

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the meeting of the Gastrointestinal Drugs Advisory Committee scheduled for April 12, 2000. This meeting was announced in the **Federal Register** of February 17, 2000 (65 FR 8180).

FOR FURTHER INFORMATION CONTACT: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12538.

Dated: March 28, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Healthcare Integrity and Protection Data Bank for Final Adverse Information on Health Care Providers, Suppliers, and Practitioners—(OMB 0915-0239)—**EXTENSION**

Section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 specifically directs the Secretary to establish a national health care fraud and abuse data collection program for the reporting and disclosure

of certain final adverse actions taken against health care providers, suppliers, and practitioners. A final rule was published October 26, 1999 in the **Federal Register** to implement the statutory requirements of section 1128E of the Social Security Act (The Act) as added by Section 221(a) of HIPAA. The Act requires the Secretary to implement the national health care fraud and abuse data collection program. This data bank is known as the Healthcare Integrity and Protection Data Bank (HIPDB). It contains the following types of information: (1) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service; (2) Federal or State criminal convictions against a health care provider, supplier, or practitioner related to the delivery of a health care item or service; (3) Actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, or practitioners; (4) Exclusion of a health care provider, supplier, or practitioner from participation in Federal or State health care programs; and (5) Any other adjudicated actions or decisions that the Secretary shall establish by regulations. Access to this data bank is limited to Federal and State Government agencies and health plans.

The Estimated Response Burden Is As Follows

| Regulation citation | Number of respond. | Respon. per respond. | Total respon. | Hrs. per respon. | Total burden hours |
|--|--------------------|----------------------|------------------|------------------|--------------------|
| 61.6 Errors & Omissions | 1,200 | 1 | 1,200 | 25 min | 500 |
| 61.6 Revisions/appeal status | 1,000 | 1 | 1,000 | 75 min | 1,250 |
| 61.7 Licensure actions: | | | | | |
| Disclosure by State licensing boards | 1,836 | 22 | 40,400 | 75 min | 50,500 |
| Reporting by State Licensing Authorities | 216 | 187 | 40,400 | 15 min | 10,100 |
| 61.8 Reporting of State criminal convictions | 54 | 13 | 700 | 75 min | 875 |
| 61.9 Reporting of Civil Judgments | 62 | 8 | 500 | 75 min | 625 |
| 61.11 Reporting of adjudicated actions/decisions. | 66 | 12 | 800 | 75 min | 1,000 |
| 61.12 Access to data (queries/self queries): | | | | | |
| State licensure Boards | 1,000 | 75 | 75,000 | 5 min | 6,250 |
| State certification agencies | 54 | 3 | 162 | 5 min. | 14 |
| States/district attorneys & law enforcement | 2,000 | 25 | 50,000 | 5 min | 4,166 |
| State Medicaid fraud units | 47 | 50 | 2,350 | 5 min | 196 |
| Health plans | 2,500 | 400 | 1,000,000 | 5 min | 83,333 |
| Health care providers, suppliers and practitioners (self query). | 60,000 | 1 | 60,000 | 25 min | 25,000 |
| Entity registration | 5,000 | 1 | 5,000 | 30 min | 2,500 |
| Entity registration update | 250 | 1 | 250 | 15 min. | 62 |
| Authorized agent designation | 100 | 1 | 100 | 10 min. | 16 |
| Authorized agent designation update | 5 | 1 | 5 | 5 min | 0.42 |
| 61.15 Disputed reports/secretarial review. | | | | | |
| Initial request | 750 | 1 | 750 | 10 min | 125 |
| Request for secretarial review | 37 | 1 | 37 | 480 min | 296 |
| Total | 76,177 | | 1,278,654 | | 186,808 |