

Amniotic Fluid Injections Are at the Center of the Federal Government's New Enforcement Effort

Article By:

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As a healthcare provider who bills Medicare, you are confronted with tremendous red tape every time you submit a claim for reimbursement. As an experienced professional, in most situations, you gain an understanding of the Medicare billing and coding regulations and conduct business accordingly. However, some services present more complex billing requirements than others. It is often in relation to these services that the federal government initiates an investigation.

Amniotic fluid injections appear to be at the center of the federal government's most recent investigatory efforts into Medicare billing fraud. Indeed, recently the Centers for Medicare and Medicare Services, as well as the U.S. Department of Justice have announced a flurry of investigations into practices that administer amniotic fluid injections as well as companies that market these services.

Why Are Amniotic Fluid Injection Such a Cause of Concern for the Federal Government?

Amniotic fluid injections involve injecting amniotic cells into damaged tissues to help them recover and regrow. The purpose of these injections is to reduce inflammation of the damaged tissue, reduce an individual's recovery time, and regenerate tissue. Amniotic fluid injections are frequently prescribed for patients for medical or surgical intervention suffering from arthritis, tendon damage, spinal injury, ligament issues, or other injured tissues.

However, there are [conflicting reports](#) regarding the effectiveness of these treatments. CMS places itself on the side of skeptics, and, as a result, most amniotic fluid injections are considered non-reimbursable under Medicare regulations. If a health care providers bills Medicare for amniotic fluid injections, they are at an increased risk of being the target of a federal Medicare fraud investigation.

An investigation is typically conducted by CMS with the assistance of the U.S. Department of Justice. An FDA review of the most recent amniotic fluid injections reveals that investigators are relying on Civil Investigative Demands to obtain the information they seek.

A Civil Investigative Demand (CID) is a type of administrative subpoena. Only certain federal agencies have the power to issue a CID. Of course, the U.S. Department of Justice is one of them.

Unlike a traditional subpoena, CIDs are not subject to judicial approval. This means that DOJ investigators can issue a CID without first obtaining a judge's approval. This provides federal authorities with maximum disease control over their investigations.

While the DOJ doesn't need to get a judge's approval to issue a CID, they are still legally enforceable. Thus, for those receiving a CID, ignoring it is not a realistic option as it can lead to additional charges. Instead, efforts should be put into a response strategy.

Healthcare Fraud Claims Related to Amniotic Fluid Injections

Providers who administer amniotic fluid injections should familiarize themselves with the possible healthcare fraud charges they could face as a result of improperly billing Medicare. Because amniotic fluid injections do not have CMS or FDA approval for pain management, the bulk of the recent investigations focus on health care providers who prescribe injections for this purpose. Below is a list of possible charges that the federal government may bring against health care providers:

Violations of the False Claims Act

As a healthcare provider who treats patients receiving Medicare benefits, you provide a service, and Medicare reimburses you. Often, this transaction goes off without a hitch; however, an increasing number of providers who bill for amniotic fluid injections are finding themselves at the center of an ongoing federal investigation as part of U.S. Public Health Service Act. The reason for this is that, while there are limited purposes for which amniotic fluid injections are reimbursable, they are not approved for pain management.

To qualify as "medically necessary" under Medicare billing requirements, a service must be "needed to diagnose or treat an illness, injury, condition, growth factors, serious disease diseases, or its symptoms and that meet accepted standards of medicine." According to CMS, an amniotic fluid injection is administered to treat a patient's pain and not the underlying condition. Thus, the service is not "medically necessary."

The result is that health care providers are put in a difficult position, as some of the patients who need amniotic injections the most are those experiencing pain. However, doing so can expose a provider to liability.

However, the recent focus on Medicare fraud related to pain management has resulted in many providers who administer amniotic fluid injections for other valid purposes finding themselves in the government's crosshairs. Thus, it is especially important for these providers to maintain documentation of medical necessity for all amniotic injections.

Improper Referral Relationships and Illegal Kickbacks

The payment and receipt of kickbacks are commonplace throughout the healthcare industry. However, any referral relationship is subject to strict regulation. Providers and other businesses who fail to ensure these relationships are appropriately structured risk committing healthcare fraud. For example, the Stark Law, the Eliminating Kickbacks in Recovery Act (EKRA), and the Anti-Kickback Statute each prohibit health care providers from paying or receiving anything of value for patient referrals when seeking reimbursement through Medicare or another federally funded healthcare program. Depending on the situation, a provider can face civil or criminal liability. Notably, EKRA and the Anti-Kickback Statute apply to non-providers as well as providers, while the Stark Law only

applies to providers. This means that companies promoting amniotic injections, including marketers and third-party referral agencies, need to exercise care when structuring a referral relationship with a provider based on the provision of amniotic fluid injections.

Medicare Billing Fraud

As a general matter, because amniotic fluid injections are not covered by Medicare for most purposes, submitting a bill to Medicare may constitute Medicare billing fraud. As a result, during any investigation related to the use of amniotic fluid injections, investigators are likely to request comprehensive documentation that a provider's practices are in compliance with the applicable laws. This includes providing documentation for the bills in question, as well as those related to compliance policies that address the risks of intentional and unintentional billing mistakes. If healthcare providers cannot provide this documentation, it may be enough to lead to unfavorable consequences in the event of an amniotic injection fraud investigation.

Five Tips for Providers Who Recently Received a CID Related to the Use of Amniotic Fluid Injections

It is imperative that providers who administer or otherwise deal with amniotic fluid injections take the necessary precautions to protect themselves in the event of an investigation. Of course, each investigation should be addressed based on its facts, as there is no one-size-fits-all approach. However, below is a list of things to keep in mind if you received a CID or otherwise are aware of a pending federal investigation into the use of amniotic fluid injections.

Put an Immediate Legal Hold into Effect

A legal hold is a formal, organization-wide effort at preserving all documentation that may potentially be relevant to the government's investigation. While it may seem as though a legal hold only preserves potentially damning evidence, failing to preserve important records comes at an even higher cost. For example, missing evidence may indicate to investigators that it was destroyed, making a provider look as though they have something to hide.

Order an Internal Audit

The best way to get an idea of how a federal investigation will go is to conduct an internal audit in advance of the investigation. This will highlight any risk areas, giving providers the opportunity to address them and coordinate a responsive strategy. Of course, an internal audit should focus on the specific nature of the alleged violations.

Have a Healthcare Fraud Defense Attorney Review the CID

Although rare, on occasion, a CID is defective and, therefore, unenforceable. The more common situation is that a CID is too broad in scope, in which case an experienced federal healthcare fraud attorney may be able to limit the scope of the CID. This can dramatically reduce the burden of complying with the CID and may impact the outcome of the investigation.

Develop an Effective Response to the CID

Assuming that the CID is valid, it is imperative to quickly begin assembling all responsive documents. While organization is not a defense, it can show investigators that you take their role seriously and

respect their time.

Keep Your Eye on the Big Picture

While it's easy to focus on challenging or responding to the CID, it is important to keep in mind that the CID is only the first step in the investigation. Federal investigators use CIDs to obtain information; what they do with the information informs how the rest of the investigation will proceed. Thus, providers should not focus exclusively on the CID at the expense of developing an overall defense strategy.

Dr. Nick Oberheiden, a federal [healthcare fraud defense attorney](#) who regularly represents providers in amniotic fluid investigations, reminds providers,

Whenever you face a CID issued by the Department of Justice, it is essential that you treat the situation with the seriousness it deserves. While providers know their business best, they may not have a detailed understanding of the complex and ever-changing Medicare regulations. This is where the assistance of an experienced healthcare fraud attorney can make the difference. When you retain a lawyer, any conversation you have is protected by attorney-client privilege, which means your questions to your attorney—and your answers to theirs—cannot be used against you. Along those lines, it is also essential to assert your rights whenever doing so is necessary to protect yourself; for example, you are not under any obligation to speak with law enforcement or federal investigators.

Amniotic fluid injections pose unique regulatory challenges to providers. It can take tremendous effort to understand these regulations, which may take a provider's focus away from their practice. Thus, providers facing an amniotic fluid injection investigation should refrain from the temptation to handle the situation on their own and reach out to an experienced federal healthcare fraud defense attorney to ensure their interests are protected, and the investigation is handled in a strategic manner.

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