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FOOTUS

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Reimbursement

The Reimbursement Shell Game

Like many of us in regulatory affairs, I seldom gave reimbursement issues much thought, until I found myself buried in requests for assistance from patients fighting their insurance companies. It all started out slowly: one letter here; a phone call there. First, the complaints were about denials from insurance companies on the grounds that a treatment was *investigational*; then *not medically necessary*; followed by *cosmetic, not a covered benefit, pre-existing, no functional impairment* ... and the list went on.

In the end, I found myself facing the question: "What can regulatory affairs professionals do, earlier in the design process, to aid with reimbursement issues down stream?" While I don't have the silver bullet, I would like to share a scenario that those of us in the trenches have come to refer to as *The Reimbursement Shell Game*.

Just as with the card table version of this sport, the object of the game is for the dealer (insurance provider) to confuse the player (you, me and the patient) by randomly placing the pea (reimbursement) under a masked shell (reason for denial) and shuffling. Assuming that the dealer is legitimate, we are left to make our best guess as to which choice will yield the prize. However, if experience teaches us anything, we know that these games are stacked to the dealer's advantage through skilled and covert maneuvers.

Here's how the game works (taken from a recent case). After a request for benefits is submitted, the patient receives a denial letter stating that the device is considered investigational or experimental. No other details are provided, and the patient is told that he may appeal the decision within 60 days. The patient, addressing the reason for denial, appeals the decision by demonstrating that the medical device has received the necessary Food and Drug Administration (FDA) approval for the indicated use. A letter from FDA substantiates this claim.

Six weeks later, the patient receives a second letter stating that the original denial has been upheld and adding that the "cosmetic use of this device is considered to be investiga-

tional, and cosmetic procedures are specifically excluded in your policy." So it appears that the reason for denial has changed—or has it? The patient, under the assumption that he has already addressed the "investigational" issue, appeals the decision and demonstrates that, according to definitions provided by the American Medical Association, this procedure is considered reconstructive not cosmetic. A letter from the referring physician substantiates this.

Six weeks later, the patient receives a third letter stating that the original decision to deny coverage has been upheld and adding that: "In the opinion of the review committee the procedure is determined to be not medically necessary because the patient has not demonstrated that without treatment he would have any functional impairment and therefore this must be considered a cosmetic procedure." And so it goes until either all appeals are exhausted or the patient simply gives up.

To be fair, one could certainly argue that in each subsequent denial the provider was supplying additional information to substantiate original position. However, this information should be clearly communicated at the onset, because we all know that appealing a denial for *investigational considerations* is not the same as appealing for *cosmetic use* which is not the same as appealing for *medical necessity*. It is no surprise that the number of patients who continue to appeal their decision beyond the first denial drops off significantly.

Consideration should also be given to the vast amount of time and resources wasted, not only by the patient and his physician, but also by the insurance provider, who will ultimately pass this expense on to the consumer. Although not the only reason, it is one contributing factor to the escalating cost of healthcare in the United States. In short, when playing *The Reimbursement Shell Game*, everyone loses.

Timothy R. Littlefield, MS, is the director of research and regulatory affairs for Cranial Technologies, Inc., a manufacturer of Class II medical devices for treating abnormal head shape (plagiocephaly) in infants. For more information, go to www.cranialtech.com.