

Eli's Rehab Report

Reader Questions: Tread Carefully With Non-FDA-Approved Devices

Question: I have a question regarding investigative studies: If a physician's office is using a device that has not been FDA-approved but performs an approved therapy (that is, the CPT codes are valid), can the center charge for the services when performed by a rehab professional, and can the practice bill Medicare for it?

Florida Subscriber

Answer: You could always check with other insurance payers, but you cannot charge Medicare for this, regardless of who's doing the service and whether you're using a valid CPT code. Why: The CMS manual states that devices not approved by the FDA used in the treatment of patients should not be billed to the Medicare program.