

was submitted on May 15, 2011, and disapproved on June 1, 2011. The SPA proposed to prohibit the State Medicaid agency from entering into a contract or grant with providers that perform abortions or maintain or operate facilities where abortions are performed, except for hospitals or ambulatory surgical centers.

CMS based the disapproval on a determination that SPA 11-011 would not comply with the requirements of section 1902(a)(23) of the Social Security Act (the Act). Whether SPA 11-011 complies with section 1902(a)(23) of the Act is the only issue in this reconsideration. Section 1902(a)(23) of the Act provides that beneficiaries may obtain covered services from any qualified provider that undertakes to provide such services. Contrary to that requirement, this SPA would eliminate the ability of Medicaid beneficiaries to receive services from specific providers for reasons unrelated to their qualifications to provide such services. It is not consistent with section 1902(a)(23) for Medicaid programs to exclude qualified health care providers from providing services that are funded under the program because of a provider's scope of practice. Such a restriction would have a particular effect on beneficiaries' ability to access family planning providers. It is important to note that access to family planning providers is an important statutory priority, as evidenced by the additional protections for beneficiary choice of family planning providers under section 1902(a)(23)(B) of the Act for managed care enrollees. It is also important to note that neither SPA 11-011 nor the disapproval affect the applicable restrictions on Federal funding of abortion services.

Section 1116 of the Act and Federal regulations at 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. CMS is required to publish a copy of the notice to a State Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as

*amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Indiana announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Patricia Casanova,  
Director, MS 07, 402 W. Washington Street,  
Room W382, Indianapolis, IN 46204-  
2739.

Dear Ms. Casanova:

I am responding to your request for reconsideration of the decision to disapprove the Indiana State Plan Amendment (SPA) 11-011 which was submitted on May 15, 2011, and disapproved on June 1, 2011. The SPA proposed to prohibit the State Medicaid agency from entering into a contract or grant with providers that perform abortions or maintain or operate facilities where abortions are performed, except for hospitals or ambulatory surgical centers.

Whether SPA 11-011 complies with section 1902(a)(23) of the Act is the only issue in this reconsideration.

Section 1902(a)(23) of the Act provides that beneficiaries may obtain covered services from any qualified provider that undertakes to provide such services. Contrary to that requirement, this SPA would eliminate the ability of Medicaid beneficiaries to receive services from specific providers for reasons unrelated to their qualifications to provide such services. It is not consistent with section 1902(a)(23) for Medicaid programs to exclude qualified health care providers from providing services that are funded under the program because of a provider's scope of practice. Such a restriction would have a particular effect on beneficiaries' ability to access family planning providers. It is important to note that access to family planning providers is an important statutory priority, as evidenced by the additional protections for beneficiary choice of family planning providers under section 1902(a)(23)(B) of the Act for managed care enrollees. It is also important to note that neither SPA 11-011 nor the disapproval affect the applicable restrictions on Federal funding of abortion services.

I am scheduling a hearing on your request for reconsideration to be held on September 13, 2011, at the CMS Chicago Regional Office, 233 N. Michigan Avenue, Suite 600, Chicago, IL 60601, in order to reconsider the decision to disapprove SPA 11-011.

If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by Federal regulations at 42 CFR Part 430.

I am designating Mr. Benjamin Cohen as the presiding officer. If these arrangements present any problems, please contact the presiding officer at (410) 786-3169. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that

has been scheduled and provide names of the individuals who will represent the State at the hearing. As you requested, I will also provide this response to Indiana Solicitor General Thomas M. Fisher.

Sincerely,  
Donald M. Berwick, M.D.

Section 1116 of the Social Security Act (42 U.S.C. 1316; 42 CFR 430.18).

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: July 20, 2011.

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2011-18831 Filed 7-25-11; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0010]

#### **Cooperative Agreement With the World Health Organization Department of Food Safety and Zoonoses in Support of Strategies That Address Food Safety Problems That Align Domestically and Globally (U01); Correction**

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 28, 2011 (76 FR 37817). The document announced the availability of funds for the support of a sole source cooperative agreement with the World Health Organization. The document published stating that the total funding available was up to \$260,000 (total costs including indirect costs) in fiscal year 2011 in support of this project. This document corrects that error.

#### **FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:**

#### **For Programmatic Questions and Concerns Contact**

Katherine Bond, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8318, e-mail: [Katherine.bond@fda.hhs.gov](mailto:Katherine.bond@fda.hhs.gov).

#### **For Financial and Administrative Questions and Concerns Contact**

Gladys Melendez, Office of Acquisition and Grant Services (HFA-

500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301-827-7175, e-mail: [gladys.Melendez-bohler@fda.hhs.gov](mailto:gladys.Melendez-bohler@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-16120, appearing on page 37817, in the **Federal Register** of Tuesday, June 28, 2011, the following correction is made:

1. On page 37819, in third column, section A. *Award Amount* is corrected to read as follows:

The total funding available is up to \$360,000 (total costs including indirect costs) in fiscal year 2011 in support of this project. One award will be made. Funding will be provided for one year, with the possibility of up to four additional years of support, contingent upon successful performance and available funding.

Dated: July 21, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2011-18881 Filed 7-25-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0239]

#### Identifying the Center for Drug Evaluation and Research's Science and Research Needs; Availability of a Draft Report; Request for Comments

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

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled "Identifying CDER's Science and Research Needs." This document identifies current priorities in regulatory science related to the mission of the Center for Drug Evaluation and Research (CDER), and will guide strategic planning of internal research efforts. Through external communication of the science and research needs outlined in the report, CDER hopes to stimulate research and foster collaborations with external partners and stakeholders to address these priorities.

**DATES:** Although you can comment on the report at any time, to ensure that the Agency considers your comment on this report before it begins work on the final version of the report, submit either electronic or written comments on the report by September 26, 2011.

**ADDRESSES:** Submit written requests for single copies of this report to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft report.

Submit electronic comments on the draft report to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Ruth Barratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4540, Silver Spring, MD 20993-0002, 301-796-2600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft report entitled "Identifying CDER's Science and Research Needs." This report is the result of an effort to identify regulatory science needs that, if addressed, would enhance CDER's ability to fulfill its regulatory mission. A publication entitled "FDA Critical Path Opportunities Report and Critical Path Opportunities List" was published in March 2006. That report focused on the scientific challenges underlying medical product development and served as a catalyst for CDER to launch an effort to identify specific areas that would benefit from additional regulatory science efforts. More recently, FDA released, "Advancing Regulatory Science for Public Health", which incorporates the Critical Path objectives into a broad framework for advancing regulatory science. In support of these initiatives, this report delineates major areas of scientific need that can contribute to the development of a strategic science and research agenda.

To begin an assessment of these needs, more than 200 representatives from CDER's offices were asked to identify: (1) Scientific challenges currently addressed on a case-by-case basis that might benefit from the development of a systematized approach; (2) recurrent science issues across teams, divisions, or offices; and (3) emerging scientific challenges. A comprehensive set of science and research needs was compiled from these discussions. Senior management from

CDER offices reviewed and prioritized topics from their offices. These science and research needs were ultimately grouped into seven categories that were reviewed and endorsed by the CDER Science Prioritization and Review Committee and CDER senior management.

Seven major categories that crossed multiple disciplines were identified: (1) Improve access to postmarket data sources and explore feasibility of their use in different types of analyses; (2) improve risk assessment and management strategies to reinforce the safe use of drugs; (3) evaluate the effectiveness and impact of different types of regulatory communications to the public and other stakeholders; (4) evaluate the links among product quality attributes, manufacturing processes, and product performance; (5) develop and improve predictive models of safety and efficacy in humans; (6) improve clinical trial design, analysis, and conduct; and (7) enhance individualization of patient treatment.

The draft report is not intended to address the need to maintain a robust scientific readiness to respond rapidly to regulatory crises, but by communicating CDER's current science and research needs, CDER hopes to stimulate research and foster collaborations with external partners and stakeholders. CDER is disseminating this document externally and soliciting input on: (1) Research and initiatives that may be ongoing; and (2) opportunities to collaborate with external partners and stakeholders to maximize resources to address the areas for development discussed previously. The input will be reviewed and incorporated as appropriate into plans for collaborations and potential external partners will be contacted for further discussion.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>.