

This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

Guidance and Considerations on Selecting a Reimbursement Consultant

Context

Because the reimbursement landscape for medical devices, diagnostics, and drugs is a complex space with many factors to consider, innovators may find it useful to engage a reimbursement consultant to help them navigate the process. Developing a strong reimbursement strategy – in parallel to a regulatory strategy and other potential commercialization efforts – and understanding the reimbursement landscape is likely to improve product utilization and acceptance.

Research the Field and Evaluate the Options

Medical product reimbursement and market access experts are generally focused on types of drugs/diagnostics/devices, specific therapeutic categories and or intended uses, or industry sectors (e.g., small biotech versus big pharma). As not all consultants may have the product-specific knowledge, expertise, or years of experience (industry and otherwise), you may find it useful to:

- **Ask your board of advisors, investors, or peers/entrepreneurs, or associations for recommendations and advice.**
- **Search for reimbursement and market access professionals on job-related websites (e.g., LinkedIn) or on university websites (e.g., medical reimbursement course instructors).**
Research professionals based on their specialty. Note that some professionals (such as professors) may have their own consulting firms which may be harder to identify via broad web searches.
- **Research reimbursement experts based on their specialty that aligns with your product/service.** Research online materials for presentations; this could give you an indication of their specialization.
- **Attend medical conferences/clinical meetings to keep up to date on current topics and meet consultants in your field (they may be speakers, panel participants, or attendees).** Seek out presentation tracks focused on your specific product category (e.g., drug, device, diagnostic) or clinical/disease category (e.g., oncology).

Meeting participants may also be able to give you recommendations.

- **Before your first phone interview, evaluate the assistance you need and develop a Statement of Work document.** Depending on your budget and the services necessary to support your medical product, you may want to look at different size firms or independent consultants. Developing a SOW will help you clarify within your leadership team what you are trying to outsource and can ensure your conversations with multiple potential vendors are focused on the same deliverables (apples to apples comparison). It can be helpful to share your SOW with potential vendors. A sample SOW for soliciting a reimbursement vendor can be found at <https://seed.nih.gov/sites/default/files/2023-10/Reimbursement-Sample-SOW.pdf>.
- **Schedule introductory calls with multiple consultants** (these calls are usually free). You may find a wide variety in their approach and cost. Also, you are likely to learn a lot during these initial which and may cause you to ask additional questions during future interviews.
- **Ask the consultants specific questions to gauge if they truly have expertise in the field** (are specialized) and have a track record (i.e., years of experience). You may want to ask about past clients, current trends in the field, their thoughts on a new CMS reimbursement pathway for novel medical devices you read about, etc.

Checklist

[The following list may serve helpful in preparation for and during the phone interview.] It is useful to create a document in advance of your call with the questions you expect to ask, use this document to take notes during the meeting. It is also useful to research potential vendors backgrounds before the call. Once you have a list of attendees you can search for articles they may have published, recent presentations, etc.

- Ask the key person/people who will perform your work about their track record.
 - How long have they been consulting?
 - What is their previous experience?
 - What is the most complex situation they have worked on thus far?
- What is their awareness of current trends in your drug, diagnostic, or device area. For example, you might ask for their thoughts on a recent article.
- Have they ever worked on launching a new drug/diagnostic/device in your specific industry? If yes, what did that look like (i.e., how successful was the launch, any lessons learned, etc.)?
- How much of your work will be done by the person/people you are interviewing versus by junior team members?
- How do the people who will work on your project stay current in their field?
- What types of services do they/ the company provide, and how is pricing determined? Are you able to choose some services (a la carte) versus an entire package (fixed price) or time and materials (hourly)?

- Are past clients (of similar size to your company) willing to provide references?

Resource: CMS – [Innovators' Guide to Navigating Medicare](#)