

# Looking to Enter the Stem Cell Market?

## 3 Key Considerations for Orthopedists

There are no off the shelf solutions when it comes to adding a new component to an ortho practice. Between navigating regulations, receiving training, and marketing the service, there's a lot to address in a short time. To get started, here is a short summary of what to expect when responding to the steady stream of patient requests for regenerative medicine treatments like stem cell, PRP or exosomes.

### Corporate Structure

The first issue is always protection when starting a business or adding a new service. The first inclination of an orthopedist that wants to add stem cell treatments (e.g. PRP) to his or her practice is usually to creating a new entity separate from the medical practice. This triggers certain self-referral laws that need to be cleared. It's important to determine if your state has this type of law and if so, how to structure the new venture before moving forward.

### Federal Regulation

The FDA has the authority to regulate stem cell products and is actively doing so! Most products are regulated by the FDA as a HCT/P while others are not. Many direct-to-consumer providers are unsure about what this means and need to know what they are able to do and say. Thus, it is imperative to be up to date on the issues and know what boundaries have been set by the FDA.

### Scope of Practice

With the rise of stem cell science and treatments, many state boards have warned physicians that they could face potential disciplinary action for failing to meet the prevailing professional standard of care or for performing an experimental procedure without first obtaining full, informed consent. Therefore, is it important to discuss the addition of new treatments with counsel before starting.

Another issue relates to delegation. Many orthos would like to have a mid-level practitioner (i.e. NP or PA) assist or provide injections. Once again, state regulations need to be reviewed to determine who can provide treatments and what level of supervision is required. The good news is that scope of practice and physician supervision requirements (on premises or telephonic) is readily ascertainable.

There is no universal formula. Contrary to popular opinion, one size does not fit all. The sheer amount and scope of healthcare statutes and regulations makes it increasingly difficult for a provider (or even for an attorney inexperienced in healthcare law) to grasp important details. To protect yourself and your practice, make sure to ask the first questions first. Measure twice; cut once.