

Memo Operating Guidance

No. 13-05

September 17, 2013

To: Clinical Trial Negotiators Contract & Grant Officers

Subject: Physician Payment Sunshine Act/NPI Registry

Reissue of RPAC Memo 12-07

The Patient Protection and Affordance Health Care Act, signed into law in March 2010, includes the Physician Payment Sunshine Act (Section 6002) (PPSA), which requires pharmaceutical, medical device, biological and medical supply manufacturers to report to the United States Department of Health and Human Services (HHS) any payment or other transfer of value to physicians and teaching hospitals.

HHS issued the final rule implementing PPSA in February 2013. The final rule does not change this guidance, previously issued on December 11, 2012 in <u>RPAC Memo 12-07</u>.

In furtherance of the PPSA and similar federal, state, and institutional initiatives, the University of California is committed to promoting transparency in its financial relationships with drug and device manufacturers and other commercial entities.

The "Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University" establishes that any extramural award in which a portion of an employee's salary is paid through the University, or whose activities use any University resources or facilities, must be made to "The Regents of the University of California."

Additionally, the policy requires that all extramural awards to the University of California for research, training, or public service are made in the University's corporate name, "The Regents of the University of California."

Thus, the University's physicians, other study staff performing University research, and the University's local research site (e.g., a campus, medical center, clinic, or other unit), are not the payee(s) to any such research, and do not directly receive any portion of such payments, and such payments are not properly attributable to them individually.

RPAC Memo 13-05 September 17, 2013 Page 2

Should a payer insist on identifying an individual, individuals, or organization as performing research on behalf of The Regents under an agreement, individual and organizational provider National Plan & Provider Emuneration System (NPPES) information may be found on publicly available websites, such as the NPI Registry at https://nppes.cms.hhs.gov/NPPES/Welcome.do.

Consistent with the University's policies, applicable law, and the roles and responsibilities of University employees, it is inappropriate for local contract and grant staff to provide or verify definitive NPI identification for any individual faculty or staff member.

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