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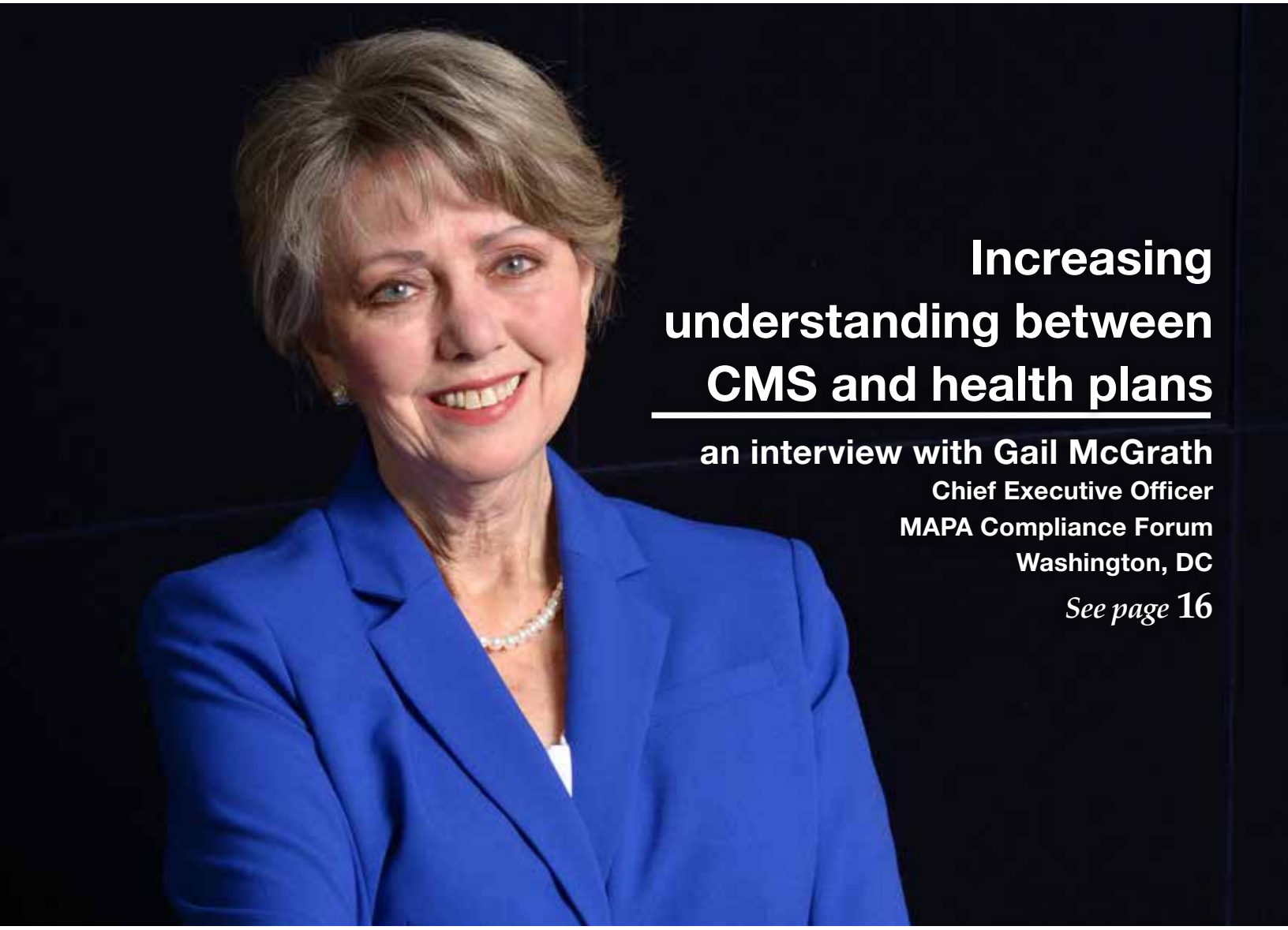

Increasing understanding between CMS and health plans

an interview with Gail McGrath
Chief Executive Officer
MAPA Compliance Forum
Washington, DC

See page 16

by Thomas N. Bulleit and Peter P. Holman, Jr.

Senate report discourages dealings with physician-owned distributorships

» Financial transactions involving physician-owned distributorships (PODs) may violate federal law.
» Law enforcement against PODs may include targeting POD-hospital relationships.
» Hospitals should adopt POD-specific policies consistent with OIG's 2013 Special Fraud Alert (SFA).
» Hospitals shouldn't deal with PODs that have any SFA "suspect characteristics."
» Hospitals should inquire and know about supplier ownership before making purchasing decisions.

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As a hospital compliance officer, you have heard of physician-owned distributors (PODs), which are physician-owned entities that derive revenue from selling or arranging for the sale of implantable medical devices used in surgery by those same physicians. You might be aware of a 2011 Senate Finance Committee (SFC) minority staff report questioning the legality and ethics of PODs.[1] In 2013, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services issued a Special Fraud Alert (SFA) calling PODs "inherently suspect" under the Anti-Kickback Statute (AKS),[2] and later that year, a report concluding that PODs are associated with higher surgery rates and increased costs.[3] And, if you've followed all of that, you probably know that SFC (now) majority staff held a hearing in November of 2015 and issued a new report in 2016, both of which were highly critical of PODs. Nonetheless, you may still be confused about whether and to what extent your hospital may be at risk if it elects to procure its implantable medical devices through a POD.

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In 2015, we wrote an article in *Compliance Today* identifying the risks associated with POD Medicare "carve-out" arrangements in which physicians propose purchasing POD implants only for private-pay patients.[4] We noted the OIG's long-standing view that limiting improper payments to only private-pay business could actually show intent to violate the AKS among the parties, and we encouraged hospitals to consider these concerns when approached by physicians with proposals to engage in "carve out" POD arrangements. Since then, new developments—including the SFC hearing in late 2015; the resulting report on PODs from the SFC majority staff in 2016; and in January 2017, the almost 20-year prison sentence imposed on a physician who acknowledged that his ownership interest in a POD had led him to cause the purchase of implants from

his POD and to perform medically unnecessary procedures—have shone an even brighter spotlight on POD concerns, and appear to have raised the stakes for those hospitals that continue to have dealings with PODs. Critically, the SFC majority staff makes clear its view that hospitals have affirmative obligations to regulate POD activity and to establish bright-line boundaries governing purchases from PODs. This article places this latest development in the context of the evolution of the federal government's increasingly negative scrutiny of PODs and suggests current implications for hospitals.

A decade of negative scrutiny on PODs

In 2006, the OIG issued a letter to AdvaMed confirming that PODs are subject to the 1989 Joint Venture Special Fraud Alert and other OIG joint venture guidance, meaning that an AKS violation would arise if one purpose of offering a physician an investment interest in a POD is to secure a stream of referrals from the physician.[5]

In 2008, the Centers for Medicare & Medicaid Services (CMS), in considering changes to the physician self-referral law (Stark Law) regulations that would have expressly addressed PODs, stated, "[w]e are concerned that some physician-owned organizations may serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician-investors use on their own patients."[6] CMS noted that, under existing regulations, many PODs would not satisfy applicable Stark Law exceptions (and thus would violate the law), and CMS also suggested that there might be other mechanisms, such as the False Claims Act (FCA) and AKS, that would be better suited for regulating PODs. At that time, CMS did not make any regulatory changes, but stated that it might make changes in the future.[7]

In 2011, the SFC (then) minority staff issued its first report, raising concerns about the proliferation of PODs and urging regulators to develop additional, clearer guidance regarding PODs.

In 2013, the OIG released its SFA calling PODs "inherently suspect" and describing as problematic a series of characteristics, many of which appear to be the essence of the POD business model. Later that year, it also released its report that showed that PODs provide no cost savings to the healthcare industry (and in some cases increased cost), and resulted in increased utilization of the implantable devices supplied by PODs compared to procedures performed with implants not acquired from PODs. By way of example, such "inherently suspect" characteristics include:

- the POD offers investment interests only or primarily to physicians who are expected to order or recommend POD implants;
- the physician-owners (and their patients) are the POD's primary customers;
- POD owners shift to the POD's products on a primary or exclusive basis after joining a POD;
- physician-owners condition their referrals to hospitals on their purchase of implants from the POD by coercion; and
- investor-physicians are few enough in number that the volume or value of a physician's own referrals correlates closely to investment return.

In 2014, the U.S. Department of Justice (DOJ) filed a civil case against California-based POD Reliance Medical Systems LLC (Reliance), two related distributors, and several of their investors, including one physician, for potential kickbacks and

submission of false claims.[8] The DOJ also pursued individuals on criminal charges related to the sale and use of POD devices; two individuals have thus far pleaded guilty.[9] Of particular significance, although the DOJ signaled in its complaint that hospitals dealing with the POD had submitted "false claims" for procedures involving Reliance implants (because the claims were tainted by illegal kickbacks from the PODs), the DOJ has not in these cases elected to pursue charges against hospitals. It seems likely that the decision to let the hospitals off the hook in the Reliance litigation may be traced to DOJ's allegations that Reliance made false, incomplete, and misleading statements to hospitals surrounding its relationships with physician owners.[10] The Reliance False Claims Act case continues to work its way through the courts.

On January 9, 2017, one physician involved in the Reliance case was sentenced to 19 years, 7 months in prison for his role in healthcare fraud totaling $2.8 million.[11] As part of his guilty plea, the physician admitted that in exchange for an ownership stake in Apex Medical Technologies LLC (Apex), a Reliance subsidiary and POD, and the share of profits he received as a result, the physician agreed to convince the hospital where he practiced to purchase Apex devices. The physician also admitted that the financial incentives of the POD induced him to perform medically unnecessary procedures. Additionally, the physician admitted that he and Apex purposefully concealed his ownership interest in the POD from hospital purchasers. The harsh criminal sentence seems to demonstrate that the concerns with overutilization, patient harm, and lack of transparency noted in the Senate Finance Committee majority staff report discussed below are alive and well in the enforcement community, and to support its admonition to hospitals to attend to these concerns.

...PODs may result in overutilization of medical care, because hospitals that purchase products from PODs tend to have higher rates of surgery.

The Senate Finance Committee report

The SFC majority staff released the report, "Physician Owned Distributorships: An Update on Key Issues and Areas of Congressional Concern" (2016 Report) on May 10, 2016, as a follow-up to its Committee hearing on November 17, 2015. The 2016 Report is remarkable in that, unlike its 2011 predecessor, it doesn't just raise questions about PODs and urge more detailed regulatory guidance. Rather, it makes relentlessly negative observations and proposes what a few years ago might have been seen as pretty extreme remedies. It really has nothing positive to say about PODs; instead, it contributes to an increasingly loud drumbeat against PODs played by all three branches of government, going back at least ten years and spanning two presidential administrations.

The 2016 Report built off of this growing list of guidance, reports, and enforcement actions to highlight the potentially detrimental impacts of PODs on patients and the healthcare system. Specifically, it noted that PODs may result in overutilization of medical care, because hospitals that purchase products from PODs tend to have higher rates of surgery. The 2016 Report also observed that such activity leads to inflated healthcare costs, including costs to federal

healthcare programs. In addition, the 2016 Report noted that, because physicians who order from PODs have an inherent conflict of interest, they may not always make the healthcare decisions that are best for patients, which in turn compromises patient safety and quality of care. Finally, the 2016 Report highlighted the typical lack of transparency associated with PODs, noting that oftentimes hospitals are unable to actually identify which entities might be physician-owned and which physicians might have a relationship with a POD.

POD risks: Spotlight turns to hospitals

Perhaps of greatest note to the Compliance community, the 2016 Report spends a great deal of time addressing the risks to hospitals from dealing with PODs. Although stating expressly that "financial transactions involving PODs may violate" federal law, the 2016 Report acknowledged that many hospitals remain confused about the legality of PODs. It observed that some hospital compliance officers found that "the rules governing POD behavior remain murky at best." But the 2016 Report concluded that, in light of increasing pressure from regulators and recent enforcement actions, it is incumbent on hospitals to develop and enforce explicit policies to manage their relationships with PODs.

Anticipating the concern that POD-restrictive policies could inadvertently stymie innovation by banning physician-owned entities engaged in the invention and development of truly cutting-edge technology, the 2016 Report suggested that there were ways that hospitals could thread this needle. For example, it pointed to Intermountain Healthcare's POD policy, which bans dealings with any entity that is owned in part by a referring physician or immediate family member, but provides an exception for disruptive technologies, as approved by the organization's chief executive officer, chief medical officer, and general counsel.[12]

The 2016 Report highlighted another hospital policy whereby the hospital identified eight suppliers from which it could order spinal implants, thus eliminating purchases from unvetted entities—including, potentially, PODs—that could pose untoward regulatory risk. In addition, several of the policies highlighted in the 2016 Report required each supplier to sign a statement or attestation that it is not a physician-owned entity and does not use PODs in the distribution of its products.

The 2016 Report recognized that some hospitals that had implemented POD policies met with physician opposition. In some cases, physician-owners of PODs threatened to leave hospitals that refused to do business with PODs. (The 2016 Report posited that such actions themselves could be a violation of fraud and abuse laws.) However, the 2016 Report provided one case study in which physicians ultimately accepted a hospital's decision to implement a "no-POD" policy, and claimed that no physicians ultimately departed as a result of its promulgation. The 2016 Report acknowledged the struggles that some hospitals might face for closing the door on some PODs, but noted that "the possibility of losing physicians must be measured against the risks [to the hospital] of noncompliance."

2016 Report recommendations: Practical steps for hospitals

In light of the increasing consensus of federal government stakeholders that PODs present serious legal and ethical concerns and the 2016 Report's pivot to implications for hospitals, there are several steps that prudent hospital compliance programs ought to consider. The following are either express recommendations

from the 2016 Report or represent what in light of its findings may be considered best practices for avoiding the compliance risks that the 2016 Report identifies for hospitals.

Adoption of POD-specific compliance policies

Hospitals should take seriously the 2016 Report's recommendation that all hospitals adopt, and rigorously enforce, specific policies that restrict dealings with PODs only "to circumstances that avoid any of the suspect characteristics identified in the OIG HHS SFA." Notably, the 2016 Report recommends that CMS establish a date by which all hospitals must implement POD policies and that non-compliant hospitals should not be reimbursed for surgeries using POD devices until they have developed and implemented a POD policy consistent with the SFA. The compliance policies should include:

- **Allowances for bona-fide innovation.** Consistent with OIG's expressed view that restrictions on PODs not interfere with genuine advances in medical technology, POD policies may consider a mechanism to allow hospitals to deal with entities that, though they have physician ownership, are involved in product invention and innovation and are not just re-selling knock-off products. The parameters and implementation of such a "disruptive technologies" rule should be closely scrutinized by the Clinical, Legal, and/or Compliance departments.
- **Allowances for non-referring physicians.** OIG defines a POD as any physician-owned entity that derives revenue from implantable device sales, but it is clear that AKS and conflict-of-interest concerns arise only when the owner-physicians are also in a position to cause purchases from their POD. Hospitals do not implicate these concerns when they purchase implantable devices from an entity owned by physicians who are not on the hospital's medical staff and are not otherwise in a position to order or influence the purchase of the supplier's products, directly or indirectly.

Verification by hospital of physician ownership

The 2016 Report expressed substantial concern about the lack of transparency concerning physician ownership and suggested that hospitals should take steps of their own to overcome this information gap. To address this issue, hospitals can take at least two steps in an attempt to pierce the veil of POD affiliations:

- **Annual open payments review**. Any POD-related policy should require an annual review of Open Payments data created under the Sunshine Act—and an accounting that such data were a factor in making purchasing decisions—if this is not already required pursuant to other policies. Hospitals taking this step would be ahead of the 2016 Report's recommendation that CMS make this an obligation for all hospitals.
- **Supplier attestations.** As highlighted in a number of the policies reviewed in the 2016 Report, hospitals reasonably may require their suppliers to provide information on physician ownership and attest that any such ownership meets the standards adopted by the hospital's policy for dealing with PODs (which, as described above, should track the SFA).

Disclosures of physician ownership to patients

The 2016 Report recommends that federal law should require physicians to disclose ownership interest in PODs to their patients. Armed with the information on physician ownership that appropriate POD policies will uncover, hospitals may assure (either directly or by requiring it of their physicians) that patients

also receive adequate disclosure of any physician-owned supplier relationships that the hospital's policy will permit.

Conclusion

The 2016 Report offers practical recommendations for hospitals that are trying to make sense of the current landscape surrounding PODs. It may also serve as a prelude to future governmental activity, given the 2016 Report's admonition that OIG and CMS both take steps to expand and clarify their position vis-à-vis PODs, and that law enforcement advance legal actions against PODs, their physicians, and hospitals. Despite the recent change in presidential administration, government scrutiny of PODs is likely to continue unabated. The OIG under both the Bush and Obama administrations was critical of PODs, and the 2016 Report was drafted by the SFC's Republican majority staff. In other words, skepticism towards PODs has been bipartisan and is likely to remain so. Therefore, hospital compliance officers should consider following the guidance offered in the 2016 Report, not only to meet current regulatory requirements, but also to prepare for future waves of regulatory and enforcement activity impacting POD-hospital relationships.

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3. Daniel R. Levinson: "Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use" October 2013. Available at http://bit.ly/2jZyPaP.
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8. *United States' Complaint, U.S. v. Reliance Medical Systems LLC*, Case No. 14-6979 (Sept. 8, 2014). Available at http://bit.ly/2j1ITAk.
9. *United States' Opposition to Reliance Defendants' Motion to Dismiss or, in the Alternative, to Lift Stay, U.S. v. Reliance Medical Systems LLC*, Case No. 14-6979 (Aug. 8, 2016).
10. See *United States' Complaint, U.S. v. Reliance Medical Systems LLC*, Case No. 14-6979 (Sept. 8, 2014), ¶¶ 304, 309, 312; 179-193.
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12. Available for download at http://bit.ly/2kbwhGF