

How Medical Device Companies Deploy Reimbursement Resources Report on the Compliance-Alliance Reimbursement Benchmarking Survey

By Stephanie Mensh
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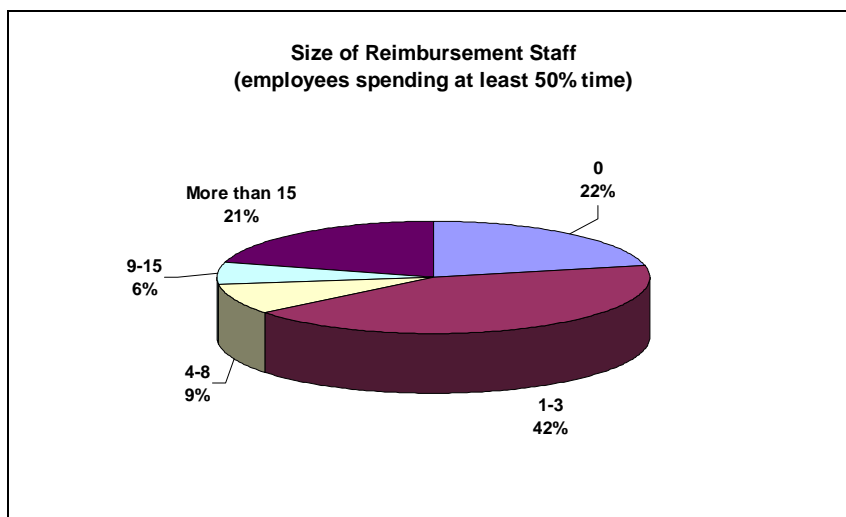
Executive Summary

To understand how medical device firms structure their reimbursement departments and deploy their reimbursement resources, Compliance-Alliance distributed a 20-question survey to personnel in medical device firms in November and December, 2006.

While a response of 30 to 35 personnel was considered sufficient to conduct an analysis, we were gratified to receive the extremely robust response of 80 completed surveys. The respondents were evenly divided among small, medium, and large companies. Almost half of the respondents cited their functional area as “reimbursement.”

Purpose. The survey asked: What were their reimbursement goals? How was their reimbursement function staffed? How did reimbursement staff achieve buy-in? What were their reimbursement challenges and solutions? We wanted to determine if larger companies had consistent responses that could serve as a model for medium and smaller companies.

Reimbursement Personnel. Device companies of all sizes reported having very small reimbursement staff, defined as employees spending 50% or more of their time on the reimbursement function. Two-thirds of the companies reported having three or fewer reimbursement personnel. There does not appear to be a clear educational or career path that leads to the reimbursement job. Almost half of the respondents were recruited externally for their expertise; about one third learned by “on-the-job training,” and 15% were “drafted because no one else would do it.”



Corporate Structure. There is no consistent location for the reimbursement function within device companies' corporate structures.

“Overall, the biggest challenge facing the reimbursement function (in any company) is that reimbursement is always reporting to another department (e.g., marketing, clinical, regulatory) and is never a stand-alone function. Therefore, it doesn't carry the same weight as other functions such as marketing, sales, clinical, etc. That is a mistake since reimbursement is just as important as the other functions, and should be treated as such.”

--*Survey respondent*

Titles confer status within the corporate structure, and may reflect the ability to influence decision-making. Many (43%) senior executives in charge of the reimbursement function had the title of Vice President; about one-third (31%) were Directors; and 13% were Managers.

There is no consistent source of funding for the reimbursement function. Almost one third (29%) of respondents indicated multiple sources of funding for the reimbursement function. This was the leading response among large companies.

Company's View on Reimbursement. Almost all of the respondents (87%) cited the reimbursement function's scope as both strategic and tactical. However, significantly fewer (61%) believed that top management views reimbursement as a strategic function involved in early product development decision-making. One-quarter view it as a tactical function involved in improving marketing and sales after FDA approval. A significant number (11%) view reimbursement as a necessary evil and 3% as limited or little value.

More than half the respondents indicated that their companies responded to product development issues based on reimbursement assessments by welcoming the input and adjusting expectations and goals. However, almost a third (29%) noted that their companies do not understand the implications; and 13% of individuals who identified themselves as reimbursement staff felt their recommendations were ignored.

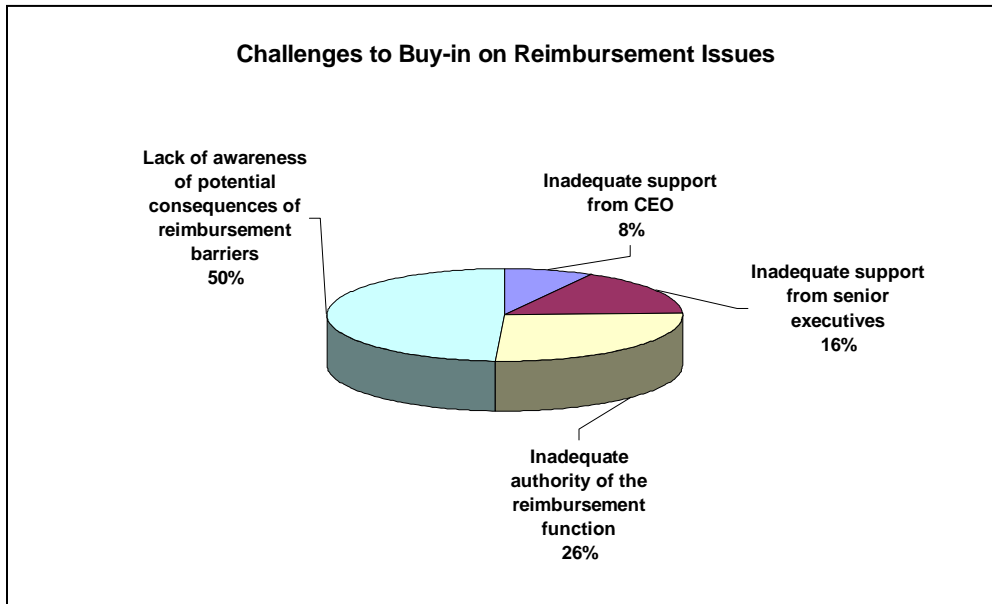
- 33% of reimbursement staff in companies of all sizes demonstrate value with data showing return on investment in managing reimbursement issues
- 30% by meetings with representatives from Medicare and/or private insurers
- 16% show value through staff relationships with reimbursement staff at hospitals, doctors' organizations, and insurers
- 14% have not been able to quantify their value; 23% among medium-size companies.

Impacting Decisions. Reimbursement staff gains cooperation internally in different ways.

- Only 26% of the companies indicated that reimbursement was part of the formal product lifecycle development process.
- 29% reported that an informal process was used by reimbursement to gain cooperation with other departments.
- 36% noted senior management's commitment (“we need reimbursement”)
- 9% were unable to gain cooperation except in a crisis.

Reimbursement staff faces many challenges to getting buy-in on their key issues:

- 50% cited the company's lack of awareness of potential consequences of reimbursement barriers
- 26% cited inadequate authority of the reimbursement function
- 16% cited inadequate support from senior executives.



Coverage, Payment & Coding Activities. Despite its small size, reimbursement staff is very productive, actively engaged in all facets of medical device reimbursement. In the prior 18 months:

- One-third (32%) had sought changes to provider payment systems
- Their main efforts (51%) were focused at the local level seeking private insurance and Medicare local coverage decisions
- 17% of companies of all sizes said they had applied for a national coverage decision.

The high number of applications for CPT codes (29%), HCPCS Level II codes (28%), and ICD-9 codes (23%) was a little surprising, given the intense level of effort and resources needed to gain success. Only 20% said that they were not pursuing new codes.

Currently, reimbursement activities outside the United States do not seem to be a significant focus among device companies: 66% said that they spent less than 5% of their time on international reimbursement issues.

Reimbursement Needs & Plans.

“Senior executives recognize the need and importance, but are not willing to put the dollars and resources toward this function at the expense of other functions.”

--Survey respondent

Most urgent need	Plans for coming year
<ul style="list-style-type: none"> • 27% said hiring personnel with expertise in reimbursement • 23% said developing data and economic models • 20% said applying for or communicating on coverage, coding and payment • 20% said using consultants to develop and implement reimbursement strategies • 7% said legal advice on reimbursement requirements. 	<ul style="list-style-type: none"> • 24% plan to retain reimbursement consultants. • 24% plan to continue in the current year without significant changes • Only 21% plan to increase reimbursement personnel • 4% plan to <u>reduce</u> reimbursement personnel or funding. • 15% plan to reorganize product development processes to incorporate reimbursement assessments in decision-making.

The survey respondents were asked what they saw as the number one challenge faced by the reimbursement function in the coming year and what steps they planned to take to deal with the challenge. There were two dominant themes:

- the need for economic data to prove the value of their products
- the need for better internal company structure and response to reimbursement issues.

Respondents also cited the challenges of monitoring and understanding the breadth of reimbursement issues, and meeting/working with federal and private policy-makers.

“The number one challenge will be to develop and articulate value related to specific products. I am on several innovation teams to produce the economic value story related to existing products and products in the evaluation stage of development.”

--Survey respondent

Analysis and Comment. We asked industry insiders to review the survey results and provide insight, analysis and comment. One suggested that the survey describes reimbursement as a corporate function in its infancy. This early stage is typically characterized by struggles for recognition, authority, and resources. As reimbursement begins to mature, to measure and demonstrate its contribution to meeting business objectives, it will begin to gain stature in the company.

Another commenter noted that a thorough reimbursement strategy has become as important as the FDA strategy in the success of a new device. Access to data, economic analyses, and other tools are vital to make the case internally and externally. Small companies with one individual overseeing reimbursement can be successful working with a consultant if the individual owns, defends internally, and pushes the reimbursement strategy to fruition.

Based on the results of this survey and comments from device company officials, the following characteristics seem important for a company's success in reimbursement:

- Senior management recognizes the importance of reimbursement.
- Reimbursement is included in formal procedures in all stages of the product's lifecycle.
- Qualified reimbursement personnel are provided with sufficient authority and resources to set and achieve goals consistent with the firm's bottom-line objectives.
- Reimbursement departments include individuals with differing skills and experience, are flexible and innovative in responding to changing demands, and can successfully manage internal and external relationships.
- Corporate structure supports a reasonable pathway for advancement by reimbursement personnel within the company and within their field.
- Reimbursement executives contribute to leadership in the healthcare community in shaping reimbursement policies that affect the success of their products, their companies, and the industry.

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About the Author: Stephanie Mensh, MPA, serves as Vice President, Reimbursement Policy, the Neocure Group, advising medical device companies on Medicare coverage, coding, and payment policies. Previously, she has served as a Senior Reimbursement Advisor for King and Spalding, LLP, advising medical device companies and health care provider groups on reimbursement issues. She served as a consultant to and as Vice President, Payment and Policy, the Advanced Medical Technology Association (AdvaMed), for more than four years. Her responsibilities included policy development on Medicare and private payer reimbursement issues affecting the medical technology industry, including product and service coverage, coding, and payment processes. She had lead staff responsibility on payment policy relating to diagnostics, competitive bidding and other issues relating to durable medical equipment, and on the hospital outpatient prospective payment system, including the program of pass-through payments for new implantable devices and the new technology APC program. Prior to joining AdvaMed's staff, she worked for the Institute for Clinical PET as Executive Director; for the Coding Institute, as Consulting Editor; the American Urological Association as Director, Department of Health Policy; and the American Academy of Ophthalmology as Assistant Director of its Washington, DC Office. She co-authored an internationally acclaimed book on stroke recovery with her husband, Paul E. Berger, "How to Conquer the World With One Hand...And an Attitude." She holds a Masters Degree in Public Administration, Finance, from George Mason University, and a Bachelor of Arts in Political Science & English from The American University.

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***This Executive Summary is extracted from the full report, "How Medical Device Companies Deploy Reimbursement Resources, Report on the Compliance-Alliance Reimbursement Benchmarking Survey," available from the author, Stephanie Mensh, or Compliance-Alliance, LLC. Contact: Stephanie.Mensh@strokesurvivor.com, 703-472-5784, or www.compliance-alliance.com.***