Spinal Metallic Bone Screws and Washers.'' They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. These guidances are not subject to Executive Order 12866.

### III. Electronic Access

Persons interested in obtaining a copy of the draft guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* These draft guidances are also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of either ''Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19008),'' ''Cutaneous Electrode for Recording Purposes—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19014),'' ''Conventional Foley Catheters—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19010),'' or ''Orthopedic Non-Spinal Metallic Bone Screws and Washers—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 19009)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the documents. Please use the document number and complete title to identify the guidance you are requesting.

### IV. Paperwork Reduction Act of 1995

These draft guidance documents refer to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved by OMB as listed in the following table:

| 21 CFR part or guidance | Topic | OMB control No. |
|---|---|---|
| 807, subpart E | Premarket Notification | 0910–0120 |
| ''Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with Food and Drug Administration Staff''. | Q-Submissions | 0910–0756 |

Dated: September 16, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–20370 Filed 9–19–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–3403]**

## The Food and Drug Administration Solicits Input on Potential Role for Abuse-Deterrent Formulations of Central Nervous System Stimulants; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket to receive comments from interested parties, including patients, patient advocates, healthcare providers, academics, researchers, the pharmaceutical industry, and other government entities, on considerations related to the development and evaluation of abuse-deterrent formulations (ADFs) of central nervous system stimulants and whether such products could play a role in addressing public health concerns related to prescription stimulant misuse and abuse. This notice provides an overview of available postmarket data on the use, misuse, and abuse of prescription stimulants and associated morbidity and mortality, along with similar data on prescription opioids to provide context; background information on the development and evaluation of ADF products; and specific questions on which FDA seeks input. The Appendix lists the sources used in developing this overview.

**DATES:** Submit either electronic or written comments by November 19, 2019.

**ADDRESSES:** FDA is establishing a docket for public comment. The docket number is FDA–2019–N–3403. The docket will close on November 19, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 19, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 19, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2019–N–3403 for ''FDA Solicits Input on Potential Role for Abuse-Deterrent Formulations of Central Nervous System Stimulants; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Janelle Derbis, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 20 North Michigan Ave., Suite 510, Chicago, IL 60602, 312–596–6516.

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

Prescription central nervous system (CNS) stimulants are important medications that are widely prescribed for the treatment of attention deficit hyperactivity disorder (ADHD) and, in some cases, narcolepsy. Currently marketed prescription stimulant drugs consist primarily of amphetamine salts and related compounds including methylphenidate, dextroamphetamine, dexmethylphenidate, methamphetamine, and lisdexamfetamine. When used properly, prescription stimulants can provide significant benefits for patients. However, these drugs have a high potential for misuse and abuse,[1] with associated morbidity and mortality. As such, these drugs are classified in Schedule II (CII) under the Controlled Substances Act, the most restrictive classification for drugs with currently accepted medical use in the United States.

Over the past several years, drug manufacturers have sought to develop novel formulations of prescription stimulants with properties intended to deter abuse. The purpose of this **Federal Register** notice is to solicit input on considerations related to the development and evaluation of such potentially abuse-deterrent formulations, referred to in this notice as *ADF stimulants,* and whether such products could play a role in addressing public health concerns related to prescription stimulant misuse and abuse. We note that although FDA has approved multiple opioid analgesic products with ADFs with labeling stating that these products are expected to deter abuse via one or more routes of administration, FDA has not approved similar labeling for any prescription stimulants. FDA recognizes the misuse and abuse of prescription stimulants as serious public health concerns. However, the scope and patterns of misuse and abuse, morbidity, and mortality associated with prescription stimulants are different from those associated with prescription opioids. Furthermore, postmarket data regarding the impact of ADF opioid analgesics in reducing abuse and associated adverse health outcomes, such as overdose, continue to be limited. FDA is interested in public comment on whether and to what extent ADF stimulants might reduce prescription stimulant abuse and on the potential public health impact of any such reduction.

## II. Background

To better understand the potential role for ADF stimulant products, FDA has reviewed available postmarket data on patterns of use, misuse, and abuse of prescription stimulants and associated morbidity and mortality. A summary of these findings is presented below. To provide context, we also include selected similar data on prescription opioids (see the Appendix for the sources used to develop this summary). Finally, we briefly describe certain key concepts associated with the development and evaluation of drug products intended to deter abuse.

### *A. Postmarket Data on Use, Misuse, Abuse, and Related Adverse Health Outcomes*

Amphetamine stimulants have been available and used for various medical purposes for roughly a century. In the 1990s, longer acting forms of amphetamine were introduced to the market. During this same period, a steep increase in the diagnosis of ADHD in the United States led to a parallel increase in societal exposure to prescribed amphetamine and related stimulant products. From 2007 to 2016, the number of individuals receiving prescriptions for stimulants increased substantially in patients older than 4 years old, with the greatest rate increases occurring in those aged 25 to 44 years. From 2012 to 2016, the estimated number of prescriptions dispensed annually for CII stimulant products from U.S. outpatient retail pharmacies increased from approximately 49.2 million to 62.8 million prescriptions. During this same period, the estimated number of prescriptions dispensed for opioid analgesics decreased from approximately 238.2 million to 193.4 million, remaining approximately three times that of CII stimulant product prescriptions dispensed in 2016.

College students and other young adults are the demographic groups with the highest prevalence of misuse and abuse of prescription stimulants. Data

[1] In this document, the term *misuse* refers to the intentional therapeutic use of a drug product in an inappropriate way and specifically excludes the definition of abuse. The term *abuse* is used here to mean the intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desirable psychological or physiological effect.

from the National Survey on Drug Use and Health (2017) suggest that among Americans aged 12 years and older, an estimated 6.8 percent have used a prescription stimulant in the past year, and 2.1 percent have misused or abused a prescription stimulant. Among those aged 18 to 25 years, an estimated 14.7 percent have used a prescription stimulant in the past year, and 7.4 percent report misusing or abusing the medications. By comparison, among those 12 years and older, an estimated 33.4 percent used and 4.1 percent misused or abused prescription opioid analgesics in the past year. Among 18- to 25-year-olds, an estimated 29.9 percent used prescription opioid analgesics in the past year, and 7.2 percent reported misusing or abusing the medications.

Most individuals misusing or abusing prescription stimulants report doing so only occasionally, primarily to stay awake or enhance academic or work performance, rather than to achieve a high. Those who misuse and abuse prescription stimulants commonly do so in the setting of polysubstance abuse involving a wide range of other prescription products and illicit substances. Limited data from surveys of college students suggest that the problem of prescription stimulant misuse and abuse may be growing in this population, although the prevalence appears to vary considerably by geographic region. Recent data from U.S. poison control centers suggest that misuse and abuse of prescription stimulants may be declining among adolescents less than 19 years of age.

In surveys, a large majority of college students who misuse or abuse prescription stimulants report doing so by the oral route. However, a sizable minority report at least sometimes using them intranasally (most estimates being between 10 percent and 30 percent, but ranging from approximately 7 percent to 50 percent). Injection of prescription stimulants appears to be very uncommon among college students, although data are limited. Among individuals being assessed for or entering substance abuse treatment—a population enriched with individuals with advanced substance use disorders (SUDs)—about 2 in 5 respondents reporting misuse or abuse of prescription stimulants indicate using them intranasally, and approximately 1 in 10 reports injecting them. Direct comparisons with routes of abuse for prescription opioids are difficult, because these patterns vary widely across class, but the routes of abuse patterns for prescription stimulants appear most similar to those seen in this population for immediate-release oxycodone/acetaminophen combination products.

A variety of serious adverse events have been reported in association with prescription stimulant misuse and abuse, including both acute and chronic cardiovascular and neuropsychiatric effects. Additional serious complications are associated with abuse via non-oral routes, including but not limited to, pulmonary complications and infections from non-sterile injection practices and syringe sharing. Misuse and abuse of prescription stimulants can result in physical and psychological dependence as well as impairment of important family, social, and occupational functioning.

Despite these concerns, available data from emergency department (ED) visits, drug-involved mortality, and treatment center admissions suggest that serious consequences of prescription stimulant misuse and abuse appear to be considerably less frequent than for prescription opioids, even after accounting for the lower prescription volume of stimulants. It is important to recognize that not all harms associated with prescription drug misuse and abuse will be captured in these data sources. Based on data from the National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance (NEISS–CADES) project, in 2016, approximately 11,000 emergency department visits were estimated to involve nonmedical use of prescription stimulants (including both misuse and abuse), or approximately 1 visit for every 5,700 prescriptions dispensed. In the same year, approximately 130,000 visits were estimated to involve nonmedical use of opioid analgesics, or 1 visit for every 1,500 prescriptions dispensed. Therefore, although survey data indicate that the prevalence of prescription stimulant misuse and abuse is similar to, or potentially even higher than, that of opioid analgesics relative to prescribed availability, the ED visit data suggest that the likelihood of acute adverse effects serious enough to require medical evaluation or treatment is considerably lower with prescription stimulants than with opioid analgesics. This finding is not surprising given the risk of profound central nervous system and respiratory depression associated with opioids.

Similarly, deaths involving prescription opioids vastly outnumber those involving prescription stimulants, despite the only modestly higher prescription volume for opioids. Based on data extracted from the text of U.S. death certificates, in 2014, approximately 1,000 deaths involved prescription stimulants (including mention of ''amphetamines'' and other prescription stimulants but excluding ''methamphetamine''), or 1 death for every 55,000 prescriptions. By comparison, in 2014, more than 14,000 deaths involved prescription opioids, about 1 death for every 16,000 prescriptions dispensed.

Data from SUD treatment center admissions indicate that prescription stimulants are a relatively uncommon drug of abuse reported among those entering treatment for SUDs (<2 percent), particularly when compared to prescription opioids (approximately 8 to 20 percent). However, as these data capture only a snapshot of recent drug use reported by people being assessed for treatment, they shed little light on the natural history of drug abuse and the development of SUDs, which often involve multiple drugs. Although there is a small body of literature on the progression of opioid use disorder and transitions from prescription opioids to heroin, there has been little research on the longitudinal trajectory of prescription stimulant misuse and abuse, the development of addiction among those misusing or abusing these drugs, or the likelihood of transitioning to illicit stimulants, such as methamphetamine and cocaine, which represent a large and growing public health concern.

In summary, prescription stimulant misuse and abuse are serious public health concerns, particularly in college students and other young adults. Most misuse and abuse of these drugs is oral, although a significant minority of those misusing and abusing the medications report non-oral routes, primarily intranasal. The risk of serious adverse outcomes and the overall magnitude of harms associated with prescription stimulants appear to be considerably lower than for prescription opioids. The relationship between misuse and abuse of prescription stimulants and the development of addiction or initiation of illicit stimulants, such as methamphetamine and cocaine, or other substances, has not been well characterized.

### *B. Development and Evaluation of ADF Products*

Some examples of types of abuse-deterrent technologies and methods for evaluating ADFs are outlined in FDA's 2015 guidance for industry entitled ''Abuse-Deterrent Opioids—Evaluation and Labeling'' (available at *https://www.fda.gov/media/84819/download*). While this document was not intended to provide guidance on the development or evaluation of abuse-deterrent

products in other drug classes, it outlines certain principles that would likely be relevant to the development and evaluation of abuse-deterrent formulations of any prescription drug product. For example, the guidance explains that the design of relevant abuse-deterrent products should target specific known or expected routes of abuse relevant to the proposed product. In addition, the guidance recommends that an evaluation of a proposed ADF should take into consideration the known routes of abuse for the non-ADF predecessor or similar products, and that an ADF should meaningfully reduce abuse of the product as well as morbidity and mortality associated with that abuse. The potential for an ADF to reduce abuse and misuse of a drug product and associated harms depends on, among other things, the pharmacologic properties and abuse liability of the drug substance itself, the scope and patterns of abuse and related harms for that drug and other drugs in the community, and the effectiveness of the ADF in actually deterring abuse and reducing related adverse outcomes associated with that drug in real-world settings. The guidance recommends that developers of ADF products should also consider possible unintended consequences of the ADF, such as the possibility that the ADF could result in shifting abuse from one route to a different, riskier route (*e.g.,* from snorting to injecting).

Although certain scientific principles described in the 2015 guidance likely would be relevant to the development and evaluation of abuse-deterrent formulations of any prescription drug product, FDA has not determined that ADF stimulants warrant the same regulatory approach as ADF opioids. FDA has approved several ADF opioids with language in product labeling stating that these products are expected to deter abuse via specific routes of administration, but has not approved similar labeling for any prescription stimulants. As discussed above, both the patterns and magnitudes of misuse and abuse, morbidity, and mortality associated with prescription stimulants are quite different from those associated with prescription opioids. Furthermore, FDA is continuing to refine its regulatory approach towards ADF opioids in light of evolving technology and science as well as the changing nature of the opioid crisis. While some stakeholders have called for FDA to take additional actions to encourage the transition of the prescription opioid market to ADF opioids, others have questioned the effectiveness of ADFs in reducing opioid abuse and have raised concerns about the possibility of unintended consequences of such a transition, including higher costs and the potential to shift abuse to even more dangerous illicit drugs.

*C. Topics for Consideration*

(1) FDA has provided a summary of its current understanding of abuse and misuse of prescription stimulant products in the United States. We are seeking new or additional information and perspectives on prescription stimulant misuse and abuse and associated harms. We are particularly interested in data on the natural history of stimulant use disorders, including the risk of developing addiction and of transitioning to abuse of illicit stimulants.

(2) Taking into account the patterns and consequences of prescription stimulant misuse and abuse by both patients and others who may access the drugs, discuss whether ADF stimulants could be expected to meaningfully reduce prescription stimulant abuse and associated harms. For which specific patient populations, if any, might it be beneficial to prescribe ADF stimulants? In particular, please discuss whether and to what extent ADF stimulants might be expected to deter the various routes of abuse (*e.g.,* oral, intranasal, injection) associated with prescription stimulants, and also whether such products, if approved and marketed, could be expected to meaningfully reduce the incidence or progression of stimulant use disorder.

(3) Please comment on how ADF stimulant products should be evaluated in premarket and postmarket studies to determine whether they can be expected to deter, or actually have deterred, abuse by the various routes associated with prescription stimulant abuse (oral, intranasal, intravenous, inhalation).

(4) Comment on whether the potentially abuse-deterrent properties of ADF stimulants should be described in product labeling. If so, how should they be described and based on what evidence? We additionally invite comment on whether terms such as *abuse deterrent stimulant* and *ADF stimulant* could be misinterpreted by the public (including prescribers) to suggest that a product is ''abuse-proof,'' or carries a lower risk of addiction. Is there alternative terminology that FDA could use to more clearly describe the expected effects of these new formulations in terms of patient safety and public health?

(5) What other actions or regulatory approaches with respect to ADF stimulants should FDA consider?

(6) Comment on any potential unintended consequences of introducing ADF stimulants to the market. For example, what is the potential for ADF stimulants to shift behavior toward more dangerous routes of abuse (*i.e.,* injection) or to more dangerous drugs (*e.g.,* illicit methamphetamine or other substances), or to result in increased costs for patients, payers, or health systems?

(7) What other actions, if any, should FDA consider to reduce misuse, abuse, and related harms associated with prescription stimulants?

## III. Appendix

The following sources were used in developing the body of this notice.


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Dated: September 16, 2019.

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[FR Doc. 2019–20372 Filed 9–19–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of HHS, HRSA (60 FR 56605, as amended November 6, 1995; as last amended at 81 FR 52450–52451 dated August 8, 2016).

This reorganization: (1) Establishes the Executive Secretariat (RB0) within the Office of the Chief Operating Officer (RB); (2) transfers the functions of the Division of the Executive Secretariat (RB41) from the Office of Administrative Management (RB4) to the newly established Executive Secretariat (RB0); (3) abolishes the Division of Executive Secretariat (RB41) within the Office of Administrative Management (RB4); (4) renames the Office of Budget (RB1) to the Office of Budget and Finance (RB1); (5) establishes the Division of Financial Policy, Analysis and Control (RB14) within the Office of Budget and Finance (RB1); (6) transfers the functions of the Office of Financial Policy and Controls (RB2) to the newly established Division of Financial Policy, Analysis and Control, within the Office of Budget and Finance (RB1); (7) abolishes the Office of Financial Policy and Controls (RB2); (8) establishes the Division of Procurement Management (RB3D) within the Office of Acquisitions Management and Policy (RB3); (9) transfers the Division of Policy and Data Analysis (RB33) and Division of Financial Support Services (RB34) functions to the newly established Division of Procurement Management (RB3D); and (10) abolishes the Division of Policy and Data Analysis (RB33) and the Division of Financial Support Services (RB34). The new chapter reads as follows:

**Chapter RB—Office of Operations**

*Section RB.10 Organization*

Delete the organization for the Office of Operations (RB) in its entirety and replace with the following:

The Office of Operations (RB) is headed by the Chief Operating Officer, who reports directly to the Administrator, Health Resources and Services Administration. The Office of Operations includes the following components:

(1) Office of the Chief Operating Officer (RB);

(2) Executive Secretariat (RB0);

(2) Office of Budget and Finance (RB1);

(3) Office of Acquisitions Management and Policy (RB3);

(4) Office of Administrative Management (RB4);

(5) Office of Information Technology (RB5); and

(6) Office of Human Resources (RB6).

*Section RB.20 Functions*

Delete the functional statement for the Office of the Chief Operating Officer (RB); Office of Budget and Finance (RB1); Office of Acquisitions Management and Policy (RB3); Office of Administrative Management (RB4); replace in their entirety.

**Office of Operations (RB)**

*Office of the Chief Operating Officer (RB)*

(1) Provides leadership for operational activities, interaction, and execution of initiatives across HRSA; (2) plans, organizes and manages annual and multi-year budgets and resources and assures that the conduct of administrative and financial management activities effectively support program operations; (3) provides an array of HRSA-wide services including Executive Secretariat, information technology, procurement management, facilities, human resources, workforce management, and budget execution and formulation; (4) maintains overall responsibility for policies, procedures, and monitoring of internal controls and systems related to payment and disbursement activities; (5) provides management expertise, staff advice, and support to the Administrator in program and policy formulation and execution; (6) provides leadership in the development, review and implementation of policies and procedures to promote improved information technology management capabilities and best practices; (7) coordinates workforce issues and works closely with the Department on recruitment and training issues; and (8) administers functions of the Chief Financial Officer.

*Executive Secretariat (RB0)*

The Executive Secretariat provides leadership, management and guidance HRSA-wide for correspondence, policy and information coordination, Federal Advisory Committees, and Freedom of Information Act requests. Specifically, the Executive Secretariat: (1) Advises the Administrator and other key agency officials on cross-cutting policy issues and assists in their identification and resolution; (2) establishes and maintains a tracking system that provide HRSA-wide coordination and clearance of policies, regulations, and guidelines; (3) plans, organizes, and directs the preparation and management of written correspondence; (4) manages the review process for HRSA-drafted reports to Congress; (5) coordinates the preparation of proposed rules and regulations relating to HRSA programs and coordinates review and comment on other Department regulations and policy directives that may affect HRSA programs; (6) oversees and coordinates HRSA's federal advisory committee management activities; (7) coordinates the review and publication of **Federal Register** notices; and (8) coordinates the implementation of the Freedom of Information Act (FOIA) for the agency.

*Office of Budget and Finance (RB1)*

(1) Reviews funds control measures to assure that no program, project or activity of HRSA obligates or disburses funds in excess of appropriations or obligates funds in violation of authorized purposes; (2) provides advice and assistance to senior HRSA management to verify the accuracy, validity, and technical treatment of budgetary data in forms, schedules, and reports, or the legality and propriety of using funds for specific purposes; (3) maintains primary liaison to expedite the flow of financial management work and materials within HRSA and/or between agency components and HHS, Office of Management and Budget (OMB), and congressional staff; (4)