QUALITY IMPLANT COALITION BACKGROUNDER

Gainsharing v. PODs

Some POD advocates claim their PODs promote the same cost-saving benefits seen in a number of "gainsharing" programs approved in recent years through OIG advisory opinions. As discussed more fully below, the "gainsharing" programs approved by the OIG have all involved proposals to share with physicians demonstrated cost savings to which the physicians have been shown to contribute by reducing expenses including, in part, by ordering only standardized products. In contrast, physician investment in PODs involves sharing with physicians not *cost* savings, but the *profits* earned by the POD based on products ordered by the referring physician investors for their own patients. These profits are maximized not by generating demonstrable cost savings, but by ordering more, and more expensive products. Product "standardization" in these circumstances is not likely to result in any cost savings.

Historical and Legal Background on "Gainsharing".

- *SAB: All Gainsharing Illegal.* In 1999, the HHS OIG released a "Special Advisory Bulletin" which concluded that all hospital-physician "gainsharing" – defined by the OIG to mean arrangements where hospitals share a percentage of savings realized when physicians adopt hospital-prescribed protocols that require them to standardize on certain products and approach medical treatment in certain ways that will reduce the hospitals' costs – violates the Medicare civil money penalty law (CMPL) provision that prohibits hospitals from giving physicians any remuneration to reduce or limit medical care. At the same time, the OIG opined that many such arrangements would also violate the Medicare antikickback statute (AKS), though since that is a criminal, intent-based statute, violations would have to be determined case by case.
- *AO 01-1: One Cardiac Gainsharing Arrangement approved.* In 2001, the OIG released an Advisory Opinion (01-1) in which it approved a particular gainsharing arrangement through which *cardiac* surgeons could share in savings resulting from following 19 specified procedures, 14 of which related to not opening surgical packs until needed, 4 of which called for substituting less costly items used by the surgeons, and one recommending limited use of an anti-hemorrhaging drug to only high-risk patients. Importantly, savings to be shared were tied to each of the 19 procedures, so a physician could still share in savings if s/he used none of the lower cost products, but did follow the "open only as needed" rules for surgical packs.
- *Key Factors in Approved Gainsharing Arrangement.* The key factors identified by the OIG in approving this arrangement were: (1) there were specific acts to be taken by the doctors, all of which were tied to the reduced cost; (2) there were numerous safeguards to avoid patient harm, including: (a) floor based on historical cost data below which no savings are shared, and ceiling of 50% of savings initially projected by the independent program administrator; (b) independent administrator reviews all cases for quality; (c) any increase in cost savings from increased number of federal health care program procedures will not be shared with the docs; (d) case mix will be monitored and surgeons terminated if they steer more costly patients to other hospitals; (e) the arrangement was limited to one year in duration, and applied only to one surgeon (not referring physician) group.
- *Additional Approved Gainsharing Arrangements: More of the Same.* In 2005, the OIG issued 6 new AOs, all involving minor variations on the theme approved in 2001. Two

involved arrangements were with cardiologists for cardiac cath procedures, two involved arrangements with cardiac surgeons, and the surgical AOs were focused predominantly on "open as needed" savings, with standardizing on less costly items a minor part. The cardiac cath AOs were more focused on standardized product use. All had floors and ceilings based on historic costs and projected savings, all were limited to 1 year in duration, all gave the physicians complete freedom to choose the same range of non-standard products they had before, all were limited to docs who already did most of their procedures at the hospital in question, all shared savings on each individual activity. The OIG also noted that these kinds of procedures are not predominantly performed on Medicare patients.

- *More recent Advisory Opinions have followed the same pattern.* Since the end of 2005, the OIG has issued an additional 7 advisory opinions on sharing a hospital's cost-savings with physicians and one on sharing a hospital's performance-based compensation with physicians. All 8 advisory opinions, one of which involved orthopaedic products, follow the same pattern.

Gainsharing arrangements do involve rewarding doctors for contributing to lower cost procedures, and one component of reducing procedure costs is to standardize on certain implant purchases for which the hospital has obtained the best pricing (usually by virtue of promises of volume). But the amount that can be earned by physicians in a gainsharing arrangement is completely circumscribed by demonstrated cost savings to which the doctor has contributed. The doctors have a financial interest in the outcome of a lower cost procedure. In contrast, the physician's earnings from ownership of a POD are the markups obtained by the physician between the price offered to the POD by the manufacturer, and the POD's resale price to the hospital. The doctors in this circumstance have no incentive to reduce the cost of a procedure, and little incentive to reduce the price of the implant. In fact, the incentive is to order the most expensive implant possible that can pass the hospital's procurement process. Since the doctors have to make a profit, the hospital is necessarily getting less of a discount than it would get if the doctors were not in the middle of transaction.

March 2012