

Regions Hospital Secondary Interest Policy FREQUENTLY ASKED QUESTIONS

1. Why does Regions have a secondary interest policy?

We all agree that patients benefit when physicians and researchers collaborate with the private sector to advance medical knowledge and to develop new drugs, medical devices and other products and methods used to care for patients. However, there is increasing concern and evidence that extensive financial and other relationships between caregivers and industry may inappropriately influence the care that patients receive, may unnecessarily increase the cost of care and may negatively impact patient safety.

This policy, and accompanying disclosure, review and management processes, will help Regions (a) identify secondary interests of our Medical Staff that could inappropriately interfere with the quality and safety of care that we provide to our patients, (b) review those relationships to determine appropriateness, and (c) ensure that there are appropriate tools in place to manage those relationships, including transparency to patients and to others in the hospital.

2. Who does the policy apply to?

The Policy applies to anyone who is applying or re-applying for privileges at Regions Hospital. This includes physicians as well as non-physician advanced practice professionals.

3. What does the policy say?

The Policy says that anyone applying or re-applying for privileges at Regions has to disclose certain “secondary interests” as part of the privileging process. The Policy also describes how Regions will review what is disclosed and may choose to implement a management plan to ensure that the interests disclosed do not inappropriately influence patient care at the hospital.

4. What are secondary interests?

The policy defines a secondary interest as a personal or financial interest that a reasonable person could reasonably conclude might adversely affect a Practitioner’s independent professional judgment in (a) making clinical care or treatment decisions, or (b) taking part in the governance or management of the Medical Staff or the Hospital (for example, by deciding materials management requests). It is not necessary for there to be evidence that a personal or financial interest *has in fact* affected the Practitioner’s judgment in order for a Secondary Interest to exist. The Conflict of Interest Disclosure Form provides additional information about what types of secondary interests need to be disclosed.

5. This seems really intrusive and I'd rather not tell Regions (or anyone else) all this personal financial information. Is there any way I can opt out?

You may not opt out. While we agree that this is personal information, some kinds of relationships between caregivers and industry could negatively impact patient care and could impede independent professional judgment, due to the potential for conflicts of interest that they create. Therefore, it is important that Regions understand, in a meaningful way, the relationships its caregivers have with third parties.

6. When will I need to disclose secondary interests?

You will need to fill out the secondary interest disclosure form the first time you apply for privileges at Regions Hospital, and each time you are up for re-appointment. If, during your current appointment, you enter into a new relationship or arrangement that would trigger disclosure under the secondary interest policy, or if during that time there is a material change in any secondary interests you previously disclosed, you would need to complete a new secondary interest disclosure form and submit it directly to Medical Staff Services at Regions Hospital.

7. Who will review what I disclose, and what will they do with it?

Regions has established a Conflict Review Team to review disclosures of secondary interests that could create a conflict of interest. The team includes physician leaders and other leaders at Regions. If the Conflict Review Team determines that the secondary interest disclosed could create a conflict of interest, it will develop a conflict management plan and recommend that it be adopted by the Credentials Committee and Medical Executive Committee. The hospital's Board will have final approval authority of any recommended management plans.

8. Will this hold up my appointment or re-appointment process?

We do not anticipate that this will hold up these processes. If you fully and materially disclose your secondary interests, then the Conflict Review Team will be able to review your disclosure quickly and pass on recommendations, if any, along with the rest of your application. However, if the Conflict Review Team needs additional information in order to conduct a full review, you will be asked to supplement your disclosure. Therefore, the best way to keep your application on track is to make full disclosure at the outset.

9. What kind of management plan would I have to comply with?

Management plans will vary, depending on the nature and extent of the secondary interest. They could include one or more of the following:

- Full written disclosure to and informed consent of patients regarding the relationship
- Limitations on royalties or other intellectual property payments tied to services provided at Regions
- Utilization reviews by department or hospital leadership
- Material change to the relationship in question

10. Do I have any appeal rights?

Practitioners may appeal decisions related to secondary interests and management plans in accordance with the Medical Staff Bylaws.

11. Will anyone else beside the review committee see my outside interests?

Consistent with Joint Commission requirements, Medical Staff Services will make copies of completed Conflict of Interest Disclosure Forms available for review by members of the Medical Staff who are reviewing the practitioner's application for appointment or reappointment, the Board, hospital administration and, upon request, patients.

12. What if I choose not to disclose a particular relationship, or details about a relationship?

If you fail to make or update the disclosure required by the Policy, you may be denied appointment/reappointment of clinical privileges, or you may have those privileges administratively suspended for failure to comply with a hospital policy. Similarly, if you don't comply with a conflict management plan that has been recommended by the Conflict Review Team and approved by the Board, it could result in disciplinary action by the Medical Staff.

13. I'm an HPMG physician and already disclose my secondary interests through an HPMG process. Do I have to do this again?

If you have disclosed your current and proposed secondary interests to HPMG leadership or through the most recent HPMG conflict of interest survey process, you do not have to re-disclose. Your prior disclosures will be reviewed again as part of the Regions secondary interest review process, and if additional information is needed or concerns are identified you will be contacted.

If, however, you have current or proposed secondary interests that you have not yet disclosed as part of the HPMG process, you *do* need to complete the secondary interest disclosure form that accompanies your credentialing or re-credentialing packet.

14. I've heard something about a Federal disclosure law, and I know that some companies have to disclose physician relationships in Minnesota. How does this process fit with those things?

You are referring to what are commonly known “physician payment sunshine” laws. The federal sunshine law requires makers and suppliers of drugs, devices, biological and medical supplies covered by Medicare and Medicaid medical device and pharmaceutical companies to disclose to the federal government (US Department of Health and Human Services) all payments to physicians and a few other categories of caregivers. Some companies must also report whether physicians have ownership or investment interest in the companies. This information will be released on a public website beginning in 2014. Minnesota (and a few other states) have similar, but more limited, sunshine laws. Likewise, many drug and device manufacturers now post some physician payment information on their websites, in response to government litigation.

As part of the secondary interest review process, Regions may consult publicly available information about physician-industry relationships, such as disclosures made to HHS, state agencies and industry web postings.

It is very important that physicians and other caregivers that provide any services to manufacturers or GPOs, or have any kind of investment or ownership interest in these organizations, understand these sunshine laws and what will be disclosed about them under the laws. Professional associations and others have put together some excellent summaries and other resources. A good place to start is the American College of Physicians website:

http://www.acponline.org/acp_policy/policies/brief_summary_of_the_national_physician_payment_transparency_act_final_rule_2013.pdf