



## **Denver Physician Details Seven Questions Stem Cell Patients Should Ask**

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Denver Regenerative Medicine, a Denver stem cell therapy clinic treating chronic joint pain, has published a seven-question framework patients can use to verify whether a regenerative medicine provider follows federal cell and tissue regulations.

The guidance addresses a consumer-protection problem federal regulators have documented for years. The U.S. Food and Drug Administration cautions that misleading information about regenerative medicine products circulates widely online, and that patients seeking relief may be drawn toward products that are illegally marketed and have not been shown to be safe or effective. For Denver residents weighing stem cell therapy against joint replacement surgery, the practical difficulty is that a compliant clinic and a non-compliant one can look nearly identical in search results. Both may advertise the same conditions, the same recovery language and the same neighborhoods, from Capitol Hill and Governor's Park to Washington Park and the Denver Tech Center.

"Patients deserve straight answers about how their cells are processed and why that meets federal standards," said Andrew Hong, MD, an interventional pain management specialist at Denver Regenerative

Medicine. "Our focus is making sure every person can evaluate that before consenting to treatment."

The framework centers on documentation rather than marketing claims. Human cells and tissue products are governed by 21 CFR Part 1271, which sets four conditions a cell product must meet to avoid requiring premarket approval: the cells must be minimally manipulated, used for the same basic function they served in the donor, not combined with a drug or device and not dependent on systemic metabolic activity. A clinic operating within that framework can explain how each step of its process satisfies those conditions and can produce written documentation on request. The framework identifies an inability to answer that question as the most useful signal a patient can gather in a single phone call.

The framework also directs patients to ask about processing protocols and injection accuracy. While federal regulations exempt self-to-self (autologous) procedures from donor screening rules, strict chain-of-custody, sterility, and traceability standards still apply to ensure what is harvested is safely processed and returned to the patient. Patients are separately advised to ask whether injections are placed under real-time ultrasound or fluoroscopic guidance rather than by feel.

Exosome products receive specific attention in the framework. Most do not meet the minimal manipulation criteria, and the FDA has issued public safety notifications regarding exosome products marketed directly to patients.

"We do not offer exosome injections, and that is deliberate rather than a gap in our services," Hong said. "When the regulatory picture is unsettled, patients deserve to hear that plainly."

Denver Regenerative Medicine performs autologous procedures using cells drawn from a patient's own bone marrow and adipose tissue, processed under minimal manipulation standards and placed under real-time imaging guidance. Hong earned his medical degree from the University of Wisconsin-Madison School of Medicine, completed his residency at the University of Colorado and is a member of the Colorado Pain Society and the American Academy of Pain Medicine. He has practiced interventional pain management in Denver since 2010.

Denver patients researching autologous stem cell therapy and PRP for knee, hip, shoulder or back pain can review candidacy criteria, the clinic's compliance protocols and consultation availability with Denver Regenerative Medicine at <https://denverregenerativemedicine.com/stem-cell-therapy/>.

This information is provided for educational purposes only and is not a substitute for professional medical advice, diagnosis or treatment. Always consult a qualified healthcare provider for personal health decisions.

About Denver Regenerative Medicine

Founded in 2015, Denver Regenerative Medicine is a regenerative medicine clinic offering autologous stem cell therapy, platelet-rich plasma treatment, hormone replacement therapy and peptide therapy to patients across Colorado's Front Range. All injections are performed under real-time imaging guidance. Andrew Hong, MD, an interventional pain management specialist, practices at the clinic. Denver Regenerative Medicine | Stem Cell Therapy, HRT, Testosterone Clinic, 455 Sherman St # 450, Denver, CO 80203, United States. Phone: (720) 583-1648. <https://denverregenerativemedicine.com/>

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### **Denver Regenerative Medicine | Stem Cell Therapy, HRT, Testosterone Clinic**

*Denver Regenerative Medicine was founded in 2015 by Dr. Joel Cherdack with a clear mission: to help patients avoid unnecessary surgeries and find lasting relief through the body's own healing power.*

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