FOR IMMEDIATE RELEASE

November 17, 2015

CONTACT: Aaron Fobes, Julia Lawless

(202) 224-4515

Hatch Statement at Finance Hearing on Physician Owned Distributorships

WASHINGTON – Senate Finance Committee Chairman Orrin Hatch (R-Utah) today delivered the following opening statement at a Committee hearing to examine physician owned distributorships (PODs), entities in which physicians derive revenue from the sale of medical devices they prescribe to patients:

Today, we are here to explore the various issues surrounding the growth and prevalence of physician owned distributors, or PODs.

Simply put, PODs are medical device businesses in which a physician is both an investor and a distributor – essentially a salesperson – of either the devices or some of the components.

While these arrangements are not always problematic, we are seeing more and more of these physician-salespeople using the very devices they sell in the surgeries and procedures they perform. Many critics have argued – with significant evidence to support their case – that this practice creates a financial incentive for these physicians to recommend and perform more and more unnecessary surgeries.

Typically, the more devices or hardware a POD physician implants in their patients, the larger the payment he or she receives from the POD. So, an incentive clearly exists for these surgeons to perform a steady stream of procedures, increasing the use of products supplied by their POD, thereby increasing their own income.

The question we'll address today is whether these arrangements and the apparent conflicts of interest that exist among POD physicians have had a negative impact on our healthcare system and the wellbeing of patients.

As some of you may recall, in June 2011, the Republican staff of the Finance Committee issued a report on PODs outlining key issues and potential areas for congressional oversight. In response to some of the concerns outlined in the report, former Chairman Baucus and I, along with Senators Kohl, Grassley, and Corker, wrote to the Inspector General of the Department of Health and Human Services to share our concerns about the proliferation of PODs and the lack of guidance as to how these arrangements square with existing federal law.

For years, the HHS Inspector General has warned about the conflict of interest created by joint partnerships between physicians and companies – including device manufacturers – that depend on them for referrals or new business. In March 2013, the OIG issued an alert calling PODs "inherently suspect" under the government's anti-kickback laws.

Later that year, the Inspector General reported that the number of spinal surgeries in hospitals that purchase implantable devices from PODs grows at a faster rate compared to other hospitals. The OIG also found that, for nearly one in five spinal fusion surgeries billed to Medicare, the device was supplied by a POD, indicating a potentially significant link between PODs and federal healthcare costs.

Most notably, this same report found that physicians with investments in PODs perform, on average, 20 percent more surgeries than their counterparts who don't have these kinds of financial relationships.

Needless to say, these findings confirmed much of my skepticism about PODs.

And, while the OIG's guidance helped to persuade many in the industry that PODs were a risky business model, we continue to see reports in the media and from our constituents that these types of arrangements are still prevalent in our healthcare system.

Because the federal government does not regulate these types of business arrangements, it is difficult to determine just how many PODs exist or where they all are. This lack of accountability is one reason why this issue so complicated.

Anecdotally, we've received reports of PODs operating in every state represented on the Committee.

From what we've heard, the growth rate of PODs has slowed since the Inspector General's March 2013 alert. However, the total number of PODs remains roughly the same as before the report.

Our information also suggests that PODs are no longer concentrated in large hospital chains, as many chains have adopted policies forbidding or strictly curtailing POD usage. As a result, many PODs have migrated to smaller and more rural hospitals.

Some proponents of PODs have argued that some of our hardline statements and positions regarding their business arrangements go too far. They claim that implementing a sweeping prohibition on physician ownership in medical technology companies might have an unintended chilling effect on legitimate business practices as well as medical breakthroughs and research.

Nevertheless, we know that a number of POD physicians have abused their positions of trust and have put their own personal financial gain above the safety of their patients.

According to Department of Justice filings, one such physician was Dr. Aria Sabit, who, within months of accepting a lucrative investment offer from a POD, more than doubled his number of instrumented spinal fusion surgeries.

Prior to making his investment, Dr. Sabit had never used the POD's products before. After his investment, he used their products in more than 90 percent of his spinal fusion surgeries.

All told, Dr. Sabit invested \$5,000 in the POD. In just over two years, he saw a return of over \$438,000.

Now, I'm not typically one to decry investments with a high rate of return. But, those numbers alone should be enough to, at the very least, raise a few eyebrows.

In the end, Dr. Sabit pled guilty to more than \$11 million in health care fraud and to causing bodily harm to patients. One of our witnesses today, Kevin Reynolds, will tell us about his mother's experience under Dr. Sabit's care.

As part of our ongoing inquiry into these issues, the Finance Committee has become aware of additional cases that warrant further review. As a result, Ranking Member Wyden and I will be making a formal referral to the HHS OIG and the Department of Justice on at least one case we feel deserves review for potential criminal action.

We will be submitting additional information to the HHS OIG and to CMS about the rate at which PODs report their ownership interests. We believe these findings will say quite a bit about the lack of accountability for these types of business arrangements.

I hope that today's hearing will be another important step in our ongoing efforts to provide appropriate oversight and enforcement on this issue.

###