

Inadequate Reimbursement Why It Exists and What Can Be Done About It

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Inadequate reimbursement under Medicare is a problem that plagues many medical device manufacturers and their customers. Yet, many manufacturers do not know that there are effective ways to remedy inadequate reimbursement. The following lists the major causes of inadequate reimbursement and suggests corrective actions that can be implemented by device manufacturers.

Hospitals may not be reporting all of their costs to Medicare. For hospitals, Medicare bases its reimbursement rates in a new year on hospital claims previously submitted for the same procedure. Numerous audits of hospital claims and Medicare charge histories have shown a widespread failure among hospitals to charge appropriately for medical devices and biological products. Medicare officials have even urged device manufacturers to educate their hospital customers on how to bill correctly for the procedures that involve use of their products. As such, device manufacturers and their hospital customers should always be mindful of the importance of appropriate billing. What is billed for today will be the basis of payment adjustments two years from now.

What device manufacturers can do:

- ❑ Educate hospital customers about correct billing and its impact on future reimbursement.
- ❑ Assist hospital customers with correcting billing errors by conducting claims audits and resubmitting incorrect claims.
- ❑ Ensure that hospitals bill correctly going forward. Some manufacturers are even sponsoring cost data collection registries to facilitate correct billing.

Physicians may not be reporting all of their costs to the American Medical Association. For physicians, Medicare reimbursements are based on survey data obtained from practitioners by the American Medical Association (AMA). These survey results are used by Medicare and other payers to set payment rates. If physician survey responses do not accurately reflect the physicians' time utilized, skills needed, and practice expenses—including purchased items—then the payers will be basing their reimbursement decisions on incomplete data. (These surveys are known as "RUC surveys," named for the AMA committee—the AMA/Specialty Society Relative Value Scale Update Committee—that conducts them.)

Reimbursement Principles, Inc. is a full-service medical device and diagnostics reimbursement firm. Our clients are medical products innovators and their investors. We help them strengthen business plans through understanding the currently available reimbursement scenarios for a product, and we help them assist their customers to obtain optimum reimbursement. When reimbursement is inadequate, we help innovators develop and execute reimbursement development plans to complement product and market development efforts. We have led such efforts for both early stage and well established companies, across a broad range of products.

What device manufacturers can do:

- ❑ Review the most current RUC survey data to confirm that practice expense items associated with your device are accurate. If any deficiency exists, contact the appropriate medical professional society for assistance with correcting the deficiency through the AMA's RUC process.

A new device will be reimbursed at the same rate as a similar, existing product. If a new device is designated by the Food and Drug Administration (FDA) and the manufacturer as substantially equivalent to some predicate product, then the new device is likely to fall under the same coding and coverage policies as the predicate product. Consequently, Medicare reimbursement for the new device will be limited to the same reimbursement rate designated for the predicate product.

What device manufacturers can do:

- ❑ Investigate potential reimbursement consequences of regulatory strategies.
- ❑ Re-define "time to market" to reflect payer acceptance at an adequate reimbursement rate.
- ❑ Develop a positioning strategy for the device that supports both the regulatory and the reimbursement objectives.

FDA approval of a medical device may not be sufficient to support reimbursement by Medicare. As one Medicare official recently stated, "The FDA just tells me the device is safe and effective. The FDA does not help me decide why I should use it." In other words, FDA approval of a new medical device is not sufficient to support a Medicare payer's decision to provide reimbursement for it. Instead, payers look for evidence comparing a new medical device to

existing alternatives, especially if the alternatives have become the established standard of care.

What device manufacturers can do:

- ❑ Research Medicare coverage policies to identify their specific terms and conditions for coverage. If coverage is not available, determine why not and then develop a strategy to counter it.
- ❑ Meet with Medicare and private payers to understand the type of data they rely on when making coverage decisions.
- ❑ Determine if there has been a technology assessment conducted. Technology assessments involve evaluating medical devices based on objective, comprehensive reviews of clinical evidence. Often, technology assessments are conducted by third-party assessors. Review the results of any assessment carefully and communicate with the assessor to provide additional information or data that attests to the device's effectiveness.
- ❑ Review any related medical literature thoroughly to determine whether the use of the new device is cost effective compared to the use of alternative products and/or the standard of care.
- ❑ Design a "piggyback" protocol for reimbursement purposes that can be conducted in tandem with the FDA trial.

Hospitals and physicians cannot obtain additional reimbursement to pay for product improvements. Generally, hospitals and physicians are paid to perform procedures. Improvements made to a medical device may offer clinical advantages but, by themselves, do not change the related procedure. If the procedure is unchanged, the payment for the procedure will be unchanged.

What device manufacturers can do:

- ❑ Incorporate this principle into product planning.
- ❑ Differentiate the procedure that involves the use of the improved device, if possible, *via* a coding and coverage strategy.
- ❑ Ensure that the device's charge history is fully and effectively created to provide a basis for comparing costs associated with the device prior to and after making the improvements.
- ❑ Develop a credible cost savings platform to show how use of the improved device saves the hospital money by requiring a shorter hospital stay, reducing complications, etc.

Seeking new codes for a device can be problematic. A common mistaken priority among device manufacturers and their investors is to seek new coding for a device as soon as possible if the existing coding either does not describe the procedure associated with the device or if the existing coding is linked to a payment which is too low.

What device manufacturers can do:

- ❑ Learn the new code application requirements and determine whether they can be satisfied.
- ❑ Seek assistance from medical societies whose members use the device to advocate with the AMA for the new code.
- ❑ Understand your other options with respect to coding, including unlisted codes.

Reimbursement may be limited to the lowest cost of an alternative product. Some products—namely, durable medical equipment and supplies used by a patient without medical supervision in the patient's normal environment—may be reimbursed at a rate that matches the lowest cost of an existing alternative product. This results in insufficient reimbursement when the product being reimbursed costs more than the alternative product.

What device manufacturers can do:


- ❑ Identify the alternative product and determine its cost.
- ❑ Analyze your pricing and document the cost-effectiveness of your device compared to the alternative product through evidence of improved patient outcomes.

Reimbursement may be limited when a device manufacturer fails to account for coding, coverage, and payment. Reimbursement is driven by the correct alignment of three critical elements: coding, coverage, and payment. If one or more of these elements is undeveloped, as is frequently the case with new devices, overall reimbursement will not be automatic and/or adequate.

What device manufacturers can do:

- ❑ Research all three critical elements—coding, coverage, and payment.
- ❑ Construct a plan that will result in the complementary development of each element. Too many reimbursement development plans focus on only one of these three elements.

Ronald Podraza is an attorney who has spent his career specializing in the fundamental legal issues of the medical device industry: reimbursement, FDA regulation, company start-ups, and technology transfer. He is CEO of Reimbursement Principles, Inc., a consulting firm that works with medical technology innovators to develop third party payment for new treatments and procedures. In addition to private consulting, Ron has served as interim CEO of 3 investor-backed medical device start-up companies and as General Counsel of a leading cardiac pacemaker company. Stanford Law School awarded his J.D. degree in 1972, and Georgetown University Law Center awarded his LL.M. degree in 1994.



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