

# Medical Instrument Sterilization Services: Is Your Facility Cleaning Instruments for Third-Party Providers?

Wade Blundell, HMS Valuation Partners

Mike Vetter, HMS Valuation Partners

---

Medical instrument sterilization services are a necessary practice in hospitals and ambulatory surgery centers (ASCs). Although on a lower scale, physician practices who utilize re-usable instruments also need sterilization services. However, many of these physician practices do not have the resources to sterilize their own medical instruments. As a result, they have looked to their local hospitals or ASCs for a solution and have established a pattern of dropping off their instruments to be cleaned. Given the small volume of instruments from these private practices, hospitals and ASCs have no problem adding them to their daily cleaning process. But for hospitals and ASCs, providing these sterilization services raises several compliance-related questions.

- Is there an undue benefit being provided by these facilities to the local physician practice?
- Does this practice of being a “good neighbor” implicate any regulatory or compliance issues?
- If so, do facilities need to concern themselves with this service to ensure compliance?

The short answer is yes.

Medical instrument sterilization services are often overlooked by hospitals and ASCs as a potential source of compliance risk. The provision of sterilization services without charging a fee could be a violation of the Stark Law and Anti-Kickback Statute (AKS). To remain compliant, facilities must verify that they are charging physician practices at a rate that contemplates the specific service provided and is within fair market value (FMV). This article reviews the various sterilization processes and delineates some of the provisions facilities need to be aware of when considering compliance.

## Resources Spent Depend on the Sterilization/Cleaning Process

There are three different types of sterilization services typically found in a hospital or ASC that are based on the specific items and/or instruments being sterilized. These include steam sterilization, endoscope cleaning, and gas plasma sterilization. Each requires a different level of facility resources and is a key determining factor in the value of the service.

### Steam Sterilization Process

Within the scope of steam sterilization, there are three different levels of cleaning services: (1) decontamination/packaging/sterilization, (2) packaging/sterilization, (3) sterilization only. The scope of work performed by the facility depends on how the instruments are delivered by the independent physician and the agreed upon service. Some independent physicians will bring the instruments in soiled (requiring all three phases of cleaning), some will bring the instruments already pre-washed and ready for packaging and sterilization, and some will bring the instruments already packaged and ready to load into the sterilizers. The resources used are based on the level of cleaning. In each case the independent practice drops off and picks up their instruments. The most comprehensive option involves all three services combined—decontamination, packaging, and sterilization, followed by packaging and sterilization, and then sterilization only.

### Other Forms of Sterilization Processes

While steam sterilization is by far the most common, hospitals and ASCs will encounter other types of sterilization contingent upon the equipment being cleaned. Two other forms are (a) endoscope cleaning and (b) gas plasma sterilization for certain instruments that cannot be cleaned using water in the process (certain rigid scopes, batteries, camera heads, etc.). One of the key distinctions between these two sterilization techniques and the more common steam sterilization process is the fact that only a few devices can be cleaned at a time. This is due to the intricate parts of these instruments that require a more intensive manual cleaning process. Therefore, the labor costs involved are much greater on a per instrument basis than with steam sterilization.

As discussed above, the resources spent to perform the cleaning can vary based on the type of sterilization performed. These resource costs should be taken into account when ultimately determining the value that the facility is providing to the physician whose instruments are being cleaned.

## Key Value Drivers in Determining the FMV Rate for Sterilization Services

Understanding the processes and resources that go into the sterilization service is the first step to determining a rate that is within FMV. These key value drivers include:

1. *Staffing Costs*, which include the processing technicians related to the specific service. Salary and benefit costs should be determined on a full-time equivalent basis.
2. *Furniture & Equipment Expenditures*, which pertain to the capital expenditures needed to provide the sterilization services. The value should also account for other costs including, but not limited to, maintenance and taxes on the equipment.
3. *Space Utilization at the Facility*. Identifying an appropriate cost for the space used by the sterilization department will require knowledge of the square footage and the market rental rate for the area. Architectural drawings as well as the use of a real estate appraiser may facilitate this process.
4. *Supply Costs*, which include the materials required to complete the instrument sterilization process. The appropriate rate will need to account for differences in the level of sterilization as well as the variability in number of supplies used.
5. *General & Administrative (G&A) Expenses*, which are typically a hidden component when calculating an FMV rate. These expenses can include human resources, building management, information technology, corporate compliance, etc.
6. *Rate of Return*. Another overlooked item in the provision of a rate that is within FMV is the rate of return applied to the provision of the service. A review of market data based on asset categories and industry-specific financial statement studies can provide the necessary data to calculate an appropriate rate of return.

Interviews with individuals working in the sterilization department are important in determining the resources utilized and the applicability of many of the above key value drivers.

## Five Critical Compliance Takeaways

Sterilization services are necessary in the provision of health care. As such, facilities are often approached by community physicians to provide these sterilization services. Below are five critical takeaways to help ensure the arrangement does not raise compliance concerns under the Stark Law or AKS.

- Identify the service provided by the facility and its potential to be seen as an undue benefit.
- Develop a comprehensive review of the resources provided by the facility according to the specific sterilization services provided.
- Document the key value drivers to serve as the necessary FMV inputs.
- Do not overlook the importance of including an appropriate rate of return.
- Periodically evaluate the services being provided and the basis for the rate to ensure that it is within FMV.

With the necessary support to ensure the sterilization service is within FMV, providing this service can be a means to foster stronger relationships with the local medical community.

After joining HMS Valuation Partners in 1997, **Wade Blundell** quickly became a partner in 1999. Dedicated to the firm's clients, he has taken primary responsibility for overseeing the business valuations, most commonly for physician medical practices, diagnostic imaging centers, ambulatory surgery centers, urgent care centers, dialysis centers, and physical therapy centers. In addition, Wade also oversees the fixed asset valuation, real estate valuation, and timeshare lease valuation service lines within the firm

**Mike Vetter** joined HMS Valuation Partners in 2003. His primary responsibility is supervising the financial statement analysis and forecasting for business valuation engagements, as well as overseeing the analysis and market research necessary to establish the fair market rate associated with all goods and services (space, furniture and equipment, and other services) provided in timeshare lease valuation arrangements. Since joining HMS Valuation Partners, he has personally performed hundreds of business and timeshare valuations for a wide variety of clients.