



Oregon

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Oregon Board of Chiropractic Examiners (OBCE)

Public Notice & E-Newsletter Update

August 2019

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President's Report



Regenerative medicine has grown dramatically in the last few decades. With such a rapidly growing field, there are companies on the market out to make money and disappear. It is important to know which companies are legitimate and which are not.

During several of my last continuing education seminars, I have been approached and aggressively marketed to by companies offering "Stem Cell" therapy. They promise to make it easy by sending a nurse practitioner to you to provide the injections and all you have to do is provide the referrals and buy the stem cells.

What are stem cells?

Currently, there are three types of recognized stem cells: 1) embryonic stem cells, 2) adult stem cells, and 3) stem cells found in umbilical cord blood and amniotic fluid. Embryonic stem cells are found in the embryo days 3-5 of development.¹ These types of cells are considered pluripotent, meaning they can turn into any type of cell. They can become any type of cell or divide into more stem cells. This makes them a potent tool for regeneration of cells that have stopped reproducing.

There are also adult stem cells found in a few locations, often in fat or bone marrow. There is ongoing research on these cells to be able to make them pluripotent and use them for regeneration.

Lastly, there are small amounts of stem cells found in umbilical cord blood and amniotic fluid. The cord blood is relatively small and does not contain enough material to treat an adult human. Amniotic stem cells are also limited in quantity. The additional concern with harvesting these cells is the collection, sterilization, and storage techniques used on the cells and if there is viability after freezing

Genetic Encoding

All adult, cord blood, and amniotic stem cells also have what is known as human leukocyte antigens (HLA) typing.² This is a marker on the cell which helps the body determine if these cells are self or non-self. We inherit our HLA typing from our parents.² We obtain a different combination from each parent. The only people who can successfully transplant cells or organs without rejection risk, are those with identical siblings.²

This is why people who need organ and bone marrow transplants must find a match before the cells can be donated to reduce the risk of their own body rejecting the new organ or injection. Having injections of stem cells from an unknown source may increase the likelihood of an adverse event due to the HLA types.

History of Stem Cells

Human embryonic stem cells and their use in research were banned by what is now the Department of Health and Human Services (DHHS) in 1973.³ These embryonic cells used to be obtained from aborted and miscarried fetuses. This ban did not include cells created in a lab via in vitro insemination until 2001.³ In 2009, the rules were opened up again to allow for very specific areas of research from donated cells stored at fertilization clinics which never ended up being implanted.¹ This is done with the donors knowing about this as a possibility and must consent to this prior to being donated.¹

To date, the FDA does not allow any fetal material for injections for orthopedic issues. The only FDA approved stem cell treatment is for specific cancers and blood disorders. There are many clinical trials researching stem cells for both spinal cord and other neurologic disorders. There is also promising research in regards to stem cells and heart failure.^{1,4}

Companies marketing to Chiropractors

There are many companies on the market appealing to chiropractors to add on this “turnkey” service. The chiropractor simply needs to refer their patients for the injections and buy the product. This could be problematic as true stem cells are regulated by the FDA. If the chiropractor has purchased a fake product, which is likely if they are purchasing it, they could face sanctions from the FDA as well their own state board. Chiropractors in the state of Oregon can refer out for many different therapies, provided there is clinical justification for the referrals. As a chiropractor, it may be best to see what companies are following the rules and obtaining FDA approval before referring out.

There are stem cell companies out there that do collect adult stem cells from your own fat or bone marrow, but have not gone through the FDA's investigational new drug (IND) application, and they are being shut down by the FDA. This means there are patients out there who had their own stem cells harvested, but did not have the opportunity to have them injected due to the clinics and labs being forcibly closed.^{4,5}

What to ask if you want the therapy

As someone who might be considering stem cell treatment make sure you know the following:

1) Ask if the clinic is FDA approved for stem cell therapy.⁴ Typically, you will have to sign a form letting you know this is an investigative drug. They will have an application number which you have the right to ask for.⁴

- 2) Appropriate stem cell therapy requires pulling cells from your body - either from fat or from bone marrow – do not believe them if they tell you it is umbilical or amniotic stem cells and much better for you. Run away immediately!
- 3) Make sure the person who is doing the injections has been well trained. Ask them how many injections have been done to the area you are having injected.
- 4) Ask about how the injections are performed, with use of fluoroscopy or ultrasound guided. Not all health professionals are trained in the use of fluoroscopy – which is live x-ray. It is important to do your own research to see if the facility is everything it purports to be. We have a radiology board in the state of Oregon (Oregon Board of Medical Imaging) which licenses and inspects all x ray equipment. If they use fluoroscopy, ask to see their license or check with the OBMI yourself.⁶

There are serious risks with having unknown materials injected into your body. Claims have included blindness after eye injections, tumor growth at the site of injection, and cells wandering to other areas of the body and regenerating elsewhere. There can also be worsening of symptoms and swelling at the site of the injection.^{1, 4-5}

References:

- 1) Mayo Clinic Stem cells: What they are and what they do. June 8th, 2019 Retrieved from <https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stem-cells/art-20048117>
- 2) Tiercy, J.M. (2016) How to select the best available related or unrelated donor of hematopoietic stem cells? *Haematologica*. 2016 Jun; 101(6): 680–687. doi: 10.3324/haematol.2015.141119 Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5013969/>
- 3) Boonstra, H.D. (2001) Human Embryo and Fetal Research: Medical Support and Political Controversy. The Guttmacher Report on Public Policy. 2001;4(1):3–5. Retrieved from <https://www.guttmacher.org/gpr/2001/02/human-embryo-and-fetal-research-medical-support-and-political-controversy>
- 4) FDA Warns about stem cell therapies. (2017) Retrieved from <https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies>
- 5) Sharpless, N.E., Marks, P. (2019) Statement on stem cell clinic permanent injunction and FDA’s ongoing efforts to protect patients from risks of unapproved products. Retrieved from <https://www.fda.gov/news-events/press-announcements/statement-stem-cell-clinic-permanent-injunction-and-fdas-ongoing-efforts-protect-patients-risks>
- 6) Oregon Board of Medical Imaging Licensee Look up. <https://hrlb.oregon.gov/OBMLicenseeLookup/index.asp>

Executive Director’s Report



Fiscal Responsibility and Accountability

Our budget bill for the 2019-2021 biennium, HB 5007, was modified by the end-of-session omnibus bill (HB 5050) and reduced the budget by \$40,563, providing an ending budget total of \$2,260,448 in Other Funds.

Our preparation for the 2021-2023 budget cycle will begin sooner rather than later and will include discussions around the continued absorption of the OHA Workforce Survey Fee and licensing and renewal fees.

Due Process, Fairness, Transparent Governance

At its July board meeting, the Board held its rulemaking hearing on many rules, one of which was our Certified Chiropractic Assistant rule, OAR 811-010-0110.

The Board voted to continue the hearing at its September 2019 meeting and keep public comment open to allow further input on this rule. Additional rules will also be reviewed per our public notice.

The OBCE meeting and location schedule for the remainder of 2019 is as follows and can be found on our website (www.oregon.gov/obce):

September 19-20	Klamath Falls - Running Y Ranch
November 14	Salem (OBCE office)

If we can be of help to you or your staff in any way, please don't hesitate to contact us.

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Rules Updates and Policy Changes REMINDERS

Chiropractic Assistant Renewal

Since the renewal for chiropractic assistants has changed to a birth month system, we've seen a couple of issues worth mentioning.

1. When should your six hours of CE be completed?

- a) ...within the 12 months immediately preceding your current renewal date;*
- b) ...prior to logging in to the OBCE's online renewal application; and, most importantly*
- c) ...prior to the last day of your birth month – your "renewal date."*

2. Who should/may complete your online renewal, including the update of your personal information, the healthcare workforce survey, and especially, your background history?

You, and only you! The Board understands that the clinic is frequently paying for the cost of the renewal, but other office staff or the supervising DC should not be completing your renewal.

Example: Recently, I received a CA renewal, and she reported a felony charge in the past 12 months. I requested documentation on that charge, and she admitted that the office manager completed the renewal for her, and mistakenly disclosed the misdemeanor charge as a felony. The matter was resolved, but the CA herself should have been the person correctly filling out the information.

Oregon Administrative Rules

The following administrative rules were amended by the Board, and became effective July 31, 2019:

- OAR 811-010-0015 Filing Addresses
- OAR 811-010-0025 Display of License
- OAR 811-010-0045 Chiropractic Students

- OAR 811-010-0066 Reciprocity
- OAR 811-010-0071 Board Members
- OAR 811-010-0080 Attendance at Board Meetings
- OAR 811-010-0110 Chiropractic Assistants
- OAR 811-015-0030 Chiropractic Obstetrics, Minor Surgery, and Proctology
- OAR 811-015-0070 Scope of Practice Regarding Examinations, Tests, Substances, Devices and Procedures

View the changes here – [July 31, 2019 Permanent Rulemaking](#)

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From Our Investigators

This article is addressed to the entire field, however, it may be of particular interest to a more specific portion of our profession.

“From the investigators” is designed to bring to light trends we see in complaints to the OBCE. Whenever possible, we share some of the issues we encounter during the investigation of complaints. We share this information not to assail licensees who have endured the investigative process or been subject to a Board outcome, good or not so good. We share it to aid licensees in the avoidance of a complaint entirely. In this particular article, we give some suggestions to both sides of a Medical File Review (records review) and an Independent Medical Evaluation (IME).

We have not seen a drastic increase in this type of complaint but we have noted a trend in an aspect of this type of complaint. As one might imagine, some of the complaints are retaliatory due to unhappiness around the IME outcome and are baseless. But some are well founded and may not be entirely due to intentional or monetarily motivated reasons. We would like to provide a couple of example cases (loosely based on actual cases).

Case # 1: Medical File Review

This case involves a licensee that provides medical opinions for an independent vendor of this service. The independent vendor offers these services to Insurance carriers.

The licensee is emailed an attached file consisting of a case history, medical records, along with specific questions. The licensee is afforded a specific timeframe to review the records and produce their opinions on medical necessity. This case in particular, the licensee opined that the patient had reached maximum medical improvement (MMI) at a specific date and care past that point would not be medically necessary based on the records they were provided to review. As a result of the licensee’s opinion, the insurance carrier for the injured patient informed both the patient and the provider that care past the point that the licensee opined as the date of MMI would not be paid for as it was not medically necessary. Despite the treating doctor’s recommendations for further testing and treatment, the patient, fearful of mounting medical bills, self-terminated care and informed their provider of the reason for ceasing care. The patient subsequently suffered a material worsening of their condition to the point they could not work and provide for their family.

As part of the complaint process, the licensee was notified of the complaint, asked to respond to the allegations in the complaint, and provide the patient records they were given to review by the vendor requesting their opinion. As part of the investigation, the OBCE subpoenaed the medical records of the patient’s provider as well as the insurance carrier’s records. It was discovered that

the licensee was only provided a portion of the patient medical records to review. When provided with the additional records, the licensee was asked if the additional documentation would have altered their opinion in any way. The licensee acknowledged that their medical opinion would have been different given the additional information.

The licensee was asked if they ever inquire as to whether they are getting a current or complete set of records to review. The licensee responded that they do not and were unsure if they had the right to make that request. We reminded licensee that there is one standard of care for all chiropractors, no matter if they are treating, rehabilitating patients, providing nutritional and life style and wellness care, medical file reviews, independent medical evaluations, or consulting/offering second opinions, we are responsible to acquire the patient's past and present history and medical records, if any.

Case # 2: Independent Medical Evaluation

This case involves a licensee that performed an Independent Medical Examination (IME) on a 47 year old Eritrean man with limited English. Patient was the passenger in the right rear seat of a vehicle, being driven by his wife, his 15 year old daughter was in the right front passenger seat.

In December 2016, Patient and his family were traveling to a holiday gathering and were stopped at a traffic signal when another vehicle attempting to stop slid on the icy road and struck the rear of the family's automobile. The impact was minor and there was no appreciable damage to either vehicle. Both parties exchanged information and left the scene of the accident. The family proceeded to the holiday gathering and arrived shortly after the accident. Upon exiting the rear of the vehicle to enter the home of the gathering, Patient felt light-headed and started to notice he had a headache centered behind his eyes. He shrugged off his symptoms and proceeded to participate in the holiday festivities and left the function in about 3 hours. Within this time frame, Patient started to develop stiffness of his neck and upper back in addition to his headache. As his wife and daughter had no complaints of pain or discomfort from the MVA, he again ignored his symptoms. The next morning, he woke with neck pain and stiffness with diffuse pain in his upper back extending out to his shoulder and a tingling sensation in his fingers of both hands. His symptoms of light-headedness seemed to have passed but he still had a persistent low grade headache.

Patient was a self-employed handyman/carpenter and proceeded to go about his job, installing tile in a client's shower. Approximately halfway through his work day, his neck pain, upper back pain, and stiffness along with the headache required he stop work and return home.

Perplexed by his symptoms, and due to the fact both his wife and daughter had no symptoms for the accident, he was reluctant to see a doctor. At his wife's urging, he consulted with a chiropractor (DC) close to his home. DC saw him the same day, one day post-accident. DC took a medical history with the aid of Patient's wife, who spoke English as a second language.

DC examined Patient, determined he had no previous history of injury. DC examined him and referred him for spinal x-rays of his neck and thoracic spine. X-rays were negative for fracture or gross osseous pathology but segmental dysfunction noted on motion studies. DC proposed a treatment plan consisting of moist hot packs, electrical muscle stimulation to his neck and upper back, 4 units of massage to his cervical and thoracic regions, and chiropractic manipulation to his cervical and thoracic spine region 3 times for week for two weeks and 2 times per week for 2 weeks.

Initially, Patient had relief of his neck stiffness and less neck pain but his upper thoracic pain/discomfort from the base of his neck to his shoulders bilaterally persisted. In addition, Patient complained of intermittent light-headedness or dizziness, and his complaint of and increasing symptom of him finding it difficult to void his urine or totally void. DC's notes,

although scant, hand-written and difficult to read, did note Patient's urinary complaint along with the symptoms of light-headedness. DC continued with the treatment plan as prescribed for 3 weeks. Patient was not progressing as expected and DC presumed it was because of Patient's work so DC requested Patient refrain from work. In addition, DC requested Patient consult his family physician about his urinary complaint presuming it may be related to prostatic issues. Patient informed, via his wife, that he did not have a family physician, so DC recommended Urgent Care.

At the end of 30 days, DC did a reevaluation of Patient, due to the lack of progress, as part of DC's reevaluation and an MRI of Patient's cervical spine was ordered. The result of the MRI found no significant articular or discogenic issues but 5.5 mm Syringomyelia was noted at C3-4. In light of the MRI findings, Patient's unexplained symptoms with the cape-like distribution of discomfort in the thoracic region and urinary symptoms, DC decided to refer Patient for a neurological evaluation.

Due to the fact that Patient had no private health insurance and it involved an MVA, it was difficult to find a neurologist or neurosurgeon who would see Patient. Approximately 6 weeks after Patient was injured, DC was able to get him an appointment with a neurosurgeon. The neurosurgeon utilized a medical interpreter instead of a family member when interviewing Patient.

During the neurosurgeon consultation, it was documented that Patient had survived meningitis as a 10 year old while living in Eritrea. It was surmised by the neurosurgeon that that was a possible etiology for the syrinx and that it remained asymptomatic until the trauma of the December 2016 MVA. The neurosurgeon's recommendations for further testing included a cystogram, and a follow up MRI. This neurosurgical report was sent to DC. The neurosurgeon did not have immediate surgical recommendations and recommended continued conservative care from DC.

In March 2017, Patient was scheduled with licensee for an IME. Due to scheduling conflicts, Patient had to reschedule with licensee for the IME. When Patient was finally seen by licensee, he did not have a medical interpreter, he was accompanied by his 15 year old daughter who spoke fluent English and Eritrean. Licensee proceeded with the interview utilizing Patient's 15 year old daughter as an interpreter.

Licensee informed investigators that they were provided DC's medical records and the initial MRI and spinal x-ray radiology reports. The neurosurgeon's report was not included in the records, they were provided prior to the interview. Licensee interviewed Patient via his daughter's translation and performed an examination. Licensee recorded normal spinal ranges of motion and static and motion palpation revealed no significant abnormalities to Patient's soft tissue.

Licensee recorded normal upper and lower reflexes, and gait analysis was documented as normal. Licensee opined that Patient had reached MMI, that his injuries of December 2016 had resolved, and no further treatment or testing was indicated. Licensee also opined that the MRI was not medically indicated. Licensee was asked by the insurance carrier to address questions following the examination of Patient. Licensee was asked if there were any preexisting conditions that could have hampered his recovery of injuries sustained in December 2016. Licensee was also asked if any further medical testing was indicated in Patient's case. Licensee opined that there were no preexisting conditions that could affect the outcomes in this case and that no further testing was indicated.

Patient was informed by his insurance carrier that any medical bills past the point his IME was performed would no longer be covered based on the results of the IME. When Patient received

this letter, he self-terminated his treatment with DC and did not follow up with the neurosurgeon, due to the mounting costs of the medical care, despite the recommendations of his doctors.

In June 2017, Patient's symptoms of urinary retention, upper extremity weakness, and increasing neck pain prompted him to go to Urgent Care where he was evaluated and an MRI was performed. It was noted that his syrinx had increased in size to 9.5 mm, and was restricting his cerebral spinal flow enough to be responsible for his increasing symptoms. It was opined that the increased size in the syrinx from the original MRI was due to spinal trauma most likely due to his December 2106 MVA. Patient was referred back to his original neurosurgeon. Patient underwent surgery by his neurosurgeon to put a shunt into his syrinx to reduce pressure. He subsequently had a good outcome and the majority of his urinary retention and extremity weakness subsided.

When this information was provided to Licensee and they were asked if they would have had this additional information prior to their IME, would it have altered any of their opinions. Licensee admitted it would have very likely altered their opinions and recommendations. Licensee acknowledged that given the lack of any structural damage to the vehicles and that no other occupants of either vehicle suffered any reported injuries, and the information culled from Patient, with his daughter as interpreter, that they based some of the symptom reports as merely symptom magnification by Patient.

Licensee, in retrospect, admitted that using a medical interpreter, and more medical information, would have produced a different outcome.

Recommendations:

Whether you are the treating physician or performing IMEs or File Reviews, obtain all the medical information available. Contact the insurance carrier or what entity is requesting your opinions, make sure they are providing all the information that they are in possession of. If you are the treating doctor, clarity and content of your records are of immeasurable importance, including documentation of all second opinions or consultations. In addition, as our population continually becomes ever increasingly diverse, utilize professional medical interpreters for patient safety.

These are two examples of why it is absolutely important to obtain all the medical information possible, prior to rendering medical opinions that could affect clinical outcomes, and potentially compromise patient safety.

We would like to refer you to the OBCE website and review the latest version of the Oregon Board of Chiropractic Examiners Guide to Policy & Practice questions most current addition, dated 01/23/2019: https://www.oregon.gov/OBCE/publications/Guide_to_Policy_Practice.pdf

INDEPENDENT MEDICAL EXAMINATION (IME)

There is one standard of care for all chiropractic physicians, whether they be IME, examining, treating, consulting, or rehabilitating physicians. A professional relationship exists between the patient and the physician, regardless of whether the physician is the examining or treating doctor.

Regardless of the role, the chiropractic physician is expected to perform an appropriate chiropractic examination based on the patient's current and past complaints, the manner of onset, and the elicited history. From this, the DC will make a diagnosis and determine any further procedures or tests necessary to clarify the diagnosis and/or prognosis. These may include, but not be limited to: diagnostic imaging, laboratory testing, or other specialized studies. If indicated, the evaluating DC will propose any of the following: a recommended course of further

care, a timeframe for reevaluation, treatment options or referrals; or discharge from care when appropriate.

All examinations should include a “functional chiropractic analysis.” The Board has always assumed this was inherent in the P & P Guidelines, even though it was not included as specific language. The Board also stated that diagnosis should be based on pertinent history and examination findings, and reflected in the record.

The issues arising out of an OBCE action in 2002 resulted in the following agreement between the OBCE and the respondent chiropractic physician:

- a. The doctor/patient relationship between examiner and the examinee is limited to the examination, the opinion, and the review of the patient history and medical records provided; and does not include ongoing treatment monitoring. The examiner shall make important health information, diagnosis, and treatment recommendations available to the patient, treating doctor, and patient’s legal counselor or guardian via the independent report. Upon receipt of a signed written request from the patient or patient’s legal guardian, a copy of the examination report shall be made available as indicated in the request - to the patient and/or any other party designated by the patient.
- b. An independent chiropractic examiner should review the dictated medical opinion of a fellow panel member of an independent or insurer examination for its accuracy and completeness, and, when necessary, to clarify biomechanical or chiropractic reasoning, the independent chiropractic examiner should supplement the dictated medical opinion with his or her independent chiropractic opinion. OAR 811-015-0010 (Clinical Justification) also governs the conduct of independent examinations.

Workers’ Compensation IMEs.

The Oregon Workers Compensation Department (OWCD) is required to maintain a list of providers authorized to perform IMEs for workers’ compensation claims as a result of SB 311 (2005). The OWCD director may remove a provider from the list after a finding of violation of standards of professional conduct for workers comp IME claims. Health professional licensing boards may adopt such standards or, if they don’t, the default standards are published by the American Board of Independent Medical Examiners (ABIME). The OBCE considered this issue at their May 18, 2006, meeting and decided to accept the ABIME standards and also submit to OWCD the OBCE’s policy as additional applicable standards for IMEs performed by chiropractic physician

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