

SUMMARY OF NIH-SPECIFIC PROVISIONS IN INTERIM FINAL RULE

Prohibited Outside Activities - 5 C.F.R. § 5501.109

What activities are not allowed?

For all NIH employees, compensated or uncompensated employment, including consulting and advisory or other board service, and compensated teaching, speaking, writing, or editing, is now prohibited with or for the following entities:

- substantially affected organizations (defined to include biotechnology, pharmaceutical, medical device companies, and others with similar interests)
- hospitals, clinics, health maintenance organizations, or other health care providers
- health insurers
- health, science, or health research-related trade organizations, professional associations, or consumer or advocacy groups
- educational institutions or non-profit independent research institutes that are or recently were NIH funding applicants, grantees, contractors, or CRADA partners

Also, employees are prohibited from engaging in self-employment activities that involve the sale or promotion of the services or products of the above entities.

What is allowed?

In general, if otherwise approvable under existing regulations, the following activities are allowed:

- Teaching a course that requires multiple presentations and is part of the established curriculum of a university or college
- Teaching, speaking, or writing performed as part of a continuing professional education program; if funding for the program is from a substantially affected organization such as a pharmaceutical company, it must be funded by an unrestricted educational grant
- Employment with political, religious, social, fraternal, or recreational organizations
- Clinical, medical, or health-related professional practice involving provision of care to individual patients
- Clerical or similar services
- Authorship of articles, chapters or textbooks that are subject to a peer review or substantially equivalent editorial review process; again, if funding is from a substantially affected organization such as a pharmaceutical company, it must be funded by an unrestricted financial contribution

Employees must terminate prohibited outside activities within 30 days, but can request an additional period of up to 60 days to allow them to responsibly conclude outstanding obligations.

Limited other exceptions may be allowed with approval.

Prohibited Holdings - 5 C.F.R. § 5501.110

NIH employees who file public (SF 278) or confidential (OGE 450) financial disclosure reports are prohibited from acquiring or holding financial interests, such as stock, in biotechnology, pharmaceutical, and medical device companies and others involved in the research, development, or manufacture of medical devices, equipment, preparations, treatments, or products.

All other employees (that is, those who do not file either of these reports) are subject to a \$15,000 cap on holdings in such companies.

There is an exception from both rules for a financial interest, such as a pension or other employee benefit, arising from employment with a substantially affected organization and widely diversified, publicly traded mutual funds.

Employees may have up to 150 days to divest of holdings to comply with the law.

Employees who qualify may apply for a Certificate of Divestiture before selling in order to defer capital gains taxes.

Awards - 5 C.F.R. § 5501.111

Senior employees may not receive gifts with an aggregate market value of more than \$200 that are an award given because of their official position or from a prohibited source. Other employees having official responsibility for matters involving the donor (even if not personally involved) may not receive the gifts with an aggregate market value of more than \$200 that are an award given from such a donor. If you are not a senior employee or you do not have official duty matters involving the donor, you may accept bona fide awards for meritorious public service if such awards have been reviewed by the an independent advisory committee (the Advisory Committee to the Director) and are recommended for approval because they meet the regulatory criteria, and you are individually approved to receive such an award.

Employees, generally, may receive awards from outside sources that are nothing more than plaques or trophies of little intrinsic value and free attendance and food at the event in which employee is honored.

There is an exception to the ban that may permit the acceptance of gifts with a aggregate market value of more than \$200 that are associated with the most prestigious awards that confer an exceptionally high honor in the fields of medicine or scientific research, e.g., Nobel, Lasker, if the award is otherwise approvable.

What happens next?

- Complete the development of a comprehensive system of oversight of outside activities of employees
- Assess the impact of the interim final regulations on the agency in the first year of implementation, including retention and recruitment of scientists

- Review the comments from various constituencies on the interim final regulations

Based on these activities, the Department of Health and Human Services will decide which, if any, provisions of the new supplemental regulations to revise. Please note that this document is intended to be a helpful guide. If you have questions about the details of these provisions or how these rules might apply to you, please contact your ethics official.