treatment recommendations. GISP was begun in 1986 as a voluntary surveillance project and now involves 5 regional laboratories and 26 publicly funded sexually transmitted disease clinics around the country. The STD clinics submit up to 25 gonococcal isolates per month to the regional laboratories, which measure susceptibility to a panel of antibiotics. Limited demographic and clinical information corresponding to the isolates are submitted directly by the clinics to CDC.

During 1986–1997, GISP has demonstrated the ability to effectively achieve its objectives. The recent emergence of resistance to fluoroquinolones, commonly used therapies for gonorrhea, has been identified through GISP and makes ongoing surveillance critical. Data gathered through GISP are used to alert the public health community to changes in antimicrobial resistance in *N. gonorrhoeae* which may impact treatment choices, and to guide recommendations made in CDC's STD Treatment Guidelines, which are published every several years. The total burden hours are 6196.

Respondent	Number of respondents	Number of responses/respondents	Avg. burden (in hrs.)
Laboratory	5	1056	1
Clinic	26	204	0.166

3. Annual Submission of the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States—New—Oral use of smokeless tobacco represents a significant health risk which can cause cancer and a number of noncancerous oral conditions, and can lead to nicotine addiction and dependence. The Centers for Disease Control and Prevention's (CDC) Office on Smoking and Health (OSH) has been delegated the authority for implementing major components of the Department of Health and Human Services' (HHS) tobacco and health program, including collection of tobacco ingredients information. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4401 *et seq.*, Pub. L. 99–252) requires that each person who manufactures, packages, or imports smokeless tobacco provide the Secretary of HHS annually with a report on the quantity of nicotine contained in smokeless tobacco products. This notice implements this nicotine reporting requirement. CDC is requesting OMB clearance to collect this information for three years. A standard methodology for measurement of quantity of nicotine in smokeless tobacco has been developed. The methodology (''Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products'') is intended to provide standardized measurement of nicotine, total moisture, and pH in smokeless tobacco products.

Background

In 1989, the smokeless industry submitted a business review letter to the Department of Justice (DOJ), in accordance with 28 C.F.R. Section 50.6. This letter requested approval of a collaborative industry effort to determine standard nicotine reporting. In January 1993, DOJ extended permission to the smokeless industry to begin the development of uniform methods for analyzing smokeless tobacco products for nicotine or moisture content. The first meeting of the work group, which represented the ten major domestic manufacturers of smokeless tobacco, was convened on July 7, 1993. After a series of meetings of the joint industry work group, a standard methodology was approved by the work group and submitted to OSH for approval. The protocol was revised by OSH based on individual comments received from peer reviewers and the Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, CDC. The total annual burden hours are 18766.*

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Tobacco manufacturers	11	1	1,706

*Please note that these figures are based on the average reporting time and cost estimations for six major smokeless tobacco manufacturers as reported by Patton Boggs, LLP.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–26987 Filed 10–7–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Hospital Infection Control Practices Advisory Committee: Meeting

In accordance with section l0(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Hospital Infection Control Practices Advisory Committee (HICPAC).

Times and Dates: 8:30 a.m.–5 p.m., November 16, 1998. 8:30 a.m.–12 p.m., November 17, 1998.

Place: CDC, Building 16, Room 1111/1111A, l600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Infectious Diseases (NCID), regarding (1) the practice of hospital

infection control; (2) strategies for surveillance, prevention, and control of nosocomial infections in U.S. healthcare facilities; and (3) updating guidelines and other policy statements regarding prevention of nosocomial infections.

Matters to be Discussed: Agenda items will include a review of the strategic direction of HICPAC; the first draft of the Guideline for Environmental Controls in Healthcare Facilities; public comments on the Draft Guideline for Prevention of Surgical Site Infections; priority areas for HICPAC/CDC guideline development; CDC activities of interest to the Committee.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michele L. Pearson, M.D., Medical Epidemiologist, Investigation and Prevention Branch, Hospital Infections Program, NCID, CDC, 1600 Clifton Road, NE, M/S E–69, Atlanta, Georgia 30333, telephone 404/639–6413.

Dated: October 2, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–26988 Filed 10–7–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Active Pharmaceutical Ingredients (API) Seminar

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), New Jersey District, is announcing the following meeting: Active Pharmaceutical Ingredients (API) Seminar. The topic to be discussed is Current Good Manufacturing Practices for API's. This seminar will address issues related to the application of good manufacturing practices to the manufacture of API's by New Jersey bulk drug manufacturers.

Date and Time: The meeting will be held on Thursday, November 19, 1998, 8:30 a.m. to 4:30 p.m.

Location: The meeting will be held at Princeton Novotel Hotel, 100 Independence Way, Princeton, NJ 08540.

Contact: Paul T. Wiener, Office of Regulatory Affairs, New Jersey District, Food and Drug Administration, 10 Waterview Blvd., Parsippany, NJ 07540, 973–526–6014, FAX 973–526–6069, e-mail ''pwiener@ora.fda.gov''.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person. Preregistration is requested, but registration will be accepted at the door based on the availability of seating from 8:30 a.m. to 9:30 a.m. on the date of the meeting.

If you need special accommodations due to a disability, please contact Paul T. Wiener at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Copies of talks can be obtained by direct request to speakers at the time of the meeting. If you need overnight accommodations, call the hotel at 609–520–1200, and request the special seminar room rate.

There is no charge for the seminar. A light breakfast will be served.

Dated: October 1, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–26927 Filed 10–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2012–N]

RIN 0938–AI66

Medicaid Program; Disproportionate Share Hospital Payments-Institutions for Mental Disease

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the Federal share disproportionate share hospital (DSH) allotments for Federal fiscal years (FFYs) 1998 through 2002. This notice also describes the methodology for calculating the Federal share DSH allotments for FFY 2003 and thereafter, and announces the FFY 1998 and FFY 1999 limitations on aggregate DSH payments States may make to institutions for mental disease (IMD) and other mental health facilities. In addition, it clarifies the DSH reporting requirements required by the Balanced Budget Act of 1997 (BBA '97).

EFFECTIVE DATE: The Federal DSH allotments apply to FFYs beginning October 1, 1997 and thereafter. The IMD limitations published in this notice apply to Medicaid DSH payments made in FFY 1998 and 1999.

FOR FURTHER INFORMATION CONTACT: Miles McDermott, (410) 786–3722, Christine Hinds, (410) 786–4578.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4721(c) of the Balanced Budget Act of 1997 (BBA '97), Public Law 105–33, added section 1923(a)(2)(D) of the Social Security Act (the Act) to require States to submit to HCFA, by October 1, 1998, a description of the methodology used by the State to identify and make payments to DSHs, including children's hospitals, on the basis of the proportion of low-income and Medicaid patients served by such hospitals. If a title XIX State plan does not specify this methodology by October 1, 1998, it is not in compliance with section 1902(a)(13)(A)(iv) of the Act. The State is also required to submit an annual report to HCFA describing the DSH payments made to each disproportionate share hospital.

Section 4721(a) of the BBA '97 amended section 1923(f) of the Act to require that Federal Medicaid DSH expenditures be limited to statutorily defined Federal share DSH allotments. These Federal share DSH allotments are listed in the statute for FFYs 1998 through 2002. For FFY 2003 and thereafter, a State's Federal share DSH allotment will be equal to the State's prior FFY Federal share DSH allotment, if the prior FFY Federal share DSH allotment is greater than 12 percent of Federal medical assistance expenditures for the current Federal fiscal year. If the prior year Federal DSH allotment is less than 12 percent of the Federal share of medical assistance expenditures for the current year, the prior FFY Federal share DSH allotment will be increased by the Consumer Price Index for all Urban Consumers (CPI–U) for the previous FFY, capped at 12 percent of the State's current FFY Federal medical assistance expenditures.

In addition, section 4721(b) of the BBA '97 added section 1923(h) to the Act to provide that Federal financial participation (FFP) is not available for DSH payments to IMDs and other mental health facilities that are in excess of a State-specific aggregate limit. Section 1923(h) of the Act could be read to set the State-specific IMD limit at the lesser of the 1995 Federal mental health DSH payments applicable to the 1995 DSH allotment (as reported on the Form HCFA–64 as of January 1, 1997), or a percentage of 1995 Federal mental health DSH payments. This reading, which compares an amount with a decreased percentage of that amount, results in a meaningless comparison because a percentage of a number is always less than that number. We do not believe Congress intended a reading that would render the comparison meaningless. Furthermore, such an