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Proposed Stark II Regulations: Potential Effects on Community Cancer Research

by James L. Wade III, M.D., F.A.C.P

On January 9, 1998, the Health Care Financing Administration promulgated a set of rules that would govern the implementation of the Stark II anti-kickback law that was passed by Congress in 1993.[1] These rules, covering more than 400 pages in the *Federal Register*, touch on many aspects of medical care delivered by all physicians. Several parts of the proposed rule directly affect medical oncologists and how they implement cancer treatments in the office setting. Specifically, one clause in the rule prohibits physicians from obtaining a discount in a chemotherapy drug price unless that discount is passed on to Medicare in the form of a lower charge for that drug. This method of paying medical oncologists the "acquisition cost" of the chemotherapy drug that they use is not a new proposal. The same payment method was included in President Clinton's budget proposals to Congress last year as well as this year. At least three other bills including similar language have been introduced in Congress in 1998.

Chemotherapy delivery and management represent a complex set of services. Medical oncology practices that provide in-office, parenteral, systemic antineoplastic treatments face several daunting tasks, including ordering, stocking, tracking, and disposing of compounds that are biologically hazardous. Furthermore, an office practice often maintains an inventory of many chemotherapy agents to provide fast and convenient treatments to patients. The cost of maintaining such an inventory may amount to many thousands of dollars per year. The practice must comply with national guidelines for including dedicated space within the office suite for treatment delivery and specialized nurses who prepare and administer such treatments.[2] All these requirements are associated with a substantial cost that has been reimbursed by Medicare using a historic fee schedule rather than a true resource-based payment formula. In fact, medical oncologists were underpaid by Medicare $274.8 million in 1996 alone.[3] Many medical oncologists have commented that cancer care in their office setting will no longer be viable if they continue to be under-reimbursed and have no other mechanism to recoup their financial losses.

The Community Clinical Oncology Program (CCOP) has been an extraordinary success since it was first implemented in 1982. CCOPs that render cancer care at the community level now account for one-third of all patients placed on National Cancer Institute-sponsored clinical treatment trials. Most of this work takes place in the oncologist's office. However, if implemented as is, the proposed Stark II regulations and/or the President's 1999 budget would have a major effect on many oncology practices where cancer research takes place.

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SURVEYING THE INVESTIGATORS

In order to find out what would happen to cancer research at the community level, in February 1998 a survey was faxed to forty-nine CCOP principal investigators (PIs) listed in the Association of Community Cancer Centers' database. A short description containing three elements accompanied the survey: 1) an explanation of the proposed Stark II regulations; 2) the purpose of the survey, which was to gather data summarizing the opinions of CCOP PIs; and 3) a sentence explaining that the results of the survey would be presented to NCI's Robert Wittes, M.D., deputy director for Extramural Science, and director, Division of Cancer Treatment and Diagnosis.

The survey consisted of four yes/no questions: 1) Would accrual to NCI treatment trials be harmed if the Stark II regulations were implemented in their current form? 2) Would accrual to NCI cancer control studies be harmed as well? 3) Would accrual to pharmaceutical industry studies increase to make up the shortfall that would occur if the Stark II regulations were implemented? 4) If the proposed Stark II regulations are implemented as written, would your CCOP reapply to renew your NCI grant? These questions were followed by an allotted section for comments.

RESULTS AND SUMMARY

The results of this survey are significant. Out of a total of forty-nine CCOP PIs, thirty-five responded to the survey, a response rate of 71 percent. A majority (about 75 percent) responded in less than two weeks.

Eighty-one percent of responding CCOP PIs believe that accrual to NCI treatment trials will suffer (Table 1). Sixty-two percent think that accrual to NCI cancer control studies will suffer (Table 2). Eighty-nine percent of CCOP PIs will increase participation in pharmaceutical industry studies to make up the shortfall (Table 3). Perhaps most importantly, 43 percent of CCOP PIs are either unsure about reapplying or will not reapply for renewal of their research grant (Table 4).

Many PIs attached comments to the survey instrument. Some of the

more striking remarks include:

- "Current reimbursement in our area is barely sufficient to cover added overhead expenses for chemotherapy (space, nursing time, and supplies). I believe we would have to stop treatment for Medicare patients (and others) if payment is reimbursed at acquisition costs."
- "Without adequate drug reimbursement, we will not be able to continue to subsidize NCI research activities."
- "A disaster. It would probably put oncologists—big and little—out of business."
- "Patients will definitely lose access to clinical trials."
- "Hospital-acquired chemotherapy would predominate in our market with its added costs to Medicare."
- "Changes in reimbursement policy will likely shift patients into a hospital setting. This will impact operations and QA measures. I cannot guess the exact impact on accrual, but any loss of accrual is problematic."

In summary, these results suggest that the CCOP program, and the research work that it accomplishes, would be seriously harmed if either the President's 1999 budget were adopted or the Stark II regulations are implemented as proposed on January 9. All persons interested in improving the outcome of those affected by cancer should be aware of this potential new threat.

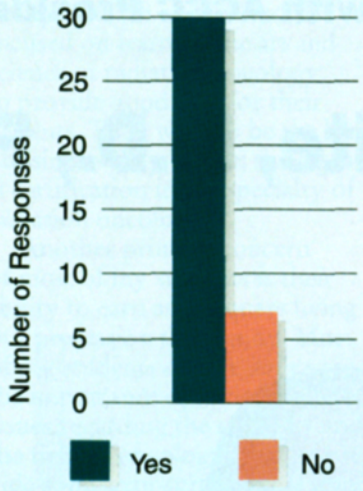

Table 1. Will accruals for NCI treatment trials suffer?

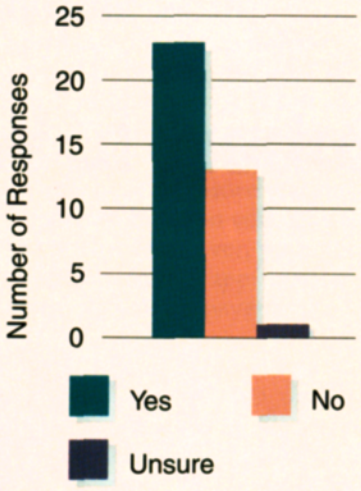

Table 2. Will accrual to NCI cancer control trials suffer?

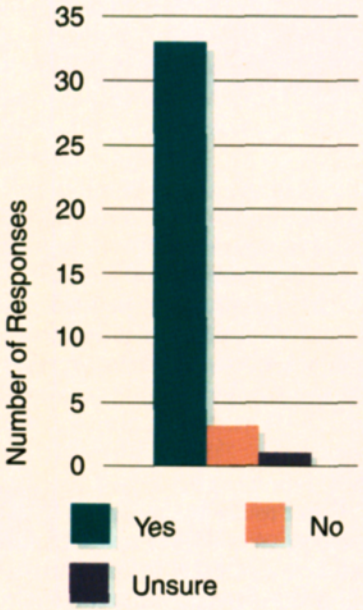

Table 3. Will accrual to industry trials increase to help make up the shortfall?

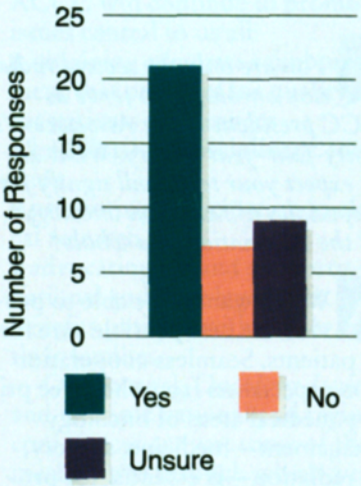

Table 4. Will you reapply to continue your CCOP grant?

REFERENCES

[1] *Federal Register*, January 9, 1998.
[2] American Society of Clinical Oncology. Criteria for facilities and personnel for the administration of parenteral systemic antineoplastic therapy. *J Clin Oncol* 15(11):3416-17, 1997.
[3] Weissman C et al., Chemotherapy administration and medicare RBRVS. *Oncology Issues* 13(2):16-19, 1998.