

OFFIT/KURMAN 2023 WHITE PAPER

PHYSICIAN DIRECT CONNECT EVENTS

A white paper on an ethical and convenient solution connecting medical technology and physicians.





When there is excellent communication between medical technology vendors and physicians, physicians have an expansive view of the technology available.

Patient safety, outcomes, and health care economics all improve. Unfortunately, several factors have interfered with this communication in recent years:

- Surveys indicate that fewer than half of all physicians take sales calls in their offices.⁽²⁾ Reasons for this include a lack of available time due to administrative burdens such as electronic medical records and concerns about transmission of infectious disease;
- Attendance at professional meetings has dropped to about half of pre-pandemic levels, due in part to concerns about infectious disease;
- Physicians are flooded with emails and phone calls, making it difficult or impossible to notice essential communications in a sea of unimportant ones; and
- Recent regulatory opinions can inhibit communication between the two parties.

In the interest of improving patient care and health care economics, Physician Direct brings together medical technology vendors (“Vendors”, and individually, “Vendor”) and physicians. Physician Direct uses a proprietary online platform to create and deliver matched, scheduled one-on-one video meetings so that the two parties can discuss the latest developments in new medical technology. The setting enables brief, focused, objective conversations that help medical providers understand new technology that may help them to provide care more safely, achieve better outcomes, and provide patients and insurers with less expensive alternative care.

Compared to the traditional in-office sales call, Physician Direct’s format is more efficient and focused (because Vendors have a maximum of 15 minutes to explain their technology) and more balanced (because, during any session, physicians may see several products that include those that compete with one another). The individual meetings also take place at “a more comfortable distance” from vendors than in-office meetings.

Compared to traditional exhibit halls, Physician Direct’s format is much less expensive, safer, more focused, more efficient, and more informative for the time invested. No travel or time away from the office is necessary. There is no risk of exposure to infectious microorganisms potentially carried by other show-goers; no consulting a map of an exhibit hall equivalent to five football fields, looking for relevant products; and no high-pressure pitches from salespeople.

Compared to educational dinner meetings sponsored by manufacturers, Physician Direct’s format provides much less opportunity for undue influence. Physicians who participate in the Physician Direct format are not served drinks or dinner

1. Disclaimers: This Memorandum provides a reasoned analysis involving the specific factual pattern, analyzing the risks of the particular fact pattern. The authors do not guarantee that any regulatory entity would arrive at the same or similar conclusions. This Memorandum does not address state laws.

2. See Sullivan, T. “Nearly Half of US Physicians Restrict Access by manufacturer Sales Reps-New Strategies to Reach Physicians.” (May 6, 2018) (accessible at Nearly Half of US Physicians Restrict Access by Manufacturer Sales Reps – New Strategies to Reach Physicians – Policy & Medicine (policymed.com)) (discussing two studies).

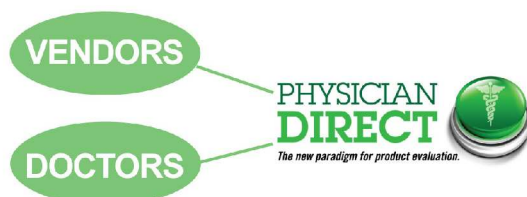
by manufacturers; they are not paid remuneration for travel, lodging, meals, refreshments, or gifts; and they are not lectured by colleagues who are actually on the payroll of the sponsoring company.

Patients benefit because their physicians do not have to give up regular office hours. Physicians can participate in Physician Direct events before or after regular hours or during lunchtime, preserving precious patient-care time.

In addition to all these benefits, Physician Direct helps level the playing field for smaller vendors that may have worthwhile technology but do not have the sales forces needed to help physicians understand it. In this way, it increases competition between product offerings, factors that tend to improve the quality and lower the cost of healthcare.

The educational, ethical, and economic advantages of Physician Direct's communication platform are readily apparent. However, in today's regulatory environment, where the U.S. Department of Health and Human Services ("DHHS") Office of the Inspector General ("OIG") is carefully scrutinizing speaker programs and other aspects of communication between Vendors and healthcare professionals, it is also vital to ensure compliance with federal law and industry codes of ethics. This document explains the unique facts and circumstances of the Physician Direct platform and the number of safeguards that mitigate the risk of fraud or abuse or otherwise merit consideration.

Physician Direct's business goal is to address the legitimate need of vendors and orthopedic physicians to communicate clearly about medical technology, legally and ethically. As a private, third-party entity, Physician Direct brings Vendors and healthcare professionals together via scheduled one-on-one video meetings curated for relevance.



Vendor participants benefit from Physician Direct's provision of technological and operational infrastructure, independent recruitment of physicians who meet the criteria set, and provision of the administrative tasks associated with producing and conducting the event. All of this results in each Vendor's opportunity to communicate for a fixed, brief amount of time with physicians in whose schedules Physician Direct has placed them.

Vendors have no role in selecting physicians with whom they shall meet, neither in physician recruitment nor the matching process that defines meeting schedules for participating physicians. Physician selection for every meeting is made independently by Physician Direct. All Physician/Vendor meeting matches are based on the Vendor's product and the surgeon's scope of practice. Vendors are allowed only to identify participating physicians with whom they have already had effective communication and physicians for whom their product or service would be inappropriate so that unnecessary meetings may be avoided for the sake of all.

Vendors pay for Physician Direct services through an established payment schedule. All Vendor payments become the general funds of Physician Direct absent vendor knowledge of which participating physicians they will meet and with no ability for the Vendor to earmark or designate use beyond simple participation. Physician Direct never holds nor transmits any vendor "funds." No Vendor can pay a premium to meet with a particular physician or pass anything of value directly on to a physician who participates in the Physician Direct platform.

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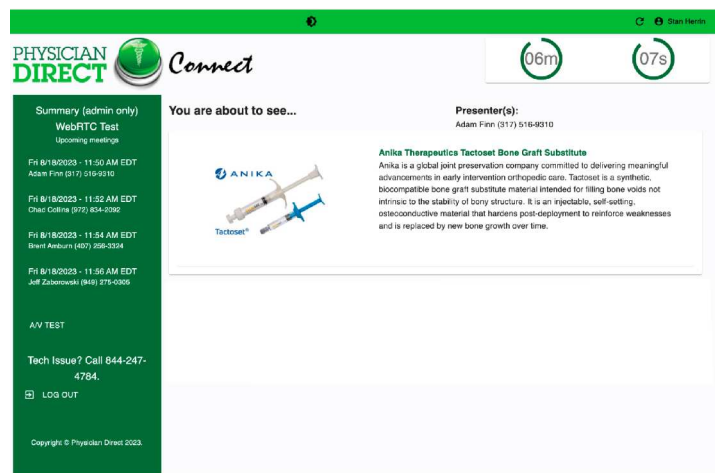


FACTUAL BACKGROUND

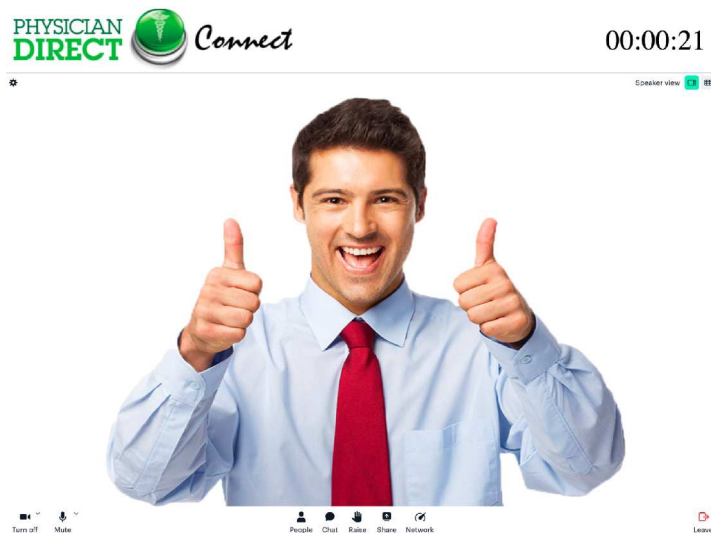
Physicians can participate in one or more two-day events in a year. Physicians pick the times that they participate. They can sign up for sessions up to two hours in length.

Their meetings with Vendor representatives are 7, 11 or 15 minutes in length (depending on what Vendor has selected). Physicians may end up meeting with up to 16 different Vendors in any one session, or as few as four or five. Physicians are reimbursed at a fair market as determined by Physician Direct. Physicians receive payment by check directly from Physician Direct. No funds flow directly from the Vendor to the physician nor indirectly in any amount or manner that could imply any improper obligation.

The actual meetings take place online via video. The Physician is given a list of meetings with an introductory screen about the product to be introduced.



The meeting automatically starts at the scheduled time, and the Vendor presenter and Physician are connected via video.



The meeting automatically concludes at the appointed time, and the physician identifies whether he is interested in learning more about medical technology.

The screenshot shows the 'PHYSICIAN DIRECT Connect' interface. On the left is a green sidebar with navigation options: 'Back to meetings', 'Summary (admin only)', 'WebRTC Test', 'Upcoming meetings', 'AV TEST', 'Tech Issue? Call 844-247-4784', and 'LOG OUT'. The main content area is titled 'You just saw...' and features an image of the 'Tactossel' bone graft substitute. Below the image, there is a section 'Are you interested in this product?' with radio button options: 'Very Interested' (selected), 'Somewhat Interested', 'Not too Interested', 'Not at all Interested', and 'Don't know'. To the right, a 'Time-frame for considering this solution:' section has radio button options: 'Near term (within 1-2 months)', 'Mid term (within 3-6 months)', 'Long term (more than 6 months)', and 'Don't know'. At the bottom, there is a 'NEXT UP' button.

The physician then sees a preview of the medical technology to be presented at the next scheduled video meeting. In the end, the physician receives a summary of the medical technology presented and the physician's own notes concerning interest in learning more about any of it. The platform also allows physicians to instruct the Vendor on how to provide additional information and follow-up, if any. These instructions are forwarded to Vendors by Physician Direct.

The screenshot shows the 'PHYSICIAN DIRECT Connect' interface at 'Page 6 of 9'. The main heading is 'Almost done — Please provide follow-up instructions for these products.' Below this, there is a section for 'Anika Therapeutics Tactossel Bone Graft Substitute' with a product image. A text box contains the instruction: 'Vendors will automatically receive your basic contact info. If you'd like them to contact you via your private email or phone, indicate that here.' Below this, there are three radio button options: 'Provide Private Email', 'Provide Private Call', and 'Text Only Please'. A dropdown menu asks 'Would a follow-up meeting be appropriate?' with 'Yes' selected. Below the dropdown, there is a 'SEND' button and a timestamp '08/24/2023, 12:00 PM'. A checkbox asks 'Vendor should email contact to arrange our next meeting.' Below this, there is a text box for 'Address follow-up requests' with the instruction 'Please send sample to my office address c/o: July Daddico, RN.' and a 'SAVE' button at the bottom.

Physician Direct randomly monitors the meeting and its contents, including the communication outlined in the physician's notes.



A. Compliance

There are several areas of compliance that are addressed here concerning the Physician Direct concept: The Anti-Kickback Statute (AKS) and the guidance surrounding it, the Sunshine Act, and voluntary industry association guidelines.

The AKS was initially promulgated to combat fraud and abuse in the Medicare and Medicaid programs.⁽³⁾ In 1997, the AKS became applicable to all healthcare programs receiving federal funding, not just to Medicare and Medicaid.⁽⁴⁾ Overall, the government's concern about AKS violations is that they increase the risk of "overutilization, increased program costs, corruption of medical decision-making, patient steering and unfair competition."⁽⁵⁾ Patients need to receive healthcare and referrals based on appropriate medical advice and patient best interests, without undue influence.

The AKS makes it a criminal offense to knowingly and willfully⁽⁶⁾ offer, pay, solicit, or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.⁽⁷⁾ Therefore, the AKS is violated when remuneration is paid purposefully to induce or reward referrals of items or services payable by a federal health care program. The Patient Protection and Affordable Care Act amended AKS to state that any claim submitted in violation of the AKS is a false or fraudulent claim for purposes of the False Claims Act.⁽⁸⁾

The meaning of "any remuneration" under the AKS is expansive and is defined to mean "anything of value in any form or manner whatsoever."⁽⁹⁾

In 1985, the United States Court of Appeals for the Third Circuit held that an AKS violation occurs even when just one purpose of the remuneration is to induce healthcare professionals to use the defendant's products or services in the future.⁽¹⁰⁾ In *Greber*, the defendant was a cardiologist.⁽¹¹⁾ He was on staff at a hospital and was also president and part-owner of a medical lab called Cardio-Med, Inc. Cardio-Med billed Medicare for Holter monitoring services and then forwarded, on average, 40% of that payment to the physician who had referred the patient to Cardio-Med.⁽¹²⁾ A jury found Dr. Greber violated section 1877(b)(2)(B). Dr. Greber appealed, arguing, among other things, that the trial judge's instruction was erroneous and should have instructed that the statute was violated only if the sole purpose of the payment was to induce future orders.⁽¹³⁾ The appellate court upheld the trial judge's jury instruction that "if one purpose of the payment was to induce future referrals, the Medicare statute has been violated."⁽¹⁴⁾ The court reasoned:⁽¹⁵⁾

1. The purposes of the section violated supported the court's conclusion;
2. The statute itself expanded the definition of remuneration to include "not only sums for which no actual service was performed, but also those amounts for which some professional time was expended"; and
3. The case law support.

Greber has become the general standard for determining whether remuneration paid is intended to induce.

3. See Pub. L. No. 92-603, §242(b), 86 Stat. 1329, 1419 (1972).

4. 42 U.S.C. §1320a-7b(f), as amended by Pub. L. No. 104-191, §204, 110 Stat. 1999-2000 (1996).

5. "A Roadmap for New Physicians: Fraud and Abuse Laws." Office of Inspector General, [roadmap_web_version.pdf](#) (hhs.gov).

6. In 2010, the AKS was amended to address the defense that was often used that prohibited activity under the AKS is activity that is acceptable in other industries. A person's conduct must be knowing and willful; i.e., purposefully intended to induce or reward referrals of items or services that are payable under a federal health care program. However, there is no requirement of a specific intent to violate nor is actual knowledge required.

7. 42 U.S.C. §1320a-7b(h). This means that the government need not prove that an individual had the intent to specifically violate the AKS.

8. 42 U.S.C. §1320a-7b(g).

9. OIG Anti-Kickback Provisions, 56 F.R. 35952, 35958.

10. See *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

11. *Id.* at 69.

12. *Id.* at 70.

13. *Id.*

14. *Id.* at 72.

15. *Id.* at 71.

B. DHS OIG Guidance

In 2003, the OIG issued Compliance Program Guidance for Pharmaceutical Manufacturers.⁽¹⁶⁾ The OIG has stated that such guidance is evidence of the OIG's "long expressed concerns" about drug and device companies providing anything of value to healthcare providers who are in a position to make referrals to the companies' products.⁽¹⁷⁾ The OIG has further noted that the Pharmaceutical Manufacturers' guidance is not limited to pharmaceutical manufacturers.⁽¹⁸⁾

On November 16, 2020, the DHHS OIG issued a Special Fraud Alert ("SFA") on Speaker Programs. According to the SFA, when a healthcare company pays a physician-speaker for presenting to other healthcare professionals about a drug, device, or disease state, the company and the speaker are in danger of an AKS violation. For the speaker, a speaking arrangement with a drug or device company could be an improper inducement to use the company's products based on loyalty to the company and getting paid more fees, rather than in the best treatment decision for a patient.⁽¹⁹⁾ The attendees are also in danger because the company typically remunerates the attendees with food and drink.⁽²⁰⁾ A key consideration is whether one purpose of the remuneration to the speakers and attendees is to include or reward referrals. A violation has occurred if an event skews their clinical decision-making in favor of their financial interests rather than the patient's best interests.⁽²¹⁾ The OIG points out that there are other ways physicians can get information about drugs and devices and disease states without remuneration, including online resources, package inserts, third-party educational conferences, and medical journals.⁽²²⁾

The OIG recognized that the lawfulness of any remunerative arrangement, including speaker program arrangements, is dependent on specific facts and circumstances.⁽²³⁾ It set forth examples of behavior it pursued in civil and criminal cases. They included (1) selecting high-prescribing healthcare providers to be speakers and rewarding them with speaker deals; (2) conditioning speaker remuneration on sales targets; (3) holding speaker programs at entertainment venues, during recreational events or at high-end restaurants; and (3) invitations to healthcare providers who previously attended a speaker program and their friends and family members who did not have a legitimate business reason to be there..⁽²⁴⁾

OIG recommended that physicians consider the propriety of any proposed relationship with a company and advised that if the basis for a physician's compensation "is your ability to prescribe a drug or use a medical device or refer patients for a particular service or supplies, then the proposed consulting arrangement likely is one to avoid because it could violate fraud and abuse laws." ⁽²⁵⁾

OIG also asserts that these issues raised in the SFA can also be associated with virtual programming. ⁽²⁶⁾

16. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003), available at <https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

17. DHHS OIG Special Fraud Alert: Speaker Programs, at 4 n.22 (November 16, 2020).

18. Id. at 4 n.8.

19. Id. (quoting A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse, HHS-OIG, 22 (Nov. 2010), available at https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf); OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434 (Oct. 5, 2000), available at <https://oig.hhs.gov/authorities/docs/physician.pdf>).

20. Id. at 2.

21. Id. at 3-4.

22. Id. at 4.

23. Id. at 5.

24. Id. at 1-2.

25. Id. at 4-5.

26. Id. at 5-6.



C. AdvaMed Code of Ethics

In addition to observing the law, members of the Advanced Medical Technology Association ("AdvaMed"), a trade association for companies producing medical devices, diagnostic products, and digital health technologies, must observe the organization's Code of Ethics.⁽²⁷⁾ The Code of Ethics is not only applicable to companies that develop, produce, manufacture, and market medical technologies and their employees, agents, dealers, distributors, but also those providing sales and marketing support interacting with healthcare professionals.⁽²⁸⁾

The Code of Ethics recognizes the importance of communication between Vendors and healthcare professionals for research, product development, and product testing to achieve new or improved and innovative medical technology.⁽²⁹⁾ Further, their communication is essential to ensure safe and effective use of medical technology and improvements in patient healthcare.

D. The Physician Payments Sunshine Act

The Physician Payments Sunshine Act (the "Sunshine Act") was enacted into law in 2010. The purpose of the law is to increase transparency of financial relationships between healthcare providers and life science manufacturers and to reduce the potential for undue influence. The Sunshine Act does not prohibit certain payments or transfers of value to physicians, but rather requires reporting of certain transactions for public access.

The general rule of the Sunshine Act is as follows: Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis. 42 C.F.R. §403.904(a)(1). The statute reads:

"Indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor)."

28. AdvaMed Code of Ethics On Interactions with U.S. Health Care Professionals (accessible at <https://www.advamed.org/compliance-ethics/>).

29. *Id.* at 2.

30. See OIG Advisory Opinion No. 10-11 (Issued July 23, 2010), at p. 6; OIG Advisory Opinion No. 04-03 (Issued May 21, 2004), at p. 5.

31. DHHS OIG Special Fraud Alert: Speaker Programs, at p.5 (November 16, 2020).

ANALYSIS:

The Physician Direct platform brings together medical technology vendors and physicians. The program is analogous to an exhibit hall at a medical conference, where vendors are set up to connect with physician attendees over several days.

Payments made to physicians in connection with sales representative activities and arrangements where a Vendor provides remuneration to a physician directly or indirectly through a conduit entity or arrangement potentially implicate the AKS.⁽³⁰⁾ Because Physician Direct pays doctors for attending the sessions at fair market value, the AKS must be considered.

The OIG has recognized that the lawfulness of any remunerative arrangement depends on the facts and circumstances and the intent of the parties.⁽³¹⁾ To violate the AKS, payment to physicians must induce the purchase of goods reimbursable by a federal healthcare program. The unique facts and circumstances of the Physician Direct platform reflect a number of safeguards that mitigate that risk of fraud or abuse or otherwise merit consideration.

First, while Physician Direct pays participating physicians fair market value for each hour of their time, physician remuneration is strictly and exclusively time-based. The payment to the physicians is made strictly to induce them to show up to the meeting. There is no variation concerning any other factor. The physician's procedural volume has no influence, nor does the value of past or potential future business generated by the physician, the physicians' ability to prescribe a drug, use a medical device, nor referral of patients for a particular service or supplies. There is no relationship to the number of Vendors with whom the physician meets. The remuneration is completely uniform from physician to physician. No physician is paid more or less per hour than any other. Physician Direct expects nothing in return for the fair market value compensation paid to the physicians other than that they reserve time for video meetings and be present, polite, and attentive during their meetings. Physician Direct does not ask the physicians to purchase any product. Payment comes directly from Physician Direct funds.

Physicians receive an essential degree of separation because vendors are kept at arm's length. Vendors cannot specify which physicians they will see. Physicians are matched to Vendors solely based on the Vendor's product and the physician's scope of practice so that the physician only sees relevant products.

28. AdvaMed Code of Ethics On Interactions with U.S. Health Care Professionals (accessible at <https://www.advamed.org/compliance-ethics/>).

29. *Id.* at 2.

30. See OIG Advisory Opinion No. 10-11 (Issued July 23, 2010), at p. 6; OIG Advisory Opinion No. 04-03 (Issued May 21, 2004), at p. 5.

31. DHHS OIG Special Fraud Alert: Speaker Programs, at p.5 (November 16, 2020).



Second, the Physician Direct platform requires each exchange of information to be accomplished in a limited, highly focused amount of time. During any event, physicians are exposed to multiple Vendors, including Vendors who compete with one another.

The vendor agreement prohibits presenters who are non-Vendor-employed health care providers. The presentations performed by the Vendor resemble those that would occur at an exhibit hall booth or an in-office sales call. However, in this case, there are more protections to prevent undue influence because of Physician Direct's structure. Physician Direct randomly reviews Vendor meeting content in advance of any presentation, transcribes the online meeting discussions and randomly reviews the written e-note communications. Physician Direct also takes steps to assure that physicians are not repeat attendees at the same Vendor pitches.

Third, Physician Direct cannot influence business referrals for the Vendors; it is not a health care provider or supplier, and apart from the services discussed here, it is not involved in the health care business. Physician Direct has no patient contact.

Physician Direct also is not paid by the Vendors anything more than the pre-determined amount set forth under contract and policy. No payments to Physician Direct by the Vendors are tied directly or indirectly to the volume or value of referrals.

Fourth, the Physician Direct platform also is not at risk for the concerns raised by the OIG of past speaker program violations of the AKS: Participating physicians are not given hundreds of thousands of dollars in remuneration, nor is it permitted on the platform; and no physician remuneration is related to sales targets.

Fifth, the Physician Direct platform does not implicate any of the characteristics of concern presented in the OIG Speaker Program SFA:

Concerning characteristic	Present in program?
· Company-sponsored-speaker programs with little or no substantive information presented;	No.
· Alcohol is available or a meal exceeding a modest value is provided to attendees;	N/A
· The program location is not conducive to the exchange of educational information;	No.
· The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information;	No.
· There has been a significant period of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;	No.
· Doctors attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic);	No.
· Attendees include individuals who don't have a legitimate business reason to attend the program;	No.
· The company selects healthcare provider speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return on investment analysis is considered in identifying participants).	No.
· The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the healthcare provider.	No.

Based on a totality of the preceding, the facts involved in the Physician Direct platform make risk of fraud or abuse extremely low. As long as the program operates within its safeguard parameters, the platform will not result in overutilization, increase program costs, corrupt medical decision-making, or enable patient steering or unfair competition. On the contrary, the Physician Direct platform minimizes the risk of fraud and abuse while providing a valuable service to the medical and healthcare community.

Section III of the AdvaMed Code of Ethics addresses Company-Conducted Programs & Meetings with Health Care Professionals. Of relevance is the section "Company Business Meetings."⁽³²⁾ The Code recognizes the legitimate need for business meetings to discuss medical technology features, sales terms, service offerings, product line offerings, demonstrate equipment, and explore product development.⁽³³⁾

32. AdvaMed Code of Ethics On Interactions with U.S. Health Care Professionals, at p. 14 (accessible at <https://www.advamed.org/compliance-ethics/>).

33. Id.

The Physician Direct events are a series of business meetings. The meetings address a legitimate need to introduce how medical technology works and benefits patients. Attendees are present for the sole purpose of a business meeting. The setting is more conducive to discussion of the information than the in-person exhibit hall:

- The time is limited.
- It is focused on the Vendor presenting the information to the physician.
- There is no remuneration for travel, lodging, meals, refreshments, or gifts paid to the participating physicians.

Physician Direct also oversees the content of the meetings. The business meetings comply with the relevant principles of the Code:

Principle	Does program satisfy the principle?
A legitimate need.	Yes.
At a setting conducive to the discussion of relevant information.	Yes.
Attendance of every healthcare professional must be for an objective, legitimate need.	Yes.
Travel and lodging must be objective and a legitimate need.	N/A
Meals and refreshments are permissible if subordinate in time and in focus to the discussion and presentation of scientific, educational, or business information.	N/A

Because the Physician Direct program involves neither direct nor indirect transfers of value from manufacturers to covered recipients, payments from manufacturers to Physician Direct do not require reporting to CMS under the Sunshine Act.

No direct payments from manufacturers to covered recipients take place under the Physician Direct program. Physician Direct invoices manufacturers for participation in meetings that it facilitates with healthcare providers. The fees received by Physician Direct from manufacturers are fees for Physician Direct services. Those fees become part of Physician Direct's revenue, to be used by Physician Direct as Physician Direct solely determines.

Nor does the Physician Direct program result in "indirect payments" under the Sunshine Act. Under no circumstance does any manufacturer require, instruct, direct, or otherwise cause Physician Direct to provide any payment or transfer of value to a physician participating on the Physician Direct program. The fees paid by manufacturers become part of Physician Direct's revenue and are co-mingled with the rest of Physician Direct's revenue sources. Physician Direct uses its revenue (without regard to source) to compensate healthcare providers for participating in Physician Direct meetings. Money never flows directly or at the direction of any manufacturer to specific healthcare providers.

Further, no manufacturer may pay extra to meet with a specific healthcare provider, and no healthcare provider may receive additional compensation for agreeing to meet with a specific manufacturer. No other form of consideration is accepted by Physician Direct or permitted by Physician Direct to secure a meeting between a specific healthcare provider and a specific manufacturer. Rather, participating healthcare providers are compensated according to fair market value.

CONCLUSION:

There is less opportunity for undue influence in the Physician Direct platform than is present in a traditional conference exhibit hall.

At a typical medical conference, there is a conference sponsor (like a medical association), speakers, attendees, and an exhibit hall full of vendors. By analogy, Physician Direct is like the sponsor of the conference, the physicians who use the Physician Direct platform are the attendees, and the Vendors that engage the Physician Direct services are the exhibit hall vendors. Just as vendors pay exhibitor fees at the conference, the vendors pay a fee to Physician Direct to educate physicians about their products. In this case, however:

- there are no free meals or alcoholic drinks on the exhibit floor;
- there are no vendor-sponsored education with excessive honoraria to the key opinion leaders who speak on behalf of exhibitors;
- there is no opportunity for a Vendor to pressure a physician.

Physicians attending a Physician Direct meeting do receive compensation for attendance at video meetings; however, they receive it from a disinterested third party, not a Vendor, and remuneration is set at fair market value rather than at some outlandish amount designed to influence referrals. The result is that valuable medical technology information is communicated to physicians, who can use that information to stay abreast of medical technological advances and possible enhancements to their patients' care. Physician Direct is a force for fairer, more accurate, less biased, and lower pressure communication between Vendors and physicians.