From: OC GCP Questions
To: [redacted]
Subject: RE: Fee for referrals to a clinical trial
Date: Tuesday, October 14, 2014 1:53:00 PM

Dear [Redacted]-

I am not able to provide you legal advice regarding your question, as FDA is not in a position to provide legal counsel. I recommend you discuss your question with your institution's legal counsel.

However, you might be asking whether there are any FDA regulations that address paying fees to physicians for referring patients to clinical trials. FDA's regulations do not specifically address your question. When the regulations are silent, institutions, IRBs, investigators and sponsors are free to develop their own procedures and practices as long as applicable regulatory requirements are met. I have provided some information below that I hope is helpful to you as you explore this issue at your organization.

You may be referring to a scenario where physicians, who are not investigators on a given study, are paid a fee simply for referring the names of any of their patients who may be eligible for inclusion in a study that the investigator is conducting; or, a scenario where physicians, who are not investigators on a given study, are paid a fee for performing a service to identify any of their patients who may be eligible for inclusion in a study that the investigator is conducting. These fees are sometimes called "referral fees" or "finder's fees", however, these terms may be defined differently by varying parties (e.g., institutions, sponsors, investigators, IRBs).

The difference between the two scenarios described above is the amount of resources (e.g., time, staff effort, and cost) involved in identifying a patient who may be a potential subject. For example, there is a difference between the amount of resources it takes for a physician to simply refer the name of a patient who might eligible to the investigator vs. the physician who actually performs a service to identify potentially eligible patients by reviewing their patient charts, assessing patients in accordance with the inclusion/exclusion criteria of the study protocol, contacting a patient/potential subject to discuss the study and assessing that patient's interest in being referred to the investigator for more information on the proposed study. The thought being that in the second scenario, the fee is being paid as a form of reimbursement for the amount of work it takes for a physician to identify patients who might be potential subjects in this detailed manner.

You may want to check with your institution and IRB on whether or not they have a policy on this topic of paying referral fees or finder's fees. If your institution does not have a policy, they may want to explore this topic and then determine whether or not to develop an institutional policy. I suggest that you take a look in the literature as you will find that there is a fair amount of information on this topic and discuss this information with the appropriate institutional officials, including your legal counsel. You may also want to take a look at the policies that other institutions and IRBs have adopted. There are various organizations who have issued ethical statements or ethical codes that prohibit the use of such fees as they are viewed by such groups as being unethical. There are other organizations that may support the payment of such fees, or varying degrees of payment to physicians based on the amount of work they do to identify potential subjects. I recommend that you discuss this topic internally at your institution with all of the appropriate institutional officials.

I'm sorry I can't be more helpful, but I do hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]

Sent: Friday, October 10, 2014 1:46 PM
To: OC GCP Questions
Subject: Fee for referrals to a clinical trial

Can you please tell me if it is legal for a company to pay physician for referring patients for a clinical trial? I.e., Company ABC Rx will pay Dr. Jones $75 for every patient referred for the XXX Clinical Study. Thank you.

[Redacted]