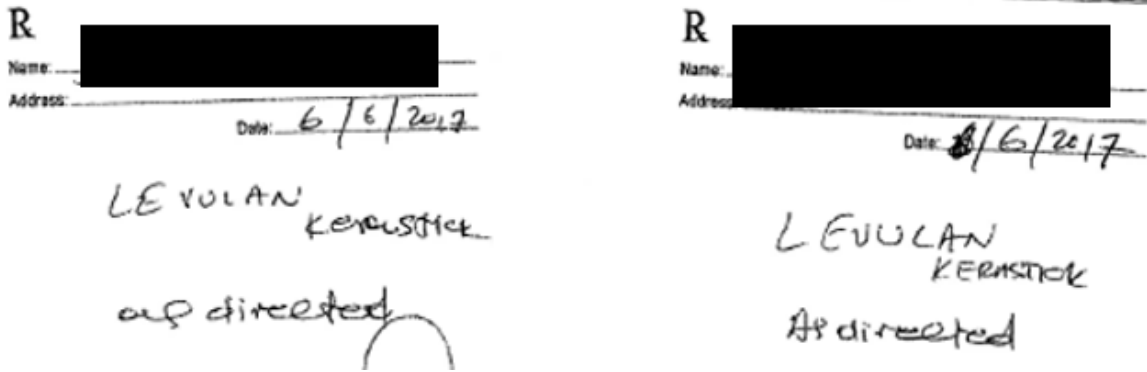
Prescription dated 3 years after treatment with drug said to have begun

Employee C's knowledge of the prescribing doctor

Employee C had been receiving Levulan treatments from the spa since 2014, while her spouse had been receiving Levulan treatments at the spa since 2015. However, both of their prescriptions from the physician are dated June 6, 2017 – several years after their treatment with the drug began, according to their spa invoices.

This is the only prescription that we were provided for Employee C and her spouse. We find it unusual for a prescription to be dated three years after a treatment with a drug began.

Figure 22: Prescriptions for Employee C and her spouse from the doctor, dated 2017



Employee C confirmed that she never met the doctor and was never diagnosed with anything from him.

AG's Office: OK. And what do you know about [the doctor who diagnosed you and prescribed you Levulan]?

Employee C: As I said I never met that doctor.

"I never met that doctor"

AG's Office: OK. Do you know that – because he's the one that is – his signature and stuff is on your prescription form for Levulan so do you know, you know, how that would have –

Employee C: No, that prescription was never provided to me. I presume that that's probably just on file at the [spa name]. I had never seen that prescription.

Further, if the drug was being used off-label, for a condition such as rosacea or toenail fungus, conditions for which Levulan Kerastick has not been approved for by Health Canada, or being applied with a laser instead of a blue light, as indicated by Health Canada, we expected to see records and consents supporting that in the treatment records. We found nothing.

Employee C believed there must have been standing orders from a doctor to help diagnose clients

We asked Employee C how it was possible to have a prescription and a diagnosis from a doctor she had never met – virtually, in person or by phone.

According to Employee C, who does work in the medical field, she believed that the staff at the spa were able to diagnose her with rosacea and actinic keratosis based on what she referred to as "standing orders" from a physician:

"I believed I was Dx [diagnosed] with the condition that could be a precursor to skin Cancer remotely through standing orders by the staff at [the spa]."

We inquired further as to what "standing orders" meant to her:

"[The spa] was working on through their physician. They probably got a set amount of criteria that they must have and they, through the physician that works with them, just like with myself working through our base hospital physicians, there's standing orders. That's what I presume. But you know, different things that would present for – I don't know whether they send that to their physician or what their interaction is with their physician or what their standing orders are for that matter."

GSC Medical Standing Orders

Her explanation was somewhat consistent with what GSC staff documented in their notes when they contacted the spa COO. They noted that the spa told them that the spa uses:

"qualified individuals under medical directive and the physicians will review notes and sign off."

[Emphasis added]

Her description of the treatment

Employee C's description of the treatment

In the interview, Employee C described the treatment she received:

"I decided to have the treatments done for the rosacea. You would just go into the office, let them know you were here. You would wait, and then there would be a room that they'd prepare, and once the room was ready you would go in. You'd lie on a, like a stretcher, like a doctor's type stretcher with paper over it. You were given eye protection and you weren't in there more than – I mean they would put the - I guess it felt like a gel on your face. And they would use a laser and then you would, you know, wipe off the gel at the end and leave... they had different technicians that would do the treatment..."

Her description of the gel

We asked her to describe the gel they used:

"I didn't actually – I didn't actually see it. It was just like a gooey type substance that would go on your face. It was clear. There wasn't any colour to it."

She said staff would leave the gel on her skin for a maximum of five minutes before starting what she called the laser treatment.

Employee C's description of how the medication was being used is consistent with the spa employee's description. However, both of their descriptions differ from what Health Canada has approved, as well as from our understanding and research.

Levulan Kerastick is a solution that contains 20% Aminolevulinic acid and is applied to specific lesions with a pen-like applicator (the stick) to ensure precision. The lesions treated with Levulan become sensitive when placed under a special light. It is not a gel that is slathered on, and it is only approved by Health Canada for treatment of actinic keratosis.

Mixing Levulan / using it with a gel

How the spa is applying Levulan

We inquired further with the spa employee who treated Employee C. Her description of how she conducts the treatment is not consistent with the description on the drug monograph.

According to a spa employee, she said that Levulan comes in a stick and they mix it within the gel, which helps spread the medication around the face. She said it sometimes would take more than one stick per treatment on a face because, as she said, the sticks are only 20 per cent active.

She also said that she "cuts" the Levulan herself, and said she would not take responsibility for a treatment she did not do herself.

The spa owner told us something similar – that after applying the Levulan, they apply a sort of gel. She said this gel's purpose is just to help the laser move along the skin.

The spa employee treating Employee B said:

"You break the ampule and there's a powder and an activator so you shake the powder and the activator, and you crack it open over the area of concern."

She explained that after that, she would go over the area with a laser.

Using a laser instead of a blue light

Using Levulan with a laser

The drug monograph, which is on the Health Canada website as mentioned earlier in this report, has approved treatment with a blue light, but there is evidence of practitioners using it off-label with other lights, including Intense Pulse Laser (IPL). Of course, the intensity of the medication combined with the intensity of the light and the type of light source are all important in the treatment of a patient.

"...the doctors, they don't tell me how to run my laser."

The spa employee treating Employee C told us that an IPL laser is used, and that it's the spa employee who decides the appropriate intensity.

"... the doctors, they don't tell me how to run my laser. They don't know how. They don't know the numbers, because every laser is like [different] It's a machine. It's like a saw. Everyone has different powers, even though they're saying that they're using so much power, every one works differently. So the laser technician has to know their laser. The doctor can't go and watch 100 lasers and tell me exactly what I have to do."

[Emphasis added]

Employee C says she was treated for rosacea

Treatment Areas

We asked Employee C where she was treated. She said she was treated on her face for rosacea, and also on her forearms and around her knees and inner calf. She told us she was advised not to shower and to stay out of direct sunlight for 24 hours after the treatment.

Spa employee says she treated Employee C for toenail fungus, rosacea and veins

This differs from what the spa employee told us – that she treated Employee C many times for toenail fungus. This is consistent with the spa treatment records, and it is also written on 22 out of 28 of Employee C's invoices (among other conditions including actinic keratosis). The spa employee also told us that she treated Employee C for rosacea and veins.

The spa invoices have multiple conditions listed on them – some of which Employee C said she had (rosacea) and some of which she said she didn't have (toenail fungus), but which the spa employee told us she did have.

To note, Employee C had multiple diagnoses for which the invoices indicate she was treated with Levulan Kerastick. The owner told us that these are generic forms with multiple conditions on them. However, our examination shows the conditions listed on the spa invoices do sometimes change, which they also did in the case of Employee B.

Spa employee's description of actinic keratosis and Levulan

The spa employee, who says she diagnosed Employee C with rosacea and several other conditions, did not seem to understand what actinic keratosis is, the condition for which the employee claimed reimbursement.

The spa employee told us that actinic keratosis and rosacea are caused by bacteria.

Spa employee says actinic keratosis is bacteria on the skin

"Actinic keratosis is bacteria living on the skin that can cause cancer. Rosacea is bacteria. Toe nail fungus is bacteria. Sun damage can be anything. We also use a main laser for damage, skin damage and we also use it for acne. What it actually does is that it kills the growth of fungus."

She also said later that rosacea is caused by sun damage.

"Then there's the rosacea which [Employee C's spouse] had a problem with because he was always out in the sun, he was always destroying his skin."

Again, this employee had no medical training but was, according to her, diagnosing, confirming treatments with the doctor, mixing the drug being applied, then setting the laser strength. No delegation materials or written medical directives were provided to us, despite our Office asking multiple times.

Employee C's explanation for the large number of treatments she received

Employee C and her husband had a handful of treatments in 2017. In 2018, that number increased dramatically.

Figure 23: Example: Employee C's Treatment Dates, June 2018-November 2018

June 2018							July 2018							August 2018						
Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
					1	2	1	2	3	4	5	6	7				1	2	3	4
3	4	5	6	7	8	9	8	9	10	11	12	13	14	5	6	7	8	9	10	11
10	11	12	13	14	15	16	15	16	17	18	19	20	21	12	13	14	15	16	17	18
17	18	19	20	21	22	23	22	23	24	25	26	27	28	19	20	21	22	23	24	25
24	25	26	27	28	29	30	29	30	31					26	27	28	29	30	31	

September 2018							October 2018							November 2018						
Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
						1		1	2	3	4	5	6					1	2	3
2	3	4	5	6	7	8	7	8	9	10	11	12	13	4	5	6	7	8	9	10
9	10	11	12	13	14	15	14	15	16	17	18	19	20	11	12	13	14	15	16	17
16	17	18	19	20	21	22	21	22	23	24	25	26	27	18	19	20	21	22	23	24
23	24	25	26	27	28	29	28	29	30	31				25	26	27	28	29	30	
30																				

According to the calendar, Employee C's invoices show she was being treated almost every week for several months in 2018.

Most clients treated with Levulan 2-6 times, according to dermatologist we interviewed

We obtained the opinion of an expert dermatologist. The dermatologist shared that most patients are treated for actinic keratosis with Levulan between three to six times, depending on the individual. The dermatologist also told us that patients generally need to wait a month between treatments in order to give the skin time to heal.

We asked Employee C why she had so many treatments, and she explained that she was worried about getting skin cancer, a condition her family member was being treated for. She said she was being treated once every two weeks. We told her this did not match up with her invoices that showed she was often going once a week. She said:

"There might have been times when it was once a week if it was different areas. But one area was never worked on more than once every two weeks."

She was asked why the number of treatments increased for her spouse also, who is not genetically related to Employee C's family member.

She said that her spouse was experiencing many of the same symptoms as she was, and that it is common for people with her spouse's skin type to "have this condition".

However, she later added that the treatment was not particularly helpful in treating what she thought was rosacea.

"Not an awful lot [of an effect on my skin]. I mean sometimes they were red – redder. And then it would calm down. But ... it was – wasn't really ... wasn't an awful lot of – it sort of kept things in check. It didn't really change anything."

We noticed that the spa's website advertises that rosacea is treated effectively and quickly.

Invoices claiming treatment for rosacea, actinic keratosis, and toenail fungus

Employee C says she was never treated for toenail fungus

Employee C told us she noticed that toenail fungus was on one of her invoices. She said she had never been diagnosed with toenail fungus, nor had she been treated for it at the spa. She said she followed up with the spa about it, but was not able to speak with anyone there.

"I did go back [to the spa] to see if I could talk to one of the – [spa employee – the technician that had treated her] there that had given me some records, because I didn't have any records. And she gave me some records. And then I went back to question her about the records because it did say on the records that I was treated for – or I don't know whether it was me specifically – but there was a toe fungus on there and I've never been treated for toe fungus. I've never had it. So I wanted to question her about that and she wasn't there."

Spa employee told us she treated Employee C for toenail fungus about 20 times, and it is listed on 22 of her invoices

We followed up with the spa employee that claimed to have treated her, the same spa employee that was identified by the COO as the person treating Employee C under written medical directives. The spa employee was clear that she treated Employee C multiple times for toenail fungus. Toenail fungus was listed on 22 invoices as a condition Employee C was treated for. The spa employee confirmed she treated Employee C with toenail fungus about 20 times with the laser.

We reviewed spa records and noted many entries for toenail fungus. The spa employee claimed that although she gave many treatments for toenail fungus, the writing on the treatment records was not hers.

Figure 24: Spa treatment records showing Employee C was treated for bacterial fungus on her toes

TREATMENT RECORD
(office use only)

Client Name: [REDACTED] Date: July 5 10

Fitzpatrick Skin Type: ① II III IV V

Areas to be treated: Bacterial Fungus + At
(Toes + Feet)

[REDACTED]	17 - YAb - 2 MM - 10MS + 210TS
[REDACTED]	17 - YAb - 2 MM - 10MS + 210TS
[REDACTED]	17 - YAb - 2 MM - 10MS + 210TS
[REDACTED]	17 - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	118 - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS
[REDACTED]	11F - YAb - 2 MM - 10MS + 210TS

RPN: [REDACTED] Name of nurse we interviewed

The spa employee who treated Employee C said that while she did treat her for toenail fungus, she did not write this record. This handwriting is indeed very different from the records the spa employee said she did, in fact, write.

We do not have any information about who wrote this, and several similar, treatment records. The handwriting specialist confirmed to us that the employee we spoke to did not write those treatment records.

We noticed a notation at the bottom of the record that said "*RPN [name of nurse] on duty*".

We asked the owner what it meant. She said that the RPN was "*the one on duty at these times*."

Nurse listed at 2 locations on same day, within an hour of each other; Nurse said she never worked at 2 locations on same day

We noticed that for one of the days that the nurse was treating Employee A in another spa location, the records indicate that the nurse was on the other side of the Greater Toronto Area (GTA) supervising Employee C's toe fungus treatments. Receipts for both treatments show that they occurred within about an hour of each other.

Concerns about reliability of spa documents

We asked the nurse about this and she confirmed that she never worked in two different spa locations on the same day. This raises concerns about the reliability of the other documents and treatment entries that have the notation that the nurse was supervising treatments.

Review of supporting documentation

As part of our investigation, we compared the following documents in order to see if there was any information to support Employee C or her spouse's claims for service from the spa. The documents we examined were:

- 28 spa invoices for Employee C
- 34 spa invoices for Employee C's spouse
- The spa treatment notes for Employee C
- The spa treatment notes for Employee C's spouse
- Debit/credit receipts from Employee C and Employee C's spouse showing payments made to the spa

Not all documents for all treatments were provided. However for the documents that were provided we noted the following:

- Some of the dates on Employee C's receipts from their point of purchase terminal matches with dates on the spa invoices Employee C submitted to GSC.
- Very few of Employee C's receipts match with the amounts listed in the spa invoices submitted to GSC.
- The service on the receipt and the person rendering the service is blacked out on the receipts from the point of purchase terminal that we obtained.
- Most of Employee C and Employee C's spouse's receipts did not match dates on their spa invoices, and the amounts paid in the receipts do not match the amounts claimed on the spa invoices.

- All 28 of Employee C's spa invoices say she was treated for actinic keratosis. However:
 - 8 of her spa treatment notes say she was treated for actinic keratosis and rosacea.
 - 24 of her spa treatment notes say she was treated for "bacterial fungus + AK (toes & feet)". She told our Office she never had toenail fungus.
 - 4 of her treatment notes say she was treated with IPL for acne.

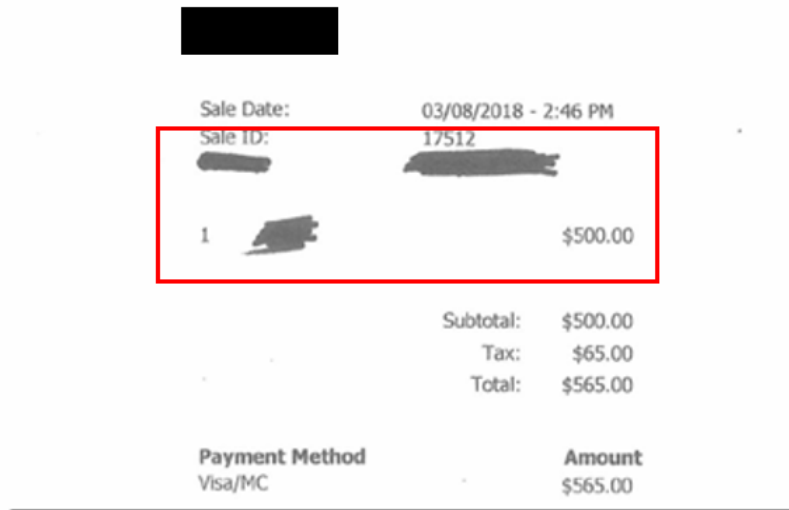
- All 34 of Employee C's spouse's spa invoices say he was treated for actinic keratosis. For the spa treatment records we could obtain, the actinic keratosis was on his face. However:
 - 27 of his spa treatment notes say he was treated for bacterial fungus of the toes and feet.
 - 1 of his spa treatment notes say he was treated with IPL for rosacea.
 - 3 dates in his spa treatment notes say he was treated with pixel long pulse. It does not say for what condition.
 - There are no spa treatment dates for 7 invoices.

Some of the receipts Employee C provided contain more information than a standard debit/credit receipt: they include the name of the client, the payment method, the amount, the date and time, as well as a brief summary of what the treatment was.

We asked Employee C to match up the invoices to the receipts because we could not. She never responded to this request.

Further to the discrepancies mentioned above, we noticed that several of these more detailed receipts from the spa had portions blacked out, as seen below.

Figure 25: One of Employee C's spa receipts with information blacked out



Spa says it did not black out receipt

We separately asked the spa's COO, the spa owner, and Employee C who blacked out the receipts, and why:

The spa COO responded:

"That just looks like a regular receipt from a POS device that was printed and then blacked out. If a client requests that [receipt], then we provide. We don't start marking receipts up."

"...I can't myself imagine what the point of blacking out a receipt is when we provide a full claim form explicitly detailing the treatment, the drug, the use, the cost, the application, the source, the clinic, and more"

The spa owner said the clinic does not black out receipts.

We asked the spa employee who was treating Employee C if she had blacked out sales receipts to which she said:

"I never blacked out anything on the sales receipts."

When we asked Employee C the same question, Employee C said:

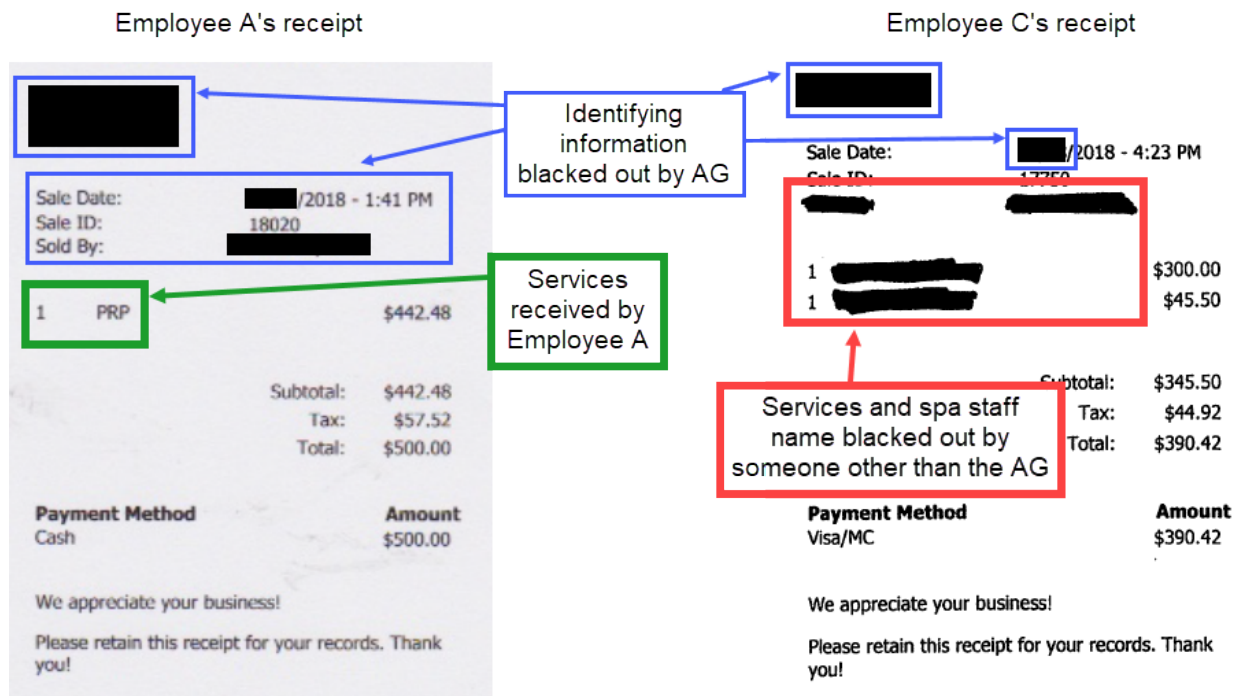
Employee C says spa
blacked out receipts

"To the best of my knowledge I have given the city all of my receipts I felt some were missing so I asked [the spa] to provide me with copies the receipt you sent to me was one of the copies that [the spa] gave me they blacked out details I do not know why they did that something about confidentiality. I told them that I have ask them to give the city and my plan all my medical details."

[Emphasis added]

When then compared to the same point of purchase receipts that Employee A received and provided to us, we noticed that the portions blacked out actually show the treatment that was provided, as well as the name of a spa employee, as seen in the figure below.

Figure 26: Employee A's receipt compared to Employee C's receipt from the spa



We asked the spa employee whether she was treating Employee C for rosacea and actinic keratosis on the face at the same time, since Levulan is only approved to treat actinic keratosis on the face and scalp by Health Canada. The spa employee said sometimes she did treat multiple conditions on the same day, and sometimes she did not. She added that actinic keratosis is a bacteria, and is the same kind of bacteria as toenail fungus.

Summary of Employee C's case

The following is a summary of Employee C's case, based on our review of all the relevant case files and based on information from our interview with Employee C:

- Between 2014 and 2016, Employee C and her husband claimed about \$4,000 each from the previous health benefits plan administrator.
- According to her invoices from the spa, she claimed \$13,842.50 on treatments in 2017, 2018 and 2019, and was reimbursed \$12,257.33.
- According to his invoices from the spa, Employee C's husband claimed \$17,232.50 on treatments in 2017, 2018 and 2019, and was reimbursed \$14,232.50.

The total amount they were reimbursed from 2017 to 2019 for their Levulan claims was \$26,392.60.

- There was a prescription for Employee C for Levulan from the doctor, dated 2017, even though her treatment began in 2014. She never met that doctor or was, according to her, diagnosed by him or treated by him.
- She told us she believed that spa staff diagnosed her with rosacea based on what she called standing orders from a physician. The spa employee confirmed to us that she did diagnose Employee C with rosacea, and that her diagnosis was approved by the doctor.
- She told us that spa staff told her that she could be treated for rosacea at the spa.
- 24 of her spa clinic notes and several invoices say she was treated for toenail fungus – a condition she told us she has never had. The spa employee who said she treated Employee C said that she did, in fact, treat her for toenail fungus, as well as veins – another condition listed on her treatment records and her invoices.
- The actual service received was blacked out on point of sale receipts provided to us.
- She told us that she believed that nurses and other staff at the spa were treating her with Levulan under 'standing orders' from the doctor. She never looked up what Levulan was nor did she look up another condition that was on her invoices, actinic keratosis.

- Her description of her treatment is inconsistent. At times she said she never saw what the spa employees did because she had protective eyewear on, but at other times she told us that the gel applied to her skin before the treatments was clear.
- From her description of her treatment, it appears that the treatment she did receive does not match with what would happen to a patient who was treated with Levulan Kerastick for actinic keratosis.

B. Medical opinions

B. 1. Dermatologist Interview

We interviewed a dermatologist

We interviewed a dermatologist to get a better understanding of the drug Levulan and its usage. We also particularly wanted to find out what sort of dosage should be administered for actinic keratosis, and whether it could be used on either rosacea or toenail fungus.

Dermatology is a specialty requiring 5-year advanced medical training and certification

According to the Canadian Dermatology Association, the term dermatologist:

"...is reserved for medical specialists who have earned a medical degree and have completed an intensive five-year program of advanced medical and surgical training in the prevention, recognition and treatment of diseases of the skin, hair and nails"

"All dermatologists must be certified by the Royal College of Physicians and Surgeons of Canada and or Federation des medecins specialists due Quebec."

Dermatologist is an expert in her field

The dermatologist we interviewed has been working in Toronto for the past 25 years. She is a member of the Canadian Dermatologists' association, and is known as an expert in her field.

During an interview, she provided information that is helpful to understand the condition of actinic keratosis and the drug Levulan.

Actinic Keratosis

An actinic keratosis is a pre-cancerous skin lesion that results from prolonged exposure to the sun. It's commonly found on the face and head, and other areas that are exposed to the sun, such as the backs of the hands or the shoulders.

Actinic keratosis happens to patients later in life

The dermatologist says it usually begins to occur later in life. She says she has seen it in a patient as young as 20 years old, but that is rare.

Full-body skin exam is done (to be sure all lesions are identified)

After a full-body skin exam, one of the treatment options is liquid nitrogen, which can burn off the lesions.

Liquid nitrogen sometimes used to burn off lesions

Another treatment for actinic keratosis lesions is the use of Levulan Kerastick. Levulan is 20 % Aminolevulinic acid HCl, a porphyrin precursor. Levulan is a solid which is then dissolved into a solution to become a liquid formulation. The topical liquid drug is applied to the actinic keratosis (with an applicator which looks like a pen or stick). It is commonly used as a field treatment in order to treat the entire surface area affected with actinic damage. It is left on the skin to incubate usually between one to four hours but a longer incubation time might be necessary depending on the patient. After that, it is activated with a specific wavelength of light, one of which is a specialized light (see Figure 29).

Levulan Kerastick is also used

Diagnosis generally done by a dermatologist

Diagnosis, prescription and treatment is generally done by a dermatologist.

Rosacea

Rosacea is an inflammatory disorder

The dermatologist says rosacea is a completely different skin condition than actinic keratosis. It is an inflammatory skin disorder characterized by redness, flushing and blushing. It tends to worsen as the patient ages.

Treated with anti-inflammatory drugs and sometimes photodynamic therapy

It is generally treated with topical anti-inflammatory drugs, antibiotics and, in rare cases, photodynamic therapy.

Levulan

Levulan is a good tool but you need a proper diagnosis and you need to treat it properly

The dermatologist says Levulan is a good tool to treat actinic keratosis.

"I do it all day, I do it commonly. I think it's a great treatment, but it has to be the right patient. As with everything, you have to have the proper diagnosis and be treating properly."

Health Canada only accepts Levulan to treat actinic keratosis

Health Canada's *only* accepted use for Levulan is to treat actinic keratosis of the face and scalp. This drug can have some risks. Health Canada advises that only qualified health professionals can use it to treat patients.

Levulan usually needs to incubate

The dermatologist says that she usually applies the Levulan to a patient and then leaves it on them to incubate for one to four hours⁹. After that, it is treated with the light therapy for anywhere from eight to 40 minutes.

In some cases, if the actinic keratosis is very thick, or hyperkeratotic, an extra layer of Levulan is applied before it is treated with light therapy.

⁹ Note: Documentation indicates the drug should be left on the skin for 14-18 hours before it is treated with the specialized light. However, in addition to the interview we did with the dermatologist who said she leaves it on for up to four hours, information from the University of Alberta says that the 14-18-hour period is not always used in a clinical practice. <https://open.alberta.ca/dataset/1d049690-a3bd-4126-92f6-7066006e749e/resource/23b69049-d2c2-4ce0-980d-a01b3b58ace6/download/ahtdp-pdt-skin-uofa-ste.pdf>

Figure 27: Levulan Kerastick being applied to a patient's skin (Levulan Kerastick circled in red)



Figure 28: Patient with Levulan on skin under specialized light



Note that this is a 'Blue Light' which is different than the laser that the spa says it is using to activate Levulan

Patients usually require 2-6 Levulan treatments, 1 month apart each

The dermatologist says it's important for a dermatologist to see a patient's lesions to ensure they are being treated properly with Levulan.

She says that on average, patients require two to six treatments of Levulan. Some patients may need one or two more sessions than that if they have very thick actinic keratosis.

These treatments are generally done about a month apart to allow the skin to heal.

Frequency of sessions appears high for some of our employees

AG's Office analysis of high number and frequency of treatments as per invoices

We noted that two of the employees, Employee B and Employee C, each had invoices that said they had more than 25 treatments with Levulan. The dermatologist told us that on average, patients are treated two to six times with Levulan for this condition.

The dermatologist also said patients are sensitive to sunlight after the treatment with Levulan, usually for 36 to 48 hours after. Both Employee B and Employee C had invoices showing they were being treated with Levulan weekly at some points.

Questions around OB/GYN treating skin conditions

We also asked the College of Physicians and Surgeons of Ontario (CPSO) about an OB/GYN diagnosing, prescribing and treating patients for actinic keratosis and some other key aspects of this case.

The Terms and Conditions of the doctor's practice, per the College of Physician and Surgeons' website, states that the doctor "*may practise only in the areas of medicine in which the doctor is educated and experienced.*"

Staff at a medical spa are not trained to diagnose and treat skin disease

Treatments at health spas

We also asked the dermatologist about whether she would ever advise her patients to be treated for actinic keratosis or rosacea at a medical spa.

She said:

"Dermatologists are specialists in diseases of the skin and are uniquely qualified to diagnose and treat skin disease. Staff at a medical spa are not trained to diagnose and treat skin disease."

C. Medical Professionals

C. 1. The doctor

Doctor says the Employees are his patients, he diagnosed them and is treating them with Levulan

The doctor in this file is listed on the prescriptions and on the Drug Special Authorization Forms for the three City of Toronto employees in this file.

As noted in previous sections, on April 1, 2019, the doctor confirmed via letter to GSC that Employee A, Employee B, and Employee B's spouse are his patients, he diagnosed them with actinic keratosis/rosacea, and that he prescribed and treated them with treatments of Levulan Kerastick. Based on the forms sent back to GSC, the doctor confirmed that the signature on the prescription Drug Special Authorization Forms was his own.

Doctor is an OB/GYN

The doctor has been registered as a physician with the College of Physicians and Surgeons of Ontario for many years. His specialty is listed as Obstetrics and Gynecology.

Difficulty getting the doctor to respond to our queries

We sought to speak to the doctor and ask him to confirm several details, including whether the City of Toronto employees and their dependents mentioned in this report were his patients and whether he treated them with Levulan for actinic keratosis.

The doctor said on a phone call that he had dealt with this issue already. We had never spoken to the doctor about his file prior to our first phone call.

We contacted him again and raised our concern that some of the writing and signatures were potentially not his and we simply wanted to confirm that the signatures on prescriptions, diagnoses and medical forms sent to GSC were his.

At first, he did not confirm his signature. Instead, his secretary called to inform us that she has worked with him for many years and it was her view that the signatures on the forms we sent to the doctor were his signatures.

Doctor finally confirms that the signatures were his

We resent our request, advising by letter we required written confirmation by the doctor of his signature on the diagnosis, forms and the handwriting for some diagnoses. He did not respond to this request.

We followed up by phone with him, and he confirmed that the signatures were, in fact, all his.

Again, the reason we insisted on following up on his signature was because we were trying to understand whether the employees or perhaps spa personnel were fabricating his signature.

Several inconsistencies between the information provided by the doctor and what the employees are saying

Inconsistencies

There are many inconsistencies with the information purportedly provided to GSC by the doctor, and what the City of Toronto employees in this file told us.

Table 1: Inconsistencies with the doctor' statements

What the doctor or spa said to GSC (via mail or by phone)	What employees told us
Employee A is his patient	Never met or spoke with the doctor
Employee B is his patient	Never met or spoke with the doctor
Employee B's spouse is his patient	Never met or spoke with the doctor
Employee C is his patient	Never met or spoke with the doctor
He treated these patients himself	None of them ever met or spoke with him
That he diagnosed these patients with actinic keratosis	None of them ever met or spoke with him

Signatures

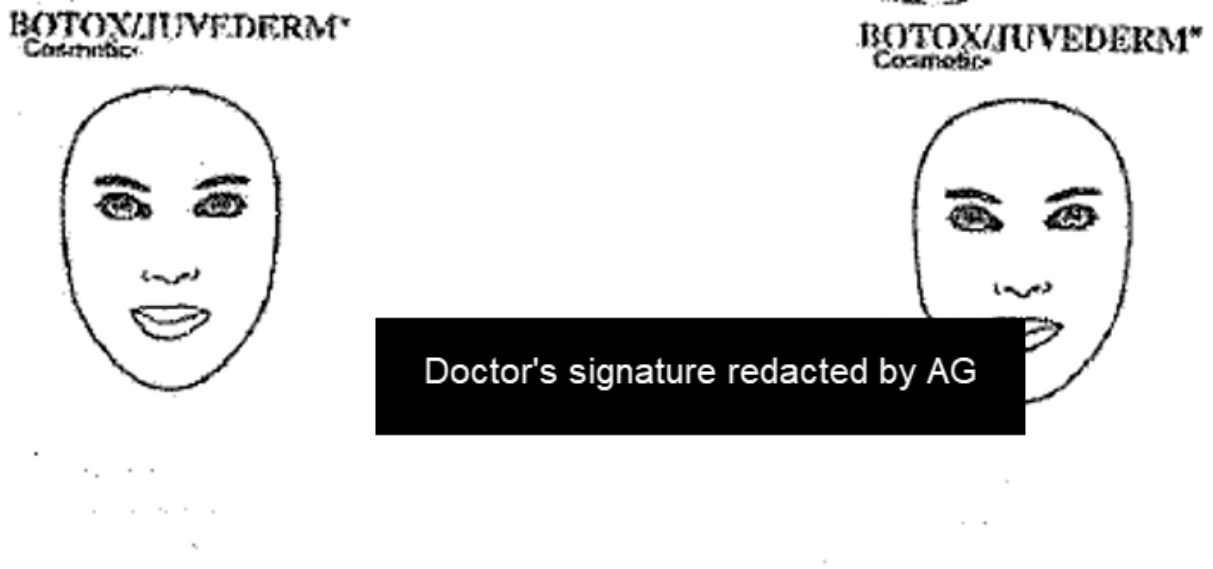
Employee B's spouse's Drug Authorization Form had the printed name of the doctor misspelled. We showed the corresponding signature to a handwriting expert. The expert confirmed that the signature on that form is suspicious because it deviates from the signature which the doctor confirmed was his to GSC.

Doctor's pre-signed clinic notes

We reviewed the treatment records for Employee A and it appears that the doctor's signature was pre-signed and/or photocopied on blank spa treatment note areas.

On the spa treatment notes for the second and third treatment dates, there are 6 'faces' with blank spaces for a person treating to add notes. Only two of those 'faces' were used – there was no doctor's signature under those faces. The doctor signature appears to be applied to the form under the remaining blank faces on several pages. His signature appears to be pre-signed or photocopied.

Figure 29: Treatment faces appear to be pre-signed with doctor's signature



City Employees never met or spoke with the doctor

Delegation of diagnosing and treatment

All of the City of Toronto employees in this file told us they had never met or spoken to the doctor, even though the spa provided prescriptions for Levulan for them and he appeared to have signed their Drug Special Authorization Forms, which GSC used to approve their Levulan claims.

Spa staff gave us very different stories about how they interacted with the doctor

In the case of Employee C, she told us that she thought spa staff were acting under standing orders from the doctor and according to GSC for the same client, the spa's COO claimed that Levulan was being administered under a medical directive. The spa employee said that she diagnosed the employee then called the doctor to describe what she was seeing, but it is she, not the doctor who decides what strength of laser light to administer to the area where Levulan is applied. However, to GSC, the doctor confirmed in writing that *he* treated the patients.

Still, we wanted to verify whether or not it was possible for a physician to delegate his authority in order for the spa to treat these employees without the physician having met the spa clients.

It appears there are special procedures in place for doctors to delegate

Based on our research with the College of Physicians and Surgeons of Ontario (CPSO), it is our understanding that doctors in Ontario are allowed to delegate certain procedures if the following conditions are met:

- They have a pre-existing relationship with the patient before the delegation begins
- The patient consents to the delegation
- They follow up with the patient

In some cases, the conditions above cannot be met for delegation because it falls under an emergency situation, such as a patient attending an emergency room at a hospital for emergency care. In those cases, care may be delegated to nurses and paramedics in order to best treat the patient in that emergency situation.

Appendix 2 outlines the rules

Further details about the rules around physicians and delegation of authority can be found in Appendix 2.

Spa COO said clients met doctor via telemedicine

When we questioned the spa COO as to how things worked at the spa in relation to the doctor diagnosing, he said:

"We were using tele-medicine at the time which was the go-to for this type of situation. So one of the things that happened was GSC considered [meeting the patient through] a telemedicine event ... [as the employee] never "met" him [the doctor]. [GSC]... would ask the clients, "what was he wearing? what colour is his eyes? did he have an accent?"

The doctor has a delegation to our nurses at the locations to conduct the medical consultation which gets reviewed by him before we proceed. Additionally, he conducted many, many telemedicine interviews himself in addition to this."

Spa employee said clients met doctor in person, on phone, or via telemedicine

A spa employee told us that the clients at the spa had consultations with the doctor, and that these were either in person, on the phone, or via web conferencing.

This does not make sense – the Employees say they never met him virtually or otherwise

Again, this does not make sense for three reasons:

1. There is no documentation on any treatment file that we reviewed to support that any consultations between the doctor and the clients and/or spa staff took place.
2. The three employees said they never met the doctor – they never spoke with him, virtually or otherwise.
3. The diagnoses generally never aligned with the treatment
 - o For Employee A, for example, the nurse was administering hair loss treatment while the doctor prescribed Levulan for his face. Her medical consultation was for hair loss, not actinic keratosis.

The College of Physicians and Surgeons have strict policies around delegation

The College of Physicians and Surgeons have strict policies when physicians are practicing via telemedicine. According to its policy:

- Physicians must establish a physician-patient relationship “*via telemedicine in the same circumstances as when a relationship is established in person*”
- The physician “*must consider the patient’s existing health status, specific health-care needs and specific circumstances, and only use telemedicine if the risks do not outweigh the potential benefits and it is in the patient’s best interest*”

The College has advised patients considering telemedicine:

"The care your doctor provides you during a telemedicine appointment must be of the same quality as care provided in-person. Your doctor must meet the same expectations that apply to in-person care. For example, they must: have your consent for the treatment, follow-up on test results, keep your health information private and confidential, and keep medical records."

The employees never spoke with the doctor so how could he talk to them about telemedicine – if that is what the spa and the doctor are claiming happened

We had consent from all three employees to receive medical records to confirm their diagnoses and treatments. Although we requested all records that the doctor had so that we could fully analyze the situation, the doctor confirmed that the spa COO had provided us with everything.

The College’s advisory to those considering telemedicine states:

"Your doctor will talk to you about whether telemedicine is an option, and will advise whether telemedicine is suitable for you. You can help your doctor by telling him or her if you have any concerns about having a telemedicine appointment. Telemedicine may not always be appropriate for you."

The employees say they never spoke with to the doctor – so he could not have discussed whether telemedicine was appropriate.

It is important to examine lesions and to follow-up

Ultimately, the delegating physician is responsible for the patient's care. It is also important to follow up with the patient. Earlier in this report, the dermatologist explained that it is important for a dermatologist to examine actinic keratosis lesions that are being treated with Levulan.

C. 2. The spa

As part of this investigation, we needed to understand more about the spa. The spa advertises that they specialize in cosmetic treatments like laser hair removal, Botox, skin tightening, skin fillers, and other cosmetic procedures.

They have several locations in the GTA.

The business was registered to a numbered company.

Attempts to retrieve documentation

GSC noted that their correspondence with the spa had been with the COO. They stopped attempting to get records from him since he repeatedly did not send the full documentation they requested.

Spa delisted

Due to its investigation into these claims, GSC delisted the spa.

As part of our investigation, we also spoke with the spa COO. He told us that he had already provided all relevant documents for this file (for all three cases) to GSC. He said:

"We have [provided all the documentation]. Furthermore, we not only confirmed them individually through phone every time Greenshield Canada had called the clinic to have them authorize throughout the years, but also when they decided to dump a massive list of requests on us and interrogate us and the clients with extreme intimidation. There was also 0 [zero] understanding that they had family plans and had their family receive treatments respectively, so they pitched it that these three did all treatments themselves."

We repeatedly asked him to confirm whether he had provided all records. He told us that he had provided all records to us, and that he had no further records to provide in relation to these claims. On Sept. 16, 2020, the COO, via his lawyer, told us:

"There is no further documentation to be provided."

Despite this, we never received the records to properly support these claims.

We also interviewed:

- The spa owner
- Three spa employees who are listed on several treatment records and invoices, and who treated the City employees
- One of the spa employees is a nurse (RPN), and her name is listed on the treatment records for Employee A. It is also printed at the bottom of several treatment records for Employee B and C as the nurse on duty at the time of their treatments.

Spa says it is dispensing Levulan to clients

In relation to dispensing Levulan Kerastick, a Schedule I drug, the spa COO stated:

"The Levulan was supplied at the clinic. We have medical consultants, med techs, nurses, doctors, and directors.

They [the Employees] purchase the treatment and the levulan right there at the clinic so it is easy and convenient for the customer, which pays GSCs bills and our bills. But they [GSC] seem to still be the victim here."

GSC requires that a drug be dispensed by a licensed pharmacist.

Figure 30: GSC Canada's drug dispensing requirements

Eligible Expenses (Benefit year January 1 – December 31)

- > Semi-private hospitalization – difference between ward and semi-private hospital room.
- > Drugs (drug card, including current generic prescription features, for use in Canada), which are prescribed by a medical doctor or dentist and dispensed by a licensed pharmacist, which:
 - Require a prescription, have a Drug Identification Number and are listed in Federal or Provincial Drug Schedules
 - Reimbursement for drugs shall be subject to a dispensing fee cap of nine dollars (\$9.00) per prescription
 - Maximum of three hundred dollars (\$300) per person per benefit year for smoking cessation medication
 - Plus other non-prescription but life-sustaining drugs if they have a Drug Identification Number.

It is our understanding that in Ontario, physicians who dispense drugs must meet the same or similar standards of dispensing that a pharmacist must meet. In addition, physicians who dispense drugs must use proper methods of procurement in order to be assured of the origin and chain of custody of the drugs being dispensed, along with other information including knowledge of who had the product, how it was stored, and how long they had it.

The physician must also:

- Keep records of the purchase or sale of drugs,
- Keep records which allow for the retrieval and/or inspection of prescriptions,
- Have an audit system in place in order to identify possible drug loss.

We attempted to ask the spa COO to clarify how this prescribing and dispensing of Levulan worked because we knew that at least one of the clients (Employee A) had never received Levulan but the City was paying for it. We asked the spa COO whether he could provide us with documentation to support the spa's purchasing of Levulan. The spa COO stopped communicating with us directly. Via his lawyer, he responded:

"The requested detail about inventory records is not within the scope of the review. Levulan is prescribed and administered by the nurse or medical aesthetician under delegation from a physician. The spa is not a pharmacy. The patient is not taking a drug home but is purchasing it to be administered at the spa as part of the treatment."

The doctor confirmed all records for these individuals have been provided by the spa.

The spa owner told us that the client does not purchase the medication, even though it says directly on the spa invoices that the patient is responsible for purchasing the medication.

Spa owner: No, the client does not purchase the medication. It's not available in the drug stores.

AG's Office: Okay, so it's from the [spa] clinics that they get it?

Spa owner: Yes, we have it in the clinic.

[Emphasis added]

The spa owner told us that they purchase Levulan from a distributor.

To note, we have not received information regarding whether the spa's purchasing of Levulan was documented and managed according to the CPSO's rules, and that is outside the scope of this investigation.

The City benefits plan requires that a prescription drug be dispensed by a pharmacist, so we were inquiring to see how the drug was dispensed. The dispensing of Schedule I drugs is controlled. Normally, these are dispensed by pharmacies, but physicians can also dispense them.

Upon further questioning, the spa COO advised us that Levulan is administered by either a nurse or *"licensed medical aestheticians under delegation from a physician"*:

"Levulan Kerastick is a topical treatment that enhances laser treatment. At [the spa], Levulan is administered by nurses and licensed medical aestheticians under delegation from a physician. The nurse is onsite and available."

As mentioned above, the spa COO said an employee at the spa administered Employee C's treatment. We spoke to that spa employee who confirmed that they did administer the treatment to Employee C. She did not provide documentation to support that she was trained in or a member of any medical profession. She told us she had training on the laser equipment.

General dispensing rules for Schedule I drugs

We were informed by a pharmacological expert that generally speaking, with products like Levulan Kerastick or other Schedule I products (e.g., injections), a physician or nurse practitioner would prescribe the product, after which a community pharmacy would then dispense the product directly to the patient who would, in turn, bring the product back to the physician's office for its application.

While it is permissible that a physician bypass the community pharmacy and dispense the very product they have just prescribed, the College of Physicians and Surgeons has strict policies that must be followed to guard against any conflict of interest (i.e., the same individual prescribing and dispensing a product) and the control over the drugs.

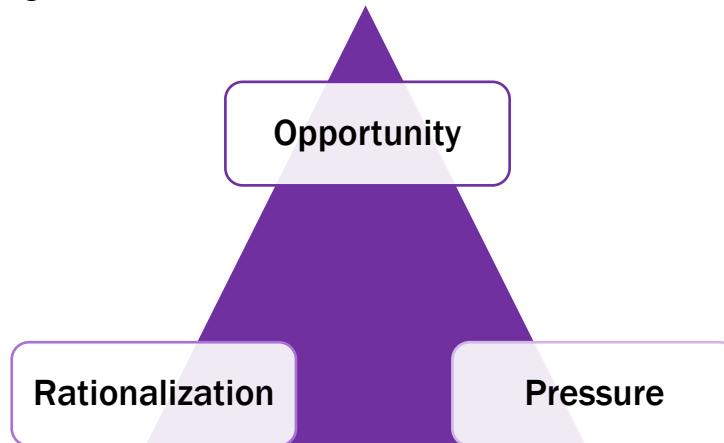
We noted that contained in the spa's records there were prescriptions written by the doctor – the same copy that the patient normally gives to the pharmacist. Employee C said she never saw the written prescription. All invoices state that the patients were responsible for purchasing Levulan.

If any of the employees in this investigation had actually purchased Levulan Kerastick at the spa (per their invoice and per the spa COO and spa owner's statements to us), it is our view that they did not realize they purchased it.

D. Overall Analysis and Conclusions

In this investigation, we examined cases that exhibited the various elements of fraud: a combination of opportunity, rationalization and pressure.

Figure 31: Fraud triangle



Opportunity is the perception that there is little chance that the fraud will be detected, penalized or that there will be consequences if carried out.

Rationalization is where there is a sense of entitlement, or potentially unawareness that taxpayer money is paying for the fraud, the feeling that there is 'no victim' no one is really getting hurt.

Pressure is where there is a desire or need for financial gain, and this can include encouragement from the provider.

The fraud triangle is important because it highlights that all the conditions were present for fraud in this case. Although the employees ultimately submitted false and/or misleading claims, other persons may have facilitated the submission of these claims where proper professional practices were not followed.

The City is the victim

Health benefits fraud is a serious matter, but some may not see it that way. The spa’s COO could not understand why GSC was pushing to get the records to verify the claims. According to the COO, employee benefit claims:

“pays GSCs bills and our bills. But they [GSC] seem to still be the victim here”.

The real victim in this case is the City of Toronto and the taxpayers who support City employees through their tax dollars. We recommend the City pursue the City employees to return what they were reimbursed.

Health benefits fraud was perpetrated against the City

Conclusion

Health benefits fraud was perpetrated against the City in relation to this file.

Exact role of each player is difficult to determine

Role of each player

The nature of fraud is that information is concealed, altered and fabricated. Thus, we cannot be absolutely sure of the extent and depth of the role each person played and their exact knowledge in this case.

However, this section includes our analyses and conclusions for the doctor, the spa, and each of the employees.

D. 1. Analysis: The doctor

The doctor never met the patients

At the center of all three cases is the diagnosing and prescribing physician. According to his replies to GSC, and according to records and verbal confirmation from the spa, the doctor diagnosed two patients with actinic keratosis and prescribed them Levulan Kerastick as treatment for that condition.

Employees say they did not meet the doctor

Employee A, Employee B and Employee C each independently told us that they never met, spoke to or were examined by the doctor.

All told us they were not being treated for actinic keratosis, but for other conditions: one was being treated for hair loss, one was being treated for toenail fungus and one was purportedly being treated for rosacea.

We believe that the employees were telling the truth about not having met the doctor – none of them knew each other, and their statements were consistent on this point. This is described in greater detail on page 62.

The doctor confirmed that he diagnosed and prescribed meds for all

They submitted to GSC invoices which said they purchased the medication Levulan and that it was used at each session for treating conditions including actinic keratosis. Actinic keratosis was the condition for which Levulan was prescribed, per the Drug Special Authorization Forms for two employees and the third had prescriptions on file at the spa for Levulan and said she was being treated for rosacea.

There are inconsistencies in how the delegation was described

Concerns about claims that treatment was delegated

In Ontario, a physician is allowed to delegate treatment for their patients under specific circumstances. This is often used in emergency medical situations. Proper delegation procedures are particularly important where Schedule I drugs are being administered. However there is a large discrepancy between what the doctor informed GSC of, what the spa is saying, and what the employees receiving treatment are saying:

- The doctor confirmed to GSC in writing that he is providing treatment to Employee A and B at the 'doctor's office,' which is different than the spa location.
- The three City employees say they never met the doctor, and they never received treatment from him. They only attended the spa, not his office.
- Notes from GSC's interview with the spa COO record that he "said they use qualified individuals under medical directive and the physicians will review notes and sign off." This conflicted with what we saw and were informed of.
- When asked by GSC who was the regulated healthcare professional administering treatment, the COO, for example, responded: "The name and credentials of the treating Regulated Health Care Professional for each treatment date/chart entry is [Name of spa employee], under written Medical Directive."
- No written medical directives could be provided. The employee who treated Employee C said prescriptions were not required until more recently, which is after this investigation began. The prescriptions that were on file were for the person she was providing treatment to.

Even if physician delegated treatment to the spa:

Patients never met physician

No documentation provided to show that patients consented to delegation

Physician never followed up with the patients

Patients were not receiving emergency medical care at the spa

Even if the doctor had delegated the treatment for all of these patients, we question if he followed proper procedures outlined by the College of Physicians and Surgeons because:

1. The patients did not have a pre-existing relationship with the doctor before he delegated their treatment – they never met him in person, by phone, or via the internet.
2. We found no evidence in their treatment files to confirm their consent for the doctor to delegate their treatment.
3. Some of these patients had been receiving treatment from the spa for years. The doctor never followed up with any of these patients to check on their conditions and the care they received from the spa.
4. None of these patients needed emergency treatment from the spa. In addition, they all went to the spa multiple times, sometimes spanning years. The treatment was clearly not urgent.

We asked the doctor to confirm several facts, some of which he had already confirmed to GSC. He provided his personal email address to us.

We emailed him the following questions:

- Did he diagnose and treat those patients?
- Were the signatures on all of the Drug Special Authorization Forms and prescriptions his? We sent samples of the signatures for him to verify.

Doctor confirms the spa provided all the records

Ultimately, after many attempts to confirm the information, the doctor confirmed that the signatures were his, and that the spa COO had provided us with all the records for these patients.

The diagnoses were questionable

Employee A – Diagnosis was not consistent with condition or treatment

In all three cases, they were treated for different issues, but billed for the same thing: Levulan to treat actinic keratosis among other things.

In the case of Employee A, he told us he was treated for hair loss. The treatment notes also confirm that was his treatment.

Employee B - Diagnosis was changed when rejected by GSC

In the case of Employee B, he told us he was only treated for toenail fungus. The Drug Special Authorization Form shows that he was diagnosed with actinic keratosis of the face and shoulders. He saw the change on the Drug Special Authorization Form change from toe fungus to a treatment on his face and shoulders.

He says he was only treated on his toenails for fungus, but the treatment notes from the spa conflict with this – they say he was treated for actinic keratosis of the face and shoulders. In our view, he was never treated with Levulan for actinic keratosis.

It is our view that the spa notes, invoices, as well as the Drug Special Authorization Form (the one that was sent the second time), do not reflect the actual services provided by the spa to this employee.

Employee C

In the case of Employee C, she told us she initially went to the spa for a facial and was treated for potentially pre-cancerous skin conditions by spa staff. She informed us that it was the spa staff who diagnosed her. A spa employee with no medical training confirmed that she checked with the doctor over the phone and he confirmed the diagnosis for Employee C of rosacea and toenail fungus.

The treatment notes indicate she was treated for acne, bacterial fungus on her toes and feet, rosacea and veins. The spa invoices she provided to GSC listed that she was treated for actinic keratosis along with other conditions – such as toenail fungus, a condition she said she never had but which appeared on the invoices over 20 times.

Receipts showing treatments were blacked out

Someone blacked out the condition treated on the point of purchase receipts. Only Employee C and spa staff likely had copies of the receipt.

Who is overseeing the application of the drug being billed for?

For Employee A, the doctor confirmed by letter to GSC that he prescribed Levulan to the employee. Employee A said he never received a prescription from the doctor, and, as mentioned earlier, he said he never met the doctor.

For Employee B, he was originally diagnosed with fungus of the toes and feet. After attending the spa, he sent a form requesting that his condition (toe fungus) be treated with Levulan. That request was denied by GSC as Levulan is not approved by Health Canada to be used for foot / toe fungus. The form was sent in again but the diagnosis was changed to actinic keratosis of the face and shoulders. GSC approved it.

A spa employee told us that she changed the diagnosis on the Drug Special Authorization Form under directions from the doctor. This raises questions about who is overseeing these clients' treatments.

The spa provided us with a prescription issued by the doctor for Levulan for Employee B.

Despite what the doctor told GSC, and despite the prescription on file at the spa, Employee B did not claim to the spa to have actinic keratosis or any condition of his face and shoulders. He went in for and was treated for toenail fungus.

For Employee C, she also told us she never met the doctor and told us she was never given a prescription for Levulan. However, the invoices say Levulan was used to treat actinic keratosis/rosacea/acne and that the patient is responsible for purchasing the medication. The spa provided GSC with a copy of a prescription for Levulan for Employee C and her husband. Employee C says she never saw it before.

Conclusion: The doctor

From the evidence of the three employees and examination of documents which included the doctor's signature, it appears that:

- The doctor never met these patients to examine and diagnose them.
- We believe it is possible that someone other than the doctor signed his name on documents presented to GSC in order to support the employees being reimbursed for treatments.
- A spa employee changed the diagnosis on an authorization form and, according to her, it was at the direction of the doctor

- On a balance of probabilities, we believe that at a minimum, the doctor is not ensuring the spa client has the condition before approving the diagnosis and treatment.
- Employees were issued invoices for purportedly receiving treatments for a condition that they did not have. It is our view that fraud was committed by two, and on a balance of probabilities, possibly three City employees.

Conclusion

There is a high risk that proper medical protocols are not being followed. This is beyond the scope of this investigation, but concerns us just the same. Beyond the concern about the public’s safety, we were unable to rely on the documentation provided by the doctor in his professional capacity.

Recommendation

We recommend that this case be referred to the College of Physicians and Surgeons of Ontario by the City of Toronto for further investigation.

D. 2. Analysis: The spa

False and/or misleading invoices

Spa provides false and/or misleading invoices

In our view, the evidence supports that the spa prepared false and/or misleading forms and /or invoices for City employees.

Diagnoses changed

Employee A said he was informed by that spa that they could get the treatment covered for him from his benefits plan, and that was the sort of thing that they did all the time. The diagnosis recorded on the Drug Special Authorization Form was actinic keratosis that was being treated with Levulan Kerastick.

Treatments not consistent with how Levulan Kerastick is supposed to be applied

Employee B said something similar – that when GSC initially refused to cover his treatment, the spa staff said the benefits carrier always causes trouble and that they would handle it for him. The diagnosis was changed at the spa that day from toenail fungus to actinic keratosis of the face and shoulders. That form was resubmitted and accepted.

Employee B was clearly treated on his toes, not his face and shoulders, and described a spa employee putting gel on his toes and then going over the area with a laser. Levulan is a clear liquid that comes in a stick form, like a pen, and is applied to specific lesions. The patient is then treated several hours later with special light, rather than being treated immediately.

His description of the treatment he received at the spa is not consistent with the drug information or with how our expert dermatologist described treatment for actinic keratosis with Levulan.

Employee C's treatment was also inconsistent with how Levulan is supposed to be used. She said the spa would apply a clear gel to her skin before treating it with a laser. Employee C's description of the treatment she received at the spa is not consistent with the drug information or with how the expert dermatologist described the way that actinic keratosis is treated with Levulan Kerastick.

Multiple conditions on the invoices, and those conditions changed

Multiple conditions listed on spa invoice

We asked the spa why multiple conditions were listed on the invoices when the employee was not treated for those multiple conditions.

The spa owner and one spa employee told us that the spa invoices were just a template with many conditions listed on them, and that those conditions are not necessarily what the client had.

This does not agree with what we saw. For Employee B, for instance, the invoice initially said toenail fungus. When it was rejected and new drug forms were submitted, the information changed.

Missing, incorrect or inconsistent treatment records

For Employee A, his three treatment records were available. However, the records described a completely different treatment than what his invoices said.

For Employee B, there were many issues with his treatment records, invoices and receipts. Many did not match up, and many seemed to show an invoice for him on a day that his spouse or child had an appointment at the spa.

Employee B's treatment records do show that Levulan was used to treat actinic keratosis of the face and shoulders. However, based on our interviews, Employee B was not treated on his face and shoulders at all – he, himself said he was only ever treated for toenail fungus on his feet.

For Employee C, the spa only had clinic notes for a handful of the dates she claimed for treatment. The bulk of the treatment records were not provided to us, or were missing.

Further, her records for the dates the spa did provide showed that in addition to being treated for actinic keratosis, she was treated for acne, rosacea, veins, and bacterial fungus on her toes and feet. She claims she was not treated for anything but rosacea.

Upon further questioning by GSC, the spa COO provided GSC with a list of dates that did, for the most part, match up with the dates Employee C made claims for. However, a list of dates is not sufficient documentation to show a patient's treatment.

One of the spa employees we spoke to, and the spa owner, said that the spa invoice dates do not always match the spa booking system dates or the treatment record dates because sometimes the patient pays for their treatment at a later date, and it is that date which is used on the invoice. We and Employee B had difficulty matching his payment receipts with his spa invoices. We also asked Employee C if she could match up her payment receipts with her invoices. She did not reply.

Patient did not pick up prescription prior to treatment

We are concerned about how prescriptions are being dispensed

In all three cases, their invoices say they are responsible for purchasing the medication. None of the patients ever picked up a prescription for Levulan from a pharmacy prior to their treatments at the spa. One employee confirmed they never saw the prescription that was written and on file. The spa confirmed that the medication Levulan was purchased by the employees at the clinic and it was supplied by the clinic. The patients never received nor saw the Levulan Kerastick applicators. They all appear to have received some sort of gel that was slathered on their treatment areas.

Spa's relationship with the doctor

The spa provided conflicting information about its relationship with the doctor. The most consistent information we received about this is discussed on page 62.

None of the three employees we spoke to said they ever met the doctor in any way.

Levulan needs to be administered by a qualified healthcare professional – treatment instructions were lacking

Spa employees' training and use of Levulan

The spa employees we spoke to confirmed that they provided the treatment, under instructions from the doctor.

One spa employee told us that when using Levulan, the doctor would specify the type and intensity of the laser to use. Another spa employee told us that the doctor never instructed her on the laser specifications for the treatments – she decided that herself. There were no records to show what, if any, instructions were given.

Spa employee using leftover medication to treat different areas – she is not a qualified healthcare professional as noted by Health Canada

The spa employee who treated Employee B said that she would treat his face with the Levulan, and would provide complimentary treatments to him on his feet, also with the Levulan, if there was any of the medication left over. This same employee told us that actinic keratosis is the medical term for skin pigment damage, which is incorrect.

The spa owner also described that the Levulan responds to the laser more aggressively, which in turn makes the laser treatment more effective.

This is not consistent with any research we have done on the drug Levulan.

Conclusion: The spa

Spa provided false and/or misleading invoices

The spa issued invoices to City Employees for treatments that were not given. Employees submitted the invoices for reimbursement.

It appears that the spa provided treatments for procedures not covered by the plan, but the invoices they supplied to their clients, City of Toronto employees, show they were treated for medical conditions that would be covered: actinic keratosis with Levulan.

In our view, it appears that the spa facilitated the process for City of Toronto employees to commit fraud by providing false and or misleading invoices that show that the employees were treated for medical conditions they did not have.

They also included in invoices that Levulan may be covered, saying *"the patient may claim the cost of the Levulan units to their Insurance Plans."*

Employees relied on medical professionals

Two of the employees in this file said they relied on medical professionals at the spa.

Employee A:

"I was taking advice from the spa. She was a nurse. The one lady said that we do this all the time; [we] can get covered, get the prescription."

Employee B

Interview question:

"Were you aware that the treatment with the laser [for your toes] was not covered?"

Employee B:

"Not covered? I think Green Shield told me something like that. And I went back there, to [the spa], and she [the technician at the spa] said, 'Oh, give me the paperwork. I'll handle this. These companies always do this' or something, she said to me."

Conclusion

With regard to the spa's role in this matter, at a minimum, there is a high likelihood that the spa issued false and/or misleading invoices which facilitated the commission of what we consider to be fraud by the City employees in this case.

Recommendation

We recommend that this case be referred to the College of Physicians and Surgeons of Ontario, or any other oversight agency, including Health Canada, that are responsible to regulate services at medical spas, as well as the Toronto Police Service for further investigation.

D. 3. Analysis: Employee A

When submitting claims, all of the employees stated that the information they were submitting, to the best of their knowledge, was truthful.

The GSC form, which the employees all signed, says:

"I certify that the information in this form and any further verbal or written statement provided by me in the future, is true and complete, to the best of my knowledge. I agree that both my claims and my coverage may be denied or terminated as a result of my providing false, incomplete or misleading information."

Employee A admitted he submitted receipts for a treatment he didn't receive.

Once at the spa, he told us he had concerns about the cost of the treatment – he said he did not feel comfortable paying. He then describes being assured by several spa employees that he could get the hair loss treatment but submit claims for a different treatment that was covered. He told us that the spa told him it was not an issue, and that they prepare these documents for the doctor to sign all the time.

Employee A knew he was wrong to submit the receipts, and he worked with the staff to obtain the forms to make it happen.

He added that he did not understand the full ramifications of making the claims. This is evidenced by him immediately repaying the monies and undertaking additional measures to make restitution for his actions.

He fully cooperated with GSC, the Division investigators and our staff. It was because of the information he provided to us that we were able to pursue this case at a much deeper level.

Insurance forms

With regards to the insurance forms, the nurse who treated him told us that she did not talk about getting insurance coverage for his treatments, even though it was written in her handwriting on two of his three treatment records. When questioned about this, she said that those notes were probably referencing some other treatment he was getting at the spa. We know that Employee A only ever got hair loss treatments at the spa – nothing else.

This lends further credibility to Employee A when he told us that the spa employees took care of the paperwork for him so that he could get covered for a condition he did not have. At the same time, it raises questions about the nurse's statements.

Further concerns

Another concern in this case is that PRP treatment is considered to be a drug under the *Food and Drugs Act*. This means that it is regulated, and that a "practitioner", meaning a physician or dentist, according to Health Canada, is supposed to be the one administering it.

We have a question as to whether the RPN was even authorized to treat Employee A with PRP. The treatment records containing her signature identify that she was treating him for a different condition and a different procedure than was listed on the drug authorization form which was signed by the doctor, and from what was listed on the spa invoices which she appears to have signed or initialed. She confirmed to us that she was acting independently to administer the PRP.

Conclusion: Employee A

In our view, Employee A committed health benefits fraud.

Employee A admitted he submitted false invoices and that the spa offered to facilitate reimbursement for services that were not covered. This is health benefits fraud. The employee reimbursed the plan immediately upon detection and was cooperative with this investigation.

D. 4. Analysis: Employee B

Employee B told us that he didn't know there was anything wrong with his claims until he was interviewed about them for his Division's investigation. However, whether he knew or not, he benefitted from the fraud committed by receiving coverage for services that would not otherwise be covered by his health benefit plan.

When asked further about the drug Levulan, Employee B said that he thought Levulan was the name of the laser or the name of the cooling gel applied to his feet after being treated with the laser.

Of Levulan, Employee B said the following:

"I thought that was part of the treatment. I thought Levulan was part of the laser."

Of actinic keratosis, Employee B said the following:

"I've been told I have toenail fungus but I've never heard it called that [actinic keratosis]... I don't even know what that is really."

In our interview, we asked Employee B if he was aware that they were submitting forms for services he did not receive. He said:

"Well I didn't know they weren't legitimate. I didn't know they weren't matching. No, I didn't know that."

When pressed further about whether he thought it was strange that the drug Levulan and the condition of actinic keratosis was mentioned in his invoices, he said the following:

"To be honest, I never thought about it. I was just happy to be getting treatment for my toes."

Issues of concern

Drug Special Authorization Form was altered to change diagnosis

Only two of his invoices from the spa did in fact list that he was being treated with Levulan for toenail fungus. The majority of the invoices listed that he was being treated with Levulan for the conditions of actinic keratosis, rosacea and acne.

His Drug Special Authorization Form was also altered. He told us that an employee at the spa or the doctor likely changed the diagnosis from "fungus toes/feet" to "actinic keratosis on the face and shoulders". The spa employee we spoke to confirmed that she did change the diagnosis, and she said she did that based on direction from the doctor.

Employee B confirmed that he saw the change that was made to his treatment form from a condition on the toes and feet to a condition on the face and shoulders.

The spa employee returned the altered form to him, which he saw, and then gave to his wife to fax to GSC.

He said he did not look closely at the invoices before submitting them.

Invoices, amounts paid and appointment dates do not match

Many of his invoices list that he was the person treated. However, the appointment dates do not match, and sometimes show that while the invoice was for him, his spouse or child had the actual appointment.

The clinic booking system shows the dates that the client attended the spa. The treatment record shows the date and type of treatment rendered. These records don't match up, and many times they don't match the service payment date.

In addition, after reviewing every invoice and every credit card statement provided to us by Employee B, and every appointment listing, we found the following:

- Only two of his invoices list nail fungus as the reason for using Levulan. All other invoices list actinic keratosis.
- Only two of his credit card statements match with his invoices from the spa.
- Some of his invoices correspond with dates that his spouse, not him, had an appointment at the spa. And again, the invoiced amounts do not match any records from Employee B or the spa.

Employee B said he did not notice the discrepancies between what he paid and the amounts on the spa invoices.

Employee B said he didn't know the condition listed on the invoice was not what he received. However, after the toenail fungus diagnosis was rejected by GSC, it was he who returned the Drug Special Authorization Form to the spa, and he who retrieved the updated form from the spa which had a *different diagnosis* of actinic keratosis on *his face and shoulders*.

Conclusion: Employee B

In our view, Employee B committed health benefits fraud.

Employee B knew he was not being treated on his face and shoulders.

Even if this employee did not understand the medical term actinic keratosis, he knew he was not being treated on his face and shoulders. He went to the spa for toenail fungus treatment. In our view, this employee committed health benefit fraud by submitting false and / or misleading forms and / or invoices for reimbursement.

We recommend that the City Manager seek repayment from Employee B for \$9,952.16.

D. 5. Analysis: Employee C

Employee C's file was complicated, partly due to the number of invoices she and her spouse had claimed for Levulan (28 for her and 34 for her spouse), and partly due to her unclear and/or inconsistent answers to our questions.

We feel some of her responses to our questions were evasive and potentially not truthful. In particular, the questions related to the medical aspects are concerning given that she works in the medical field.

Issues of concern

She said a spa employee diagnosed her with rosacea

She clearly explained that it was not her family doctor, but a spa employee who diagnosed her with rosacea.

She was attending the spa from 2014 to 2019. In relation to the invoices she submitted, she told us it was always for rosacea. She did not mention that she ever went back to her family doctor – who told her that her skin condition *might* have been rosacea – to update her doctor on her treatment.

It seems unusual that Employee C did not update her physician on her diagnosis from the spa, particularly because Employee C said she was told by staff at the spa that rosacea could turn into cancer.

She did not inquire about her diagnosis or the drug treatment

Since she began treatment in 2014 and her husband in 2015, every invoice indicates that the spa is using Levulan Kerastick to treat actinic keratosis. She says she neither looked up actinic keratosis to find out what it was, nor inquired about the drug Levulan Kerastick.

She said she thought the spa was following a physician's standing orders when they administered her treatment

We do not feel that it was likely that her treatment at the spa fell under a physician's standing orders or delegation because it does not meet that criteria:

- she never met the delegating physician before starting the treatment,
- her condition was not an emergency, and
- the delegating physician never followed up with her on her treatment that was ongoing for several years.

Standing orders are commonly used in emergency medical settings – settings that some health professionals like her would be routinely exposed to.

We find her answer that she assumed her treatment was given to her under a physician's standing orders to be concerning given that she has been working in the medical field for many years, and she should be well-versed in the conditions in which standing orders are given and used.

Her treatment records do not always match her invoices

Similarly to the other two cases, her treatment records do not always match her invoices. Her treatment records cited acne and veins, while her invoices cited actinic keratosis. While we recognize that she may not have seen her treatment records, acne was a condition that she had first discussed with her family doctor.

In addition, every invoice since 2014 says she was treated for actinic keratosis, a condition she never inquired about. Further, the majority of her invoices in 2018, over 20 of them, said she was also being treated for toenail fungus, a condition which she told us she never had and was never treated for, whereas the spa employee described her treating Employee C many times for toenail fungus.

In our view, it's unlikely she did not read any of her 44 invoices since 2014 before submitting to GSC

In our view, it is unlikely that, since 2014, she did not read any of her 44 invoices before submitting them to GSC. These invoices had multiple inaccuracies: they had multiple conditions listed on them – some conditions which she told us she never had or was not treated for, treatment descriptions that do not match her own descriptions, and the amounts paid on the invoices do not match with most of the amounts paid on her receipts.

Many treatment invoices despite little improvement

She claimed for treatments 28 times over a span of two years, not including the treatments she claimed under the City's previous benefits plan administrator. She said that the treatments did not seem to be particularly effective, and she stopped.

In summary, her explanation for why the number of treatments increased so much in 2018 for herself and her spouse does not seem reliable. She did not mention that skin cancer was a concern on her intake form. She also did not inform her family doctor that she was later diagnosed with rosacea, a condition which Employee C was told by spa employees could turn into cancer.

Her description of the treatment

She claimed she had protective eyewear on while undergoing the treatment and therefore did not see what was happening. However, she also told us the gel used on her skin was clear. These two statements appear to be contradictory.

The treatment description on the spa invoices list that the client would be treated with Levulan with an incubation time of 60 minutes, and then with the specialized light for 16 minutes.

Employee C said that from start to finish, her treatment would last about 20 minutes to a half hour. She further explained that the application of the Levulan would take 15 to 20 minutes, and then *"the laser may be another 10 minutes or so."*

Blacked out receipts

Some of her receipts from the spa blacked out the conditions and name of person who did the treatment. The spa COO told us that they do not black out receipts, and the spa owner said it is not normal for them to black out receipts.

We did not establish conclusively who blacked out the information on the receipts. Employee C may have blacked out the receipts herself in order to conceal the description of the services she received at the spa. The spa employee treating Employee C, the owner and the COO all say they did not or would not black out the receipt.

Conclusion: Employee C

It is our view, on a balance of probabilities, that this employee also committed health benefits fraud.

Employee C told us that she believes she was being treated for rosacea.

She never questioned the invoices that said she was being treated for actinic keratosis or even toenail fungus. Every invoice since 2014 lists that she was being treated for actinic keratosis, which is a condition she says she never looked up, and with a drug that she also never looked up. Over 20 invoices show that she was being treated for toenail fungus along with other conditions.

The treatments she received were blacked out on the point of sale receipts. Given her experience in the medical field, her statements at times did not make sense.

She conveyed that she doesn't really know what actinic keratosis is, and that she doesn't know much about the medication Levulan, despite both items being listed on her and her husband's invoices since 2014. She denies receiving toenail fungus treatments – but over 20 invoices, spa records and the spa staff who treated her appear to demonstrate otherwise.

In any event, if she didn't receive treatment for toenail fungus, she should not have submitted invoices showing that she was treated for conditions she didn't have.

The employee knew or ought to have known that the majority of invoices had services on them that she says she never received. It is our view that, on a balance of probabilities, benefit fraud was committed. We recommend this employee repay the amount they had been reimbursed (over \$26,000) since 2017¹⁰.

We recommend that the City Manager seek repayment from Employee C and her spouse for \$26,392.60.

¹⁰ This employee and her spouse also had about \$8,000 in Levulan claims from 2014 to 2016 when the City had a different health benefits provider.

E. Confirming there are no wider concerns

E. 1. Did we identify all cases?

	<p>One of the remaining questions is whether our investigation identified all cases involving the spa, the doctor and Levulan.</p>
<p>All cases of concern have been identified for the City of Toronto's health benefit plan</p>	<p>Through data analytics and working with the Benefits Administrator, GSC and its Claim Watch program confirmed that these are the City of Toronto employees billing through the spa.</p> <p>We have performed extra work to confirm that all cases of concern have been identified.</p>
<p>There may be cases involving other plans</p>	<p>However, we have been alerted that a similar situation to this file has affected clients in other organizations and other benefit plans. It is important for those plans to take note of this case to protect their plans.</p>
<p>Potential future work</p>	<p>Future work may include reviewing the billings submitted for services provided from spas, including health and medical spas. In the meantime, we continue to work with GSC to review data on unusual drug claim patterns, any spikes in claiming patterns, and anything unusual.</p>

Lessons Learned

There are several important lessons to be learned from these cases:

1. The City paid about \$150 million in 2019 for a robust health benefits plan for its employees. It is taxpayer money and should not be taken advantage of.
2. The City of Toronto's ability to detect potential health benefits fraud has improved with the new administrator contract and new detection procedures. The incidents of fraud being detected will likely go up in the near term because of improved detection tools and practices.
3. All City of Toronto staff should be reminded that they are subject to audits of their benefits claims. These audits are to ensure that claims are legitimate to protect taxpayers' money and the sustainability of the plan for all City employees.
4. Employees would benefit from additional training on fraud. Staff must have a crystal-clear understanding of the various forms it can take, the warning signs, the potential repercussions, and each employee's responsibility to report suspected wrongdoing.

Recommendations

- 1. City Council request the Director, Pension, Payroll and Employee Benefits, and Green Shield Canada, to implement training for staff around the issue of health benefits fraud. This should be recurring and updated as the nature of common types of fraud evolve.**
- 2. City Council request the Director, Pension, Payroll and Employee Benefits, undertake extra verification procedures to examine health claims coming from health spas.**
- 3. City Council request the Director, Pension, Payroll and Employee Benefits, to direct all employees in this case to reimburse the City for all past claims for themselves and their spouses for services involving the spa because they are not properly supported by legitimate invoices for approved services.**
- 4. City Council request the Director, Pension, Payroll and Employee Benefits seek to include in future collective agreements that health services must be medically necessary, and that 'off-label' use be supported by a physician and authorized by Green Shield Canada (GSC) prior to reimbursement.**
- 5. City Council to direct the City Manager to provide an update on actions taken related to this report, including any referrals that are made to other agencies and regulatory bodies.**

Appendix 1: Background

Levulan and actinic keratosis

As discussed in this report, all of the three cases outlined in this report involve a drug called Levulan Kerastick and a diagnosis of actinic keratosis and, in some cases, also rosacea.

Levulan Kerastick used for actinic keratosis

Levulan Kerastick is a topical solution used in conjunction with specialized light irradiation/photodynamic light therapy for the treatment of actinic keratosis. The drug monograph on Health Canada's drug information database says Levulan is intended for actinic keratosis of face and scalp.

Actinic keratosis is a rough, scaly patch that develops on a person's skin after prolonged exposure to the sun.

According to Health Canada, using Levulan Kerastick is a two-step process: the drug is applied topically to targeted lesions with a pen-like stick, and then treated by irradiation with specialized light 14-18 hours later.

Application of the drug can vary

Not all applications are done exactly this way. We interviewed a dermatologist for this investigation to better understand how it can be used. This dermatologist said she uses this treatment slightly differently. She said she waits two to three hours after application to expose the area with a specific light treatment.

Levulan is photosensitive

From the time that Levulan is applied, to when it is exposed to the specialized light, the actinic keratosis lesions become photosensitive. Patients are advised to avoid exposing their lesions to sunlight or any bright indoor light such as examination lamps, operating room lamps, or unshaded light bulbs at close proximity.

Exposure to light can cause a burning or stinging sensation, and can also cause erythema (redness) and edema (swelling) of the lesions.

The patient is advised to wear protective clothing or hats when outside. UV Sunscreen will not protect against photosensitivity reactions during this time.

About 90% of patients experience moderate to severe stinging or burning sensations while being treated with Levulan Kerastick and specialized light treatment.

Levulan comes in different forms

There is another form of Levulan, a 10% topical solution in the form of a gel. This is used in a similar manner: the gel is applied to the affected skin, and left to dry. Once dry, a covering is placed over the skin to keep it from being exposed to light.

It is left on the skin for several hours, and then the patient undergoes the light therapy.

Conditions to get Levulan covered by GSC

Drug authorization form needed

Employees who want to submit claims for treating actinic keratosis with Levulan Kerastick need to provide a Drug Special Authorization Form to GSC.

Restrictions for reimbursement

According to GSC:

"This schedule drug must be prescribed by a physician, dispensed by a pharmacist or a physician, and application must be done by a qualified health care professional. GSC will only allow this benefit to be reimbursed under these conditions as regulated by Health Canada and CPSO."

Green Shield provided the following eligible criteria to Employee B.

*"ELIGIBLE CRITERIA
For the treatment of actinic keratosis of the face or scalp.
(Please note that the treatment for acne will not be considered.)"*

Restricting coverage to the face and scalp is consistent to the information obtained from Health Canada.

Figure 32: Dosage and administration for Levulan from the drug monograph

DOSAGE AND ADMINISTRATION

LEVULAN KERASTICK for Topical Solution is intended for direct application to individual lesions diagnosed as actinic keratoses and not to perilesional skin. This product is not intended for application by patients or unqualified medical personnel. Application should involve either scalp or face lesions, but not both simultaneously. The recommended treatment frequency is: one application of the LEVULAN Topical Solution and one dose of illumination per treatment site per 8-week treatment session. Each individual LEVULAN KERASTICK should be used for only one patient. Photodynamic therapy for actinic keratoses with LEVULAN KERASTICK for Topical Solution is a two stage process involving a) application of the product to the target lesions with LEVULAN KERASTICK, followed 14 to 18 hours later by b) illumination with blue light using the BLU-U Blue Light Photodynamic Therapy Illuminator. The second visit, for illumination, must take place in the 14-18 hour window following application. Patients in clinical trials usually received application in the late afternoon, with illumination the following morning.

Figure 33: Instructions for Levulan from product monograph

Treated lesions that have not completely resolved after 8 weeks may be treated a second time with LEVULAN KERASTICK for Topical Solution Photodynamic Therapy. Patients did not receive follow-up past 12 weeks after the initial treatment, so the incidence of recurrence of treated lesions past 12 weeks and the role of further treatment is not known.

Levulan may be used for other things but proper documentation is needed

GSC forms provided to the employee also notes that

"These drugs may have the potential for other users outside of the indications identified but are only eligible benefits of the controlled formularies under the conditions specified with the proper documentation."

Due to their investigation, GSC suspended all claims for Levulan coming from the spa pending their investigation and the College of Physicians and Surgeons of Ontario's investigations. The spa was later delisted.

Schedule I Drugs

Levulan is a Schedule I Drug

Health Canada has the authority and responsibility to regulate drugs in Canada. There are four schedules for drugs: I, II, III, and unscheduled drugs. Levulan (or its medical name Aminolevulinic acid hydrochloride) is a Schedule I drug.

We have confirmed with the database of the National Association of Pharmacy Regulatory Authorities (NAPRA), the national body that determines drug scheduling, and Health Canada's drug product database that Levulan is a schedule (I) prescription drug product. We also consulted pharmacological experts.

Levulan Kerastick falls under the rules of prescribing and dispensing in the province of Ontario as per the College of Physicians and Surgeons of Ontario and is regulated under the Controlled Drug and Substances Act.

Figure 34: National Drug Scheduling Factors - Schedule I drugs
NATIONAL DRUG SCHEDULING FACTORS

SCHEDULE I

- #1 The need for the drug is identifiable only by the prescribing practitioner.
- #2 Use of the drug requires adjunctive therapy or evaluation.
- #3 Appropriate use of the drug may produce dependency.
- #4 Serious adverse drug reactions are known to occur or have a recognized potential to occur at normal therapeutic dosage levels.
- #5 There is a narrow margin of safety between the therapeutic and toxic dosages of the drug, either in the general population or in identified subpopulations, or in patients with multiple medical problems.
- #6 Serious drug interactions are known to occur.
- #7 Use of the drug has contributed to, or is likely to contribute to, the development of resistant strains of microorganisms.
- #8 The medicinal ingredient is new, or is being used for a new indication that is not amenable to self-treatment, and the consequences of widespread use are not adequately established.

Levulan requires a prescription for sale

According to the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA):

"Schedule I drugs require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner. The sale is controlled in a regulated environment as defined by provincial pharmacy legislation."

Appendix 2: Physicians and Delegation of Authority

Only certain individuals are authorized to do certain things when treating patients

While studying the evidence in this case, we reviewed information on the College of Physicians and Surgeons' website and other laws to better understand if spa staff had the authority to diagnose, communicate diagnoses and perform certain procedures with what appeared to be little oversight. We have outlined below our understanding of how medical procedures can be delegated, including exceptions for emergency situations.¹¹

Legislation outlines conditions for delegating

There are three acts which lay out the conditions for delegating:

1. *Regulated Health Professions Act*, 1991, S.O. 1991, c. 18, as amended;
2. *Personal Health Information Protection Act*, 2004, S.O. 2004, c.3, Sched A;
3. *Health Care Consent Act*, 1996, S.O. 1996, c.2, Sched A

To perform 'controlled acts' in the health profession you need to be authorized

Certain acts in the healthcare profession are controlled – meaning only certain individuals are authorized to perform them or direct others to do them.

According to the [Regulated Health Professions Act, 1991](#):

27 (1) No person shall perform a controlled act set out in subsection (2) in the course of providing health care services to an individual unless,

- (a) the person is a member authorized by a health profession Act to perform the controlled act; or*
- (b) the performance of the controlled act has been delegated to the person by a member described in clause (a). 1991, c. 18, s. 27 (1); 1998, c. 18, Sched. G, s. 6.*

¹¹ We performed research to assist us in assessing if employees were being truthful and/or if they were working with spa personnel to obtain invoices and treatment records for services they did not receive. To do this, we gained a basic understanding of the role of physicians and the requirement for direct orders to perform controlled acts. While doing our work, sufficient information came to our attention that raised concerns about whether spa staff were undertaking procedures they are not authorized to perform. Out of an abundance of caution, have recommended that this file be forwarded to the College of Physicians and Surgeons and the College of Nurses of Ontario for further consideration.

Only authorized individuals can communicate a diagnosis

According to the legislation, a controlled act is:

(2) A “controlled act” is any one of the following done with respect to an individual:

Only authorized people can give an injection

1. Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.
2. Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth.
3. Setting or casting a fracture of a bone or a dislocation of a joint.
4. Moving the joints of the spine beyond the individual’s usual physiological range of motion using a fast, low amplitude thrust.
5. Administering a substance by injection or inhalation.
6. Putting an instrument, hand or finger,
 - i) beyond the external ear canal,
 - ii) beyond the point in the nasal passages where they normally narrow,
 - iii) beyond the larynx,
 - iv) beyond the opening of the urethra,
 - v) beyond the labia majora,
 - vi) beyond the anal verge, or
 - vii) into an artificial opening into the body.

Prescribing, dispensing, selling or compounding a drug is controlled

Levulan Kerastick, for example, is a drug that needs a prescription and controlled as a Schedule I drug under the *Drug and Pharmacies Regulation Act, Schedule I*

7. Applying or ordering the application of a form of energy prescribed by the regulations under this Act.
8. Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.
9. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses other than simple magnifiers.

10. Prescribing a hearing aid for a hearing impaired person.
11. Fitting or dispensing a dental prosthesis, orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning.
12. Managing labour or conducting the delivery of a baby.
13. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.
14. Treating, by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning. 1991, c. 18, s. 27 (2); 2007, c. 10, Sched. L, s. 32; 2007, c. 10, Sched. R, s. 19 (1).

[Emphasis added]

A physician needs to diagnose a patient and communicate the diagnosis

It is our understanding that once a physician diagnoses and communicates a diagnosis to patients, the physician can then either treat the patient or delegate the treatment (i.e. a controlled act) under certain circumstances.

Some treatments can be delegated

Further reading shows that a physician generally does not delegate treatment before establishing a physician-patient relationship.

Delegation is a mechanism that allows a physician who is authorized to perform a controlled act to confer that authority to another person (whether regulated or unregulated) who is not independently authorized to perform the act. It is not considered delegation to authorize the initiation of a controlled act that is within the scope of practice of another health professional. It is also not considered delegation to refer a patient to another physician or health professional for care. For the purposes of this policy, "delegation" occurs only when a physician directs an individual to perform a controlled act that the individual has no statutory authority to perform.

[Emphasis added]

Our understanding is that delegation is done through a medical directive or a direct order – meaning the physician is directing what is to be done.

A direct order to carry out a controlled act is to take place after a physician-patient relationship is established

Direct Order

*A direct order provides instructions from an individual physician to another health care provider or a group of health care providers. The order relates to only one patient and initiates a specific intervention or treatment to be delivered at a specific time. It may be verbal (over the telephone, via videoconferencing, or in person) or written. **A direct order is to take place after a physician-patient relationship has been established...***

In most situations where a physician delegates the performance of controlled acts, he or she should have current knowledge of a patient's clinical status.

Patient's consent required for delegation

A patient's consent is needed prior to delegation.

[Emphasis added]

"The physician must confirm that patients provide informed consent for the performance of controlled acts, whether consent is obtained by the physician him or herself or by the delegate. This will include providing the patient with appropriate information about the person who will be performing the controlled act (i.e., the delegate). If the patient requests information about how the delegate has obtained authorization to perform the controlled act, an explanation must be provided to the patient. In circumstances where the delegation takes place pursuant to a medical directive, the protocol for the directive must include obtaining the appropriate patient consent. The patient's consent must be documented in the medical record."

Patient consent must be documented in medical record

Some exceptions apply – like an emergency situation

Medical directions can be given under a circumstance other than a direct order – a medical directive. This is applied in emergency situations.

"Medical directives are written orders by physicians (often more than one) to other health care providers that pertain to any patient who meets the criteria set out in the medical directive. When the directive calls for acts that will require delegation, it provides the authority to carry out the treatments, procedures, or other interventions that are specified in the directive, provided that certain conditions and circumstances exist."

However, the policy makes it clear that medical directives can only be used under specific conditions, and patient care is the top priority.

"Controlled acts must not be delegated solely for monetary or convenience reasons and quality patient care must not be compromised by the delegation."

Follow-up with the patient is important

Doctors are required to have a doctor-patient relationship with a patient prior to delegating treatment *"unless patient safety and best interests dictate otherwise"*.

"In some instances, the patient's best interests will be served by having the controlled act performed prior to assessment by the physician (in a hospital emergency room, for example, where it is common for some tests to be ordered before a physician has seen the patient). In such circumstances, the delegation may take place pursuant to a medical directive. When this happens, it is expected that a delegating physician under whose authority the controlled act has been performed will meet and assess the patient as soon after it has been performed as possible."

Appendix 3: Scope and Objectives

This is an investigation, not an audit

This is an investigation, not an audit. The work performed in relation to this investigation report does not constitute an audit conducted in accordance with Generally Accepted Government Auditing Standards (GAGAS). However, we believe we have performed sufficient work and gathered sufficient appropriate evidence to provide for a reasonable basis for our findings, conclusions and concerns.

Our objective was to verify whether the claims were valid.

Methodology: Work performed was extensive

Our investigation was extensive. It involved interviews with the City Employees who were involved, the spa owner, the spa's Chief Operations Officer, and three spa employees, many of which were interviewed under oath. We also reviewed treatment records, spa invoices, spa receipts, emails, and analyzed health claim data. We sought information from subject matter experts, including in handwriting, dermatology, and pharmacology, and conducted research on the drug Levulan Kerastick and how it is dispensed, the condition actinic keratosis, and the rules for physicians and nurses in Ontario.

Scope limitation

As noted throughout this report, not all documentation was available to us because many documents were missing, including treatment records and receipts.

In addition, we interviewed some witnesses via Webex because of the coronavirus pandemic. This means that we could not totally control the interview environment.

Review provides reasonable basis for our findings and conclusions

Despite these limitations, based on the detailed analysis and the evidence obtained, we believe we have gathered and reviewed sufficient appropriate information to provide a reasonable basis for our findings, conclusions and concerns.

Appendix 4: Management's Response to the Auditor General's Report Entitled: "Employee Health Benefits Fraud Involving a Medical Spa"

Recommendation 1: City Council request the Director, Pension, Payroll and Employee Benefits, and Green Shield Canada, to of health benefits fraud. This should be recurring and updated as the nature of common types of fraud evolve implement training for staff around the issue.

Management Response: <input checked="" type="checkbox"/> Agree <input type="checkbox"/> Disagree
Comments/Action Plan/Time Frame: During its functional review, PPEB has identified education related to the Benefits Program and other programs as a key gap. With its transformation, PPEB had addressed this gap by making education an important and strategic function to achieve compliance, reduce fraud and encourage consumerism and Benefits plan ownership by employees. To that effect, PPEB has created two Education Specialist positions within the newly created Policy and Program Management unit and will be developing and marketing a number of education vignettes regarding different aspects of the Benefits Program including benefits fraud. Additionally, PPEB is currently exploring the merit of implementing mandatory education sessions as part of enrollment in the Benefits Program which will include training on Fraud. PPEB is also working on developing a Benefits Fraud framework that includes a Benefits Fraud Policy, Fraud Education component, Fraud Deterrence component and a Fraud Enforcement component.

Recommendation 2: City Council request the Director, Pension, Payroll and Employee Benefits, undertake extra verification procedures to examine health claims coming from health spas.

Management Response: <input checked="" type="checkbox"/> Agree <input type="checkbox"/> Disagree
Comments/Action Plan/Time Frame: The Director, Pension, Payroll and Employee Benefits will work with the Benefits Administrator to implement additional systematic or manual controls where possible to identify and examine health claims from health spas.

Recommendation 3: City Council request the Director, Pension, Payroll and Employee Benefits, to direct all employees in this case to reimburse the City for all past claims for themselves and their spouses for services involving the spa because they are not properly supported by legitimate invoices for approved services.

Management Response: <input checked="" type="checkbox"/> Agree <input type="checkbox"/> Disagree
Comments/Action Plan/Time Frame: The Director, Pension, Payroll and Employee Benefits, has already requested that all employees in this case reimburse the City for all unsupported past claims for themselves and their spouses and dependents for services involving the spa. Furthermore, The Director, Pension, Payroll and Employee Benefits has directed the Benefits Administrator to suspend Benefits for these employees and their dependents pending full reimbursement or agreement on a reimbursement plan for these unsupported claims. One of the employees has already fully repaid.

Recommendation 4: City Council request the Director, Pension, Payroll and Employee Benefits seek to include in future collective agreements that health services must be medically necessary, and that 'off-label' use be supported by a physician and authorized by Green Shield Canada (GSC) prior to reimbursement.

Management Response: <input checked="" type="checkbox"/> Agree <input type="checkbox"/> Disagree
Comments/Action Plan/Time Frame: The Director, Pension, Payroll and Employee Benefits already attempted to and will continue to seek to include in collective agreements, where it's not already included, that health services must be medically necessary, and that 'off-label' use be supported by a physician and authorized by Green Shield Canada (GSC) prior to reimbursement. Even though the attempt during the last round of bargaining was not successful, The Director, Pension, Payroll and Employee Benefits will seek to address this issue through the Joint Benefits Committee that each of the Bargaining Units, through the current bargaining process, has agreed to establish to look at the Benefits Program holistically.

Recommendation 5: City Council to direct the City Manager to provide an update on actions taken related to this report, including any referrals that are made to other agencies and regulatory bodies.

Management Response: <input checked="" type="checkbox"/> Agree <input type="checkbox"/> Disagree
Comments/Action Plan/Time Frame: The City Manager through the Director, Director, Pension, Payroll and Employee Benefits has already directed the Benefits Administrator to refer the case to Police and to the appropriate professional bodies. The Director, Pension, Payroll and Employee Benefits, on behalf of the City Manager, will also provide updates to the Auditor General on actions taken related to this report, including any outcomes of the referrals that are made to other agencies and regulatory bodies.

**AUDITOR
GENERAL**

TORONTO