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SENATORS REACT TO SPECIAL FRAUD ALERT INVOLVING PHYSICIAN OWNED ENTITIES

HHS Office of Inspector General Exposes Flawed Structure, Questions Doctors Profiting From Medical

Devices Used in Medicare Patients

WASHINGTON – U.S. Senator Orrin Hatch (R-Utah), Ranking Member of the Senate Finance Committee, today said a new Special Fraud Alert issued by the U.S. Dept. of Health and Human Services Office of Inspector General (HHS-OIG) regarding Physician Owned Distributorships (PODS) confirms the middleman entities that allow doctors to financially profit from the medical devices they use in their patients are at high-risk to be in violation of the Medicare anti-kickback statute. Hatch, along with Finance Committee Chairman Max Baucus (D-Mont.) and Judiciary Committee Ranking Member Chuck Grassley (R-Iowa) have <u>questioned</u> the legality of PODs and <u>requested</u> the OIG investigate their structure and potential adverse impact on the Medicare program and its beneficiaries in 2011.

"Anytime a few bad actors determine the treatment and care of patients, as this warning makes clear, patient safety is put at risk and millions of dollars are lost to fraud. This is simply unacceptable," said Senator Hatch. "Moving forward I will continue to scrutinize these high-risk structures and demand answers from HHS. Our patients and American taxpayers deserve nothing less."

"There are serious, unanswered questions about how these physician-owned distributorships affect patient care. Patients have a right to know they're getting treatment that's tailored to them – not someone else's bottom line – but physician-owned distributorships may put that guarantee in doubt," Senator Baucus said. "The Department of Health and Human Services is doing the right thing by issuing this special fraud alert. We have a responsibility to protect Medicare and Medicaid beneficiaries and patients across the country."

"This crackdown is good news," Senator Grassley said. "Anything that drains money from Medicare, away from patient care and into questionable profits, has to be shut down. Every dollar that goes into Medicare has to be spent on beneficiary care, nothing else. This alert along with the inclusion of Physician Owned Distributorships in the Physician Payments Sunshine Act will help shed light on these types of questionable relationships. HHS is right to act on this issue."

In recent years, there has been an uptick in PODs, which allow physician investors to purchase ownership shares in an entity that, in turn, purchases or serves as a medical device distributor for the products the physician utilizes in surgery. In June 2011, Hatch released a <u>report</u> which identified the rapid proliferation of PODs in at least 20 states, exposed the lack of specific legal guidance issued by the Office of Inspector General for HHS to govern the structure and establishment of PODs and brought into

question the utilization and appropriateness of services provided by doctors participating in some of the PODs, particularly with respect to Medicare, which is funded by taxpayers.

Today's Special Fraud Alert was a direct result of the Senators' 2011 <u>letter</u> to HHS-OIG asking them to look into whether or not PODs were a high risk for fraud and to issue additional guidance to the health care industry if it was determined that they were. HHS-OIG issues Special Fraud Alerts to publicize the national trends on fraudulent practices within the healthcare industry and address violations specific to the Medicare Anti-Kickback Law.

Key findings from the Fraud Alert follow and a full copy of the alert can be found here:

- The attributes and practices of PODs produce substantial fraud and abuse risk and pose dangers to patient safety;
- The OIG views PODs as "inherently suspect" under the anti-kickback statute;
- PODs that have arrangements which solicit capital contributions, select and retain investors, and distribute factors pose a risk and raise the following concerns: corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition;
- Financial incentives PODs offer to their physician-owners may induce the physicians to perform medically unnecessary procedures and to use devices sold by the POD in lieu of others which may be more clinically appropriate;
- Disclosure to the patient of the physician's financial interest in a POD is not in itself sufficient given the structure of the PODs; and
- OIG is concerned about the proliferation of PODs and the Special Fraud Alert specifically
 addresses why OIG now deems many of these arrangements to be at risk to constitute an illegal
 remuneration under the anti-kickback statute.

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