

**SOAH DOCKET NO. 453-04-1317.M2**

<b>RS MEDICAL,</b>	§	<b>BEFORE THE STATE OFFICE</b>
<b>Petitioner</b>	§	
	§	
<b>V.</b>	§	<b>OF</b>
	§	
<b>CITY OF EL PASO,</b>	§	<b>ADMINISTRATIVE HEARINGS</b>
<b>Respondent</b>	§	

**DECISION AND ORDER**

RS Medical requested a hearing to contest an Independent Review Organization (IRO) decision denying preauthorization of a RS 4i Sequential Stimulator (RS 4i Stimulator) for indefinite use by an injured worker (Claimant). The Administrative Law Judge (ALJ) concludes the RS 4i Stimulator was not shown to be medically necessary.

A hearing convened on May 4, 2004, before ALJ James W. Norman at the State Office of Administrative Hearings, Austin, Texas. Patrick K. Cougill represented RS Medical. Tommy W. Lueders represented the City of El Paso (El Paso).<sup>1</sup> Susan Keese, RS Medical's Insurance Relations Manager, and Claimant testified for RS Medical. Leonard Hershkowitz, M.D., testified for El Paso.<sup>2</sup> There were no contested issues of notice or jurisdiction. The record closed on May 18, 2004, with the submission of additional documentation.

**I. DISCUSSION**

**A. Background**

The Claimant, a \_\_\_ year old male at the time, sustained a work-related injury to his lower back on \_\_\_, while working as a paramedic. He was carrying a 300-pound patient on a stretcher that collapsed, causing his back to jerk. He could not work for almost a year. After chiropractic treatment and epidural steroid injections, his condition failed to improve and he was referred to a neurosurgeon, David L. Masel, M.D. Dr. Masel performed a lumbar discectomy on the Claimant in February 2002, resulting in mild improvement at first but followed by intensified pain. In July 2002, Dr. Masel performed a lumbar fusion. The Claimant could not work for a time after his surgeries. The Claimant's low-back pain has remained debilitating. Although he has returned to work, performing Atransitional@ (administrative) duties while assisting his supervisor, his pain has kept him from resuming his previous job.

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<sup>1</sup> In some documents, the insurer is shown as the City of El Paso and in others it is shown as El Paso Independent School District. Since the Respondent refers to itself as the City of El Paso, that term will be used.

<sup>2</sup> RS adopted Ms. Keese's testimony from appeals by RS in Docket Nos. 453-04-1018.M2 and 453-04-1189.M2. El Paso adopted Dr. Herschkowitz's testimony from the same dockets.

Dr. Maisal prescribed the RS 4i Stimulator for two months on November 18, 2002, and then for an indefinite use period on January 28, 2003. El Paso denied a request for preauthorization of indefinite use and on October 30, 2003, the IRO concluded the purchase should be denied.

The United States Food and Drug Administration (FDA) has cleared the RS 4i Stimulator to Arelieve acute pain@ and Arelieve and manage chronic pain.@<sup>3</sup> The FDA said, AThe RS-4i family is substantially equivalent to its legally marketed predecessor the RS-4M+ (K000114) muscle stimulator.@<sup>4</sup>

El Paso did not contest the efficacy of the RS 4i Stimulator for use during the acute phase of an injury. The only issue in this proceeding is whether the device is reasonable and medically necessary for the Claimant as of the date of the hearing, several years after his injury.<sup>5</sup>

Employees have a right to necessary health treatment under TEX. LABOR CODE ANN. ' ' 408.021 and 401.011. Section 408.021(a) provides, AAn employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. The employee is specifically entitled to health care that: (1) cures or relieves the effects naturally resulting from the compensable injury; (2) promotes recovery; or (3) enhances the ability of the employee to return to or retain employment.@ Section 401.011(19) of the Labor Code provides that health care includes Aall reasonable and necessary medical . . . services.@

As Appellant, RS Medical had the burden of proof.<sup>6</sup>

## **B. Testimony and Contentions**

### **1. RS Medical**

Dr. Masel wrote the following on May 12, 2003, in what appears to be an office note:<sup>7</sup> He continues to improve with the use of the muscle stimulator. As noted from previous letter on January 30, 2003, that Mr. [T] . . . has had great success in keeping his pain and discomfort to a minimum with the use of the stimulator. His intake of

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<sup>3</sup> Ex. 6 at 3 and 5. The device was also cleared for muscle stimulation for relaxing muscle spasms, preventing or retarding disuse atrophy, maintaining or increasing range of motion, increasing local blood circulation, re-educating muscles, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

<sup>4</sup> *Id.* at 4.

<sup>5</sup> The ALJ adopts the reasoning in SOAH Docket No. 453-03-4229.M2, MDR No. M2-03-1308-01; *RS Medical v. City of El Paso* (January 6, 2004), that the issue of medical necessity is present need, as of the date of the hearing, rather than past need, as of the date of the prescription.

<sup>6</sup> 1 TEX. ADMIN. CODE (TAC) ' 155.41; 28 TAC ' 148(h).

<sup>7</sup> Ex. 2 at 10.

Medication has decreased from 2x a day, down to 1x a day and his pain level has decreased down from a pain scale of 7-8 down to tolerable 2-3 pain level. . . . I feel the indefinite use of the stimulator is medically necessary for this patient to manage his pain on a daily basis, and maintain the progress he has experienced to date.

Dr. Masel made similar comments in a letter dated January 28, 2003,<sup>8</sup> and also said the use of the RS 4i Stimulator was a cost-effective measure that helped decrease the need for medication.

Dr. Masel wrote in a letter dated May 12, 2003,<sup>9</sup> that many of his patients have had a great deal of success using the RS 4i Stimulator to reduce pain and return to a more comfortable and functional lifestyle.

The Claimant testified he uses the RS 4i Stimulator primarily at work, where he is unable to take pain medications. He said he uses it quite a bit to control his pain. He had a TENS unit, but does not think it helped. He believes the RS 4i Stimulator stimulates his muscles and causes them to Asettle down.@ He indicated he is able to use the RS 4i Stimulator instead of Vicodin, and this helps him continue working. He thinks he would need to take off work without the device.

Ms. Kessie testified that the interferential current portion of the RS 4i Stimulator is a unique modality that is different from other types of electrotherapy.<sup>10</sup> It involves introducing simultaneous two-medium-frequency electrical signals into the body that cross, or interfere, with one another. She said this causes a pulsing wave that very effectively reduces pain. According to Ms. Kessie, medium interferential frequency minimizes skin resistance and allows much deeper penetration. This distinguishes it from a TENS unit, which is a low-frequency device that meets significant skin resistance. She said the device has three pain-relief mechanisms compared to a TENS unit, which has only one.

According to Ms. Kessie, the APhiladelphia Panel Physical Therapy Study@ (Philadelphia Study), cited by El Paso ' s experts and the IRO doctor, reviewed TENS, not interferential, devices.

Ms. Kessie cited a study by Anthony Yeung entitled, AEffect of Sequential Elective Surface Stimulation on Medication Utilization Following Selective Endoscopic Discectomy,@ in the *Journal of Minimally Invasive Spinal Technology*. Dr. Yeung concluded there was significantly reduced drug consumption by patients using the RS 4i Stimulator after minimally invasive back procedures.

There are several reports in the evidentiary record showing the Claimant ' s use of the RS 4i Stimulator. At the end of November 2002, he used it a total of 12 times over seven days.<sup>11</sup> In

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<sup>8</sup> Ex. 2 at 4.

<sup>9</sup> Ex. 2 at 11.

<sup>10</sup> Ms. Kessie was not shown to be a medical expert.

<sup>11</sup> Ex. 2 at 20.

December 2002, he used it a total of 63 times over 24 days.<sup>12</sup> In January 2003, he used it a total of 48 times over 22 days.<sup>13</sup> In February, he used it a total of 23 times over 13 days.<sup>14</sup> In March, he used it a total of 27 times over 15 days.<sup>15</sup> In April, he used it a total of 39 times over 16 days.<sup>16</sup> In May, he used it a total of 27 times over 16 days.<sup>17</sup> In June, he used it a total of five times over five days.<sup>18</sup>

In July, he used it a total of 10 times over six days.<sup>19</sup> In August, he used it a total of seven times over six days.<sup>20</sup> There were no records for September through December 2003. In January, he used it a total of three times over two days.<sup>21</sup> There were no records for February and March 2004. In April, he used it a total of 11 times over five days.<sup>22</sup>

In a February 2003<sup>23</sup> RS Medical questionnaire, the Claimant said the RS 4i Stimulator was extremely helpful, helped minimize the use of pain medications, and was effective in quickly treating pain. He said he uses it more than twice a day. However, he also said his use and reliance on pain medications had increased since he began using the device in November 2002.

RS Medical introduced testimonials from several sports teams extolling the RS 4i Stimulator.<sup>24</sup> Many said they used it for chronic pain relief as well as the acute phase following an injury.<sup>25</sup>

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<sup>12</sup> Ex. 2 at 18.

<sup>13</sup> Ex. 2 at 16.

<sup>14</sup> Ex. 8 at 18.

<sup>15</sup> Ex. 8 at 16.

<sup>16</sup> Ex. 8 at 14.

<sup>17</sup> Ex. 8 at 12.

<sup>18</sup> Ex. 8 at 10.

<sup>19</sup> Ex. 8 at 8.

<sup>20</sup> Ex. 8 at 6.

<sup>21</sup> Ex. 8 at 4.

<sup>22</sup> Ex. 8 at 4.

<sup>23</sup> Ex. 2 at 23.

<sup>24</sup> Ex. 7.

<sup>25</sup> Ex. 7 at 3, 6, and 9.

RS Medical argued that the Claimant was a very credible witness. It maintained he is clearly receiving a benefit from the RS 4i Stimulator, including a reduction in pain medication. It argued that the Claimant's failure to use the device for two months (see Claimant's testimony below) merely meant he was unable to make it operate properly, not that he did not need it.

## **2. El Paso**

Dr. Herschkowitz testified that the interferential current is like two TENS units set to interfere with one another. He acknowledged that the unit Ais said to give a deeper penetration than a TENS unit alone. He maintained the device is a passive modality that is legitimately used in the acute phase, or first six to eight weeks, following an injury or at the latest in the subacute phase.

Dr. Herschkowitz agreed with IRO and peer reviewers' opinions that the device is inappropriate for use several years after an injury. He said that although he would always factor in patient statements about care, he would also need objective evidence on how a treatment is working. He explained there is a well-recognized, large placebo effect that patients may receive from care that actually has no objective value. To demonstrate medical necessity, he said he would expect to see, in written progress notes, such objective measures as an analog pain scale, what a patient could do by using the device, or medication reductions. He referred to this approach as evidence-based medicine and cited it as the medical standard for determining medical necessity.

Dr. Herskowitz referred to the Philadelphia Study, which concluded that electrical stimulators are not helpful after the acute phase of an injury. He agreed that the study did not mention the interferential modality, but testified the RS 4i Stimulator is similar to a TENS unit. He indicated he has not seen studies or other evidence to recommend electrical stimulation after the acute phase.

The IRO doctor<sup>26</sup> concluded the primary care physician (PCP) failed to produce competent, objective, independently confirmable medical evidence demonstrating the RS 4i Stimulator's usefulness. He pointed out that the utilization curve from December 2002 through February 2003 documented no measurable improvement in the Claimant's condition. He indicated there was no data to show that the Claimant's pain medications had been reduced. He said the PCP's progress notes did not mention the device and the only letters of medical necessity were boilerplate vendor-generated documents.

The IRO doctor maintained the Claimant should be engaged in active rather than passive care at this stage of his injury. He cited the Philadelphia Study as finding little or no supporting evidence for using devices like the RS 4i Stimulator after the acute phase of an injury. He cited another study on TENS units which said they were no more effective than a placebo.

A peer review provided to El Paso on August 15, 2003, concluded scientific studies do not demonstrate the long-term efficacy of the RS 4i Stimulator, as shown in this case where the Claimant

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<sup>26</sup> Ex. 5 at 3-4. The IRO doctor is board certified in physical medicine and rehabilitation.

is still experiencing pain.<sup>27</sup> An August 12, 2003, peer review found that the Claimant's ability to exercise, as described by Dr. Masel's July 17, 2003, progress note, shows the device is unnecessary.<sup>28</sup>

The Claimant acknowledged that he did not use the RS 4i Stimulator for two months because he could not get it to work. He did not specify which months he was talking about, but the record shows he did not use the device from September through December 2003 and in February and March 2004. He said he thinks he complained to his doctor that the device was not working, but he did not call RS Medical. There was a toll-free "800" number on the back of the device for calling RS Medical.

El Paso maintained the Claimant has used the RS 4i Stimulator very little over the last few months. It pointed out that the Claimant did not contact RS Medical when it was not working. It cited the fact that the Claimant's medical records, including his condition, history, doctor recommendations, and surgical procedures,<sup>29</sup> did not mention the RS 4i Stimulator, except for Dr. Masel's letters specifically saying it was useful.

### **C. Analysis**

The ALJ concludes that RS Medical did not carry its burden of proving the RS 4i Stimulator was medically necessary as of the date of the hearing. RS Medical's primary expert evidence on the need for the device is from Dr. Masel, who said it has been helpful to the Claimant and other patients. Dr. Masel's recommendation was written about a year before the hearing date, at a time the Claimant was actively using the device. The FDA said the RS 4i Stimulator is useful for chronic pain relief, but the weight of evidence from medical experts was that it is not useful after the acute phase on an injury.

With conflicting evidence on the efficacy of the device, evidence from the Claimant concerning its effectiveness was important. He said it has helped him at work and said specifically that he was able to reduce his pain medications by using it. However, his use of the device has declined dramatically over recent months. There is no evidence of his using it during the last four months of 2003 and he used it on only two days in January 2004. Although the Claimant's failure to use it in February and March of 2004 may have been because it was not working, the evidence indicates he did very little to try to get it fixed or replaced, including failing to notice the 800 number on the back of the device for calling RS Medical.

In summation, although the Claimant was shown to use the RS 4i Stimulator on five days during the last eleven days of April (in the two and one-half week period before the hearing), the evidence also shows he used it on only seven days in 2004 and not at all in the last four months of

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<sup>27</sup> Ex. 1 at 4.

<sup>28</sup> Ex. 1 at 5.

<sup>29</sup> Ex. 9 at 11 *et. seq.*

2003. This evidence does not show the RS 4i Stimulator is medically necessary as of the date of the hearing.

## II. FINDINGS OF FACT

1. The Claimant, a \_\_\_ year old male at the time, sustained a work-related injury to his lower back on \_\_\_, while working as a paramedic.
2. The Claimant was carrying a 300-pound patient on a stretcher that collapsed, causing his back to jerk.
3. The Claimant could not work for almost a year.
4. After chiropractic treatment and epidural steroid injections, the Claimant's condition failed to improve and he was referred to a neurosurgeon, David L. Masel, M.D.
5. Dr. Masel performed a lumbar discectomy on the Claimant in February 2002, resulting in mild improvement at first but followed by intensified pain.
6. In July 2002, Dr. Masel performed a lumbar fusion.
7. The Claimant's low-back pain continued to be debilitating and he could not work after his surgeries.
8. Although the Claimant has returned to work, performing Atransitional@ (administrative) duties assisting his supervisor, his pain has kept him from resuming his previous job.
9. Dr. Maisal prescribed the RS 4i Stimulator for two months on November 18, 2002, and then for indefinite use on January 28, 2003.
10. The City of El Paso (El Paso) denied a request for preauthorization of the Stimulator for indefinite use.
11. On October 30, 2003, an IRO concluded the purchase should be denied.
12. It is undisputed that RS Medical requested a hearing not later than the twentieth day after receiving notice of the IRO decision.
13. El Paso did not contest the efficacy of the RS 4i Stimulator for use during the acute phase of an injury.
14. The Claimant's use of the device was as follows:
  1. At the end of November 2002, he used it seven days a total of 12 times.

2. In December 2002, he used it 24 days a total of 63 times.
3. In January 2003, he used it 22 days a total of 48 times.
4. In February 2003, he used it 13 days a total of 23 times.
5. In March 2003, he used it 15 days a total of 27 times.
6. In April 2003, he used it 16 days a total of 39 times.
7. In May 2003, he used it 16 days a total of 27 times.
8. In June 2003, he used it five days a total of five times.
9. In July 2003, he used it six days a total of 10 times.
10. In August 2003, he used it six days a total of seven times.
11. There was no evidence of use from September through December 2003.
12. In January 2004, he used it two days a total of three times.
13. There was no evidence of use in February and March 2004.
14. In April 2004, he used it five days a total of 11 times.
15. The RS 4i Stimulator is not shown to be reasonably required by the nature of the Claimant ' s injury as of the date of the hearing.
16. All parties received not less than ten days= notice of the time, place, and nature of the hearing; the legal authority and jurisdiction under which the hearing was to be held; the particular sections of the statutes and rules involved; and a short, plain statement of the matters asserted.
17. All parties had an opportunity to respond and present evidence and argument on each issue involved in the case.

### **III. CONCLUSIONS OF LAW**

1. The State Office of Administrative Hearings has jurisdiction over matters related to the hearing in this proceeding, including the authority to issue a decision and order, pursuant to TEX. LAB. CODE ANN. ' 413.031(k) and TEX. GOV'T. CODE ANN. ch. 2003.
2. RS Medical timely requested a hearing in this matter pursuant to 28 TEX. ADMIN. CODE (TAC) ' ' 102.7 and 148.3.

3. Notice of the hearing was proper and complied with the requirements of TEX. GOV'T. CODE ANN. ch. 2001.
4. RS Medical has the burden of proof in this matter, which was the preponderance of evidence standard. 28 TAC ' 148.21(h); 1 TAC ' 155.41(b).
5. The only issue in this proceeding is whether the RS 4i Stimulator is reasonable and medically necessary for the Claimant as of the date of the hearing. 28 TAC ' 134.600.
6. RS Medical did not prove the RS 4i Stimulator is medically necessary for the Claimant as of the date of the hearing. TEX. LAB. CODE ANN. ' 408.021(a).
7. El Paso should not be required to provide the RS 4i Stimulator to the Claimant.

### **ORDER**

**IT IS THEREFORE ORDERED** that RS Medical ' s request that the RS 4i Stimulator be preauthorized for use by the Claimant be, and the same is hereby, denied.

**SIGNED June 10, 2004.**

**JAMES W. NORMAN  
ADMINISTRATIVE LAW JUDGE  
STATE OFFICE OF ADMINISTRATIVE HEARINGS**