

for the State AIDS Drug Assistance Programs that receive assistance under Title XXVI of the PHS Act.

(C) The State ADAP Section 340B Rebate Option

In light of the comments and responses set forth above, the guideline for the state ADAP 340B rebate option is as follows: HRSA recognizes rebates obtained by the State ADAPs or their components that equal or exceed the 340B discount provided by the statutory ceiling price as a method of participating in the 340B program, subject to compliance with other requirements for participation. Standard business practices, such as those reflected in the Medicaid Rebate Program and current voluntary manufacturer rebate programs (consistent with the requirements of section 340B and all program guidance published in the **Federal Register**) are appropriate for the development of rebate contracts and agreements between State ADAPs and manufacturers. State ADAPs or their components and manufacturers wishing technical assistance in developing a rebate program and rebate agreements should contact HRSA's Office of Drug Pricing at (301) 594-4353 or (800) 628-6297.

State ADAPs or their components determined to be eligible for participation in the State ADAP 340B rebate program will be listed on the Office of Drug Pricing (ODP) Electronic Data Retrieval System (EDRS) on the first quarterly update of the EDRS which occurs 30 days following the effective date of this **Federal Register** notice. State ADAPs or their components listed on this update may submit rebate claims to participating manufacturers for covered drugs that are purchased starting 30 days after the date of this final notice publication. State ADAPs or their components listed on a later EDRS update may claim rebates only on purchases made after their effective date of listing on the EDRS.

Section 340B(a)(5)(A) reflects Congressional recognition that there is a potential for a covered drug purchased by a covered entity at the 340B discount price to be subject to a Medicaid rebate, if the drug is reimbursed by the Medicaid program. All program guidance regarding the prevention of such duplicate discounting must be followed by ADAPs participating in the rebate program as well as those participating in the discount program. Guidance regarding billing State Medicaid Agencies at actual acquisition

cost plus a dispensing fee (established by the State Medicaid agency) and the prevention of duplicate discounting was published in the **Federal Register** on May 7, 1993 (58 FR 27293) entitled "Duplicate Discounts and Rebates on Drug Purchases." Further guidance was published in the **Federal Register** on May 13, 1994 (59 FR 25112). State ADAPs may find it necessary to work with State Medicaid Agencies to adapt these guidelines to meet the unique circumstances of each individual State, such as provisions permitting retroactive reimbursement of drug purchases while Medicaid eligibility was pending.

The HRSA is sensitive to concerns about diversion of covered drugs to individuals who are not patients of the covered entities. Guidelines have been issued to minimize this potential, and manufacturers have available to them specified remedies if they believe diversion has occurred. These guidelines and remedies will apply fully to drugs purchased under a rebate option, and we believe that instituting rebates will not increase the potential for diversion.

Dated: May 22, 1998.

Claude Earl Fox,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment of the Secretary's Advisory Committee on Genetic Testing

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Secretary's Advisory Committee on Genetic Testing (Committee).

This Committee will advise the Secretary of Health and Human Services on all aspects of the development and use of genetic tests, including making recommendations on policies and procedures for the safe and effective incorporation of genetic technologies into health care; assessing the effectiveness of existing and future measures for oversight of genetic tests; and identifying research needs related to the Committee's purview.

Unless renewed by appropriate action prior to its expiration, the charter for the

Secretary's Advisory Committee on Genetic Testing will expire two years from the date of establishment.

Dated: June 22, 1998.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 98-17168 Filed 6-26-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group Subcommittee D—Clinical Studies.

Date: August 2-5, 1998.

Time: 7:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Martin H. Goldrosen, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institute of Health, 6130 Executive Boulevard, Rm. 635F, Rockville, MD 20852-7405, (301) 496-7930.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 23, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-17172 Filed 6-26-98; 8:45 am]

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