HCCA
hcca-info.org

Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

JANUARY 2018

Compliance and behavioral health

an interview with
Marla Berkow

Contents

January 2018

FEATURES

Compliance Today is printed with 100% soy-based, water-soluable inks on recycled paper, which includes 10% post-consumer waste. The remaining fiber comes from responsibly managed forests. The energy used to produce the paper is Green-e® certified renewable energy. Certifications for the paper include Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Programme for the Endorsement of Forest Certification (PEFC).

COLUMNS

DEPARTMENTS

by Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

Medicare DISadvantage in clinical trials

Kelly M. Willenberg *(Kelly@kellywillenberg.com) is President and CEO of Kelly Willenberg, LLC in Chesnee, SC.*

A Medicare Advantage Plan (MAP) is a type of a Medicare health plan offered by a private company that contracts with Medicare to provide Part A and Part B benefits for beneficiaries. If a patient chooses to join a Medicare Advantage Plan, *some* clinical trial costs may be covered by the plan. What exactly does that mean for the patient?

Willenberg

According to the *Medicare Claims Processing Manual*, Chapter 68.4, clinical trials involving an investigational device are billable to Medicare as long as the services are a routine cost. The Category B device is also allowed to be billed as long as the trial is approved by Medicare. The *Medicare Managed Care Manual* then goes on to explain (in Chapter 10.7.2—Payment for Investigational Device Exemption (IDE) Studies) that the MAP is responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the Medicare Contractor that has jurisdiction over the MAP's service area. So, the MAP is supposed to cover routine costs in IDE studies but not drug studies. Why is there a difference? Can we make this process any more confusing?

If you want to discuss this with a health insurance administrator at Medicare who oversees the MAPs, the questions regarding billing and specific coverage policies can be brought to the Center for Clinical Standards and Quality (CCSQ) and CMS overall. The real questions remain: (1) Why do MAPs sometimes not cover device studies when they should according to CMS? (2) Why do MAPs direct sites to bill traditional Medicare for device studies in writing? (3) Why do MAPs sometimes cover drug trials when all do not?

As a clinical trial billing consultant, the questions about differences based on drug vs. device trials deserve answers. It takes a tremendous amount of personnel to manually submit claims to original Medicare, then ensure that the MAP covers the difference between original Medicare cost-sharing incurred for qualified clinical trial items and services, and the MAP's in-network cost-sharing for the same category of items and services. Many practices and hospitals struggle to get this correct, because it is a totally manual process.

I challenge Medicare and the CCSQ to review the distinction. CMS provided the clinical trial policy in 2000 and the device rules in 1995. Can we move towards a re-evaluation of this multifaceted process? Help beneficiaries avoid finding themselves in a Medicare DISadvantage situation for the trial they want to participate in!