

Manuals of Operation based on resolutions adopted by voting delegates of the ISSC and with which FDA concurs.

The success of the NSSP is largely dependent on the States adopting and implementing the recommended shellfish control practices for the operation of effective programs. These recommended practices, which traditionally have been incorporated into the NSSP Manuals of Operation have been reconstituted in the form of a "NSSP Guide for the Control of Molluscan Shellfish." The purpose of the "NSSP Guide for the Control of Molluscan Shellfish" handbook is twofold. First, it serves to redraft existing guidelines contained in the NSSP Manuals of Operation into a NSSP Model Ordinance, which contains language that can be readily codified into law or regulation by a State. Second, it sets forth supportive documentation pertinent to the codified language of the Model Ordinance, including: The NSSP's history, public health reasons and explanations specific to the guidelines contained in the Model Ordinance, NSSP guidance documents, suggested NSSP forms, shellfish policy-setting documents, pertinent Federal regulations, and references to the public health reasons and explanations.

Redrafting of the NSSP Manuals of Operation was accomplished through the efforts of the ISSC working in cooperation with FDA. This effort began in 1989 and continued through December 1997. Wherever possible, the concepts and language contained in the NSSP Manuals of Operation were used in the NSSP Model Ordinance. Where language did not exist to explain a requirement (e.g., flow charts), an explanation was developed. In cases where the intent of the NSSP Manuals of Operation was not clear, new definitions were developed. Apparently conflicting requirements in the Manuals of Operation were resolved by selecting the requirement that most clearly reflected the intent of the NSSP or by selecting the more restrictive requirement.

In 1997, FDA was asked by the ISSC to adopt the Model Ordinance. FDA recognized that if it were to do so, the NSSP Model Ordinance would be a FDA guideline, and as such, it would be subject to the policy of FDA relating to the development, issuance, and use of guidance documents, as expressed in the **Federal Register** of February 27, 1997 (62 FR 8961 at 8969 through 8971). This policy states that the public will be afforded an opportunity to comment on guidance documents in accordance with Level 1 Good Guidance Practices

documents as set out in the **Federal Register** of February 27, 1997 (62 FR 8961).

The annual meeting of the ISSC, in the past and again at the July 1997 meeting, provided an essential forum for the development of revisions to the NSSP. The participatory process that occurs at this meeting serves the purposes and principles set forth in the agency's guidance documents policy. Therefore, in a notice published in the **Federal Register** of June 26, 1997 (62 FR 34480), FDA announced that the Model Ordinance was to be discussed at the July 1997 ISSC meeting, and that this meeting would act as the forum for public comment on the Model Ordinance as an FDA guidance document. FDA requested comment on the procedure, but received none.

With concurrence from FDA, the NSSP Model Ordinance was adopted by the ISSC at its July 1997 meeting in Sturbridge, MA. With this notice, FDA is announcing the availability of the Model Ordinance as contained within the guide "NSSP Guide for the Control of Molluscan Shellfish." At the Federal level, the Model Ordinance has the status of guidance and, as such, does not create or confer any rights for or on any person and does not operate to bind FDA or the public. However, through their participation in the NSSP and the ISSC, participating States have voluntarily agreed to follow the Model Ordinance as the requirements which are minimally necessary for membership.

The public may comment on this document at anytime. The public may comment in one of two ways: (1) By attending the ISSC conference held annually for the purpose of, among other things, considering changes to the Model Ordinance; or (2) by commenting to FDA. Those comments that the agency finds meritorious will be offered by FDA for consideration and vote at a subsequent ISSC.

The NSSP Model Ordinance will facilitate uniform adoption of the recommended shellfish control practices by States for regulation of their shellfish industry. Adoption of the NSSP Model Ordinance by each State will strengthen the credibility of the National Shellfish Sanitation Program and the "Interstate Certified Shellfish Shippers List" (ICSSL), which identifies shellfish dealers certified by their State of residence as being in compliance with NSSP guidelines. Assurance that all shellfish dealers are meeting the minimum criteria will foster confidence in product safety.

Interested persons may, at any time, submit to the Dockets Management

Branch (address above) written comments on the guide. Two copies of any comments should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. At the discretion of FDA, received comments will be used to develop issues for submission to the ISSC for consideration at its July 1999, annual meeting.

Dated: July 8, 1998.

William K. Hubbard,
*Associate Commissioner for Policy
Coordination.*

[FR Doc. 98-19029 Filed 7-16-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental Research; 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 Commission: National Institute of Dental Research Special Emphasis Panel, Emphasis Panel 44 & 45.

Date: July 26-28, 1998.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Yong A. Shin, PhD, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594-2372.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and

Disorders Research, National Institutes of Health, HHS)

Dated: July 10, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-19069 Filed 7-16-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in section 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-8 02.

Date: July 22-24, 1998.

Time: July 22, 1998, 7:00 pm to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Hotel, 625 El Camino Real, Palo Alto, CA 94301-2380.

Contact Person: Robert J. Haber, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS-37, National Institutes of Health, Bethesda, MD 20892-6600, (301) 594-8898.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB-D (01).

Date: July 27, 1998.

Time: 10:00 am to adjournment.

Agenda: To review and evaluate grant applications.

Place: Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Ann Hagan, Chief, Review Branch, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Phs, Dhhs, Rm. 6as37, Bldg. 45, Bethesda, MD 20892, (301) 594-8886.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes,

Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institute of Health, HHS)

Dated: July 10, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

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 meetings.

The meetings 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, International Drug Abuse Epidemiology Data Bank.

Date: July 17, 1998.

Time: 9:00 am to 5:00 pm.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Drug Abuse, 5600 Fishers Lane, Room 10-49, Rockville, MD 20857 (Telephone Conference Call).

Contact Person: Eric Zatman, Contract Review Specialist, Office of Extramural Program Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 5600 Fishers Lane, 10-42, Rockville, MD 20857, (301) 443-1644.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Neurological Effects of Drug Addiction Therapies.

Date: August 3, 1998.

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Kesinee Nimit, MD, Health Scientist Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 5600 Fishers Lane, Room 10-22, Rockville, MD 20857, (301) 443-9042.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: July 10, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Children With Serious Emotional Disturbance; Estimation Methodology

AGENCY: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final notice.

SUMMARY: This notice describes the final methodology to identify and estimate the number of children with a serious emotional disturbance (SED) within each State. This notice is being published as part of the requirements of Public Law 102-321, the ADAMHA Reorganization Act of 1992.

EFFECTIVE DATE: October 1, 1998.

Background

Public Law 102-321, the ADAMHA Reorganization Act of 1992, amended the Public Health Service Act and created the Substance Abuse and Mental Health Services Administration (SAMHSA). The Center for Mental Health Services (CMHS) was established within SAMHSA to coordinate Federal efforts in the prevention and treatment of mental illness, and the promotion of mental health. Title II of Public Law 102-321 establishes a Block Grant for Community Mental Health Services, administered by CMHS, that permits the allocation of funds to States for the provision of community mental health services for children with a SED and adults with a serious mental illness (SMI). Public Law 102-321 stipulates that States estimate the incidence (number of new cases) and prevalence (total number of cases in a year) of individuals with either SED or SMI in their applications for block grant funds.