

Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;

- Plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared;
- Plans for considering the impact of drug shortages on research and clinical trials; and

- An examination of whether to establish a “qualified manufacturing partner program” as described in section 506D(a)(1)(C) of the FD&C Act.

II. Scope of Public Input Requested

Per the directive in section 506D, FDA has formed an internal Drug Shortages Task Force (Task Force) to develop and implement the drug shortages strategic plan. The Task Force is seeking comments from the public on issues related to the development of this strategic plan. Importantly, although FDASIA refers only to a drug shortages strategic plan, we anticipate that the strategic plan will consider prevention and mitigation of both drug and biological product shortages. Accordingly, we are interested in receiving comments on these questions from all parties, including those with an interest in biological products. The Task Force is specifically interested in seeking public input on the following questions:

1. In an effort to address the major underlying causes of drug and biological product shortages, FDA is seeking new ideas to encourage high-quality manufacturing and to facilitate expansion of manufacturing capacity.

- a. To assist in the evaluation of product manufacturing quality, FDA is exploring the broader use of manufacturing quality metrics. With that in mind, FDA would like input on the following issues: What metrics do manufacturers currently use to monitor production quality? To what extent do purchasers and prescribers use information about manufacturing quality when deciding how to purchase or utilize products? What kinds of manufacturing quality metrics might be valuable for purchasers and prescribers when determining which manufacturers to purchase from or which manufacturers' products to prescribe? What kinds of manufacturing quality metrics might be valuable for manufacturers when choosing a contract manufacturer? How frequently would such metrics need to be updated to be meaningful?

- b. The use of a qualified manufacturing partner program similar to one used under the Biomedical Advanced Research and Development Authority (BARDA) has been suggested as a potentially useful approach to expanding manufacturing capacity and preventing shortages. FDA recognizes that there are important potential differences between the BARDA program and the use of a parallel program to address shortages. For example, the BARDA program covers a relatively stable and limited number of products, but drugs at risk of shortage are many, may change rapidly over time, and are difficult to predict in advance. In addition, FDA does not have funding to pay manufacturers to participate in a drug shortages qualified manufacturing partner program or to guarantee purchase of the end product. With these differences in mind, is it possible to design a qualified manufacturing partner program that would have a positive impact on shortages?

- c. Are there incentives that FDA can provide to encourage manufacturers to establish and maintain high-quality manufacturing practices, to develop redundancy in manufacturing operations, to expand capacity, and/or to create other conditions to prevent or mitigate shortages?

2. In our work to prevent shortages of drugs and biological products, FDA regularly engages with other U.S. Government Agencies. Are there incentives these Agencies can provide, separately or in partnership with FDA, to prevent shortages?

3. When notified of a potential or actual drug or biological product shortage, FDA may take certain actions to mitigate the impact of the shortage, including expediting review of regulatory submissions, expediting inspections, exercising enforcement discretion, identifying alternative manufacturing sources, extending expiration dates based on stability data, and working with the manufacturer to resolve the underlying cause of the shortage. Are there changes to these existing tools that FDA can make to improve their utility in managing shortages? Are there other actions that FDA can take under its existing authority to address impending shortages?

4. To manage communications to help alleviate potential or actual shortages, FDA uses a variety of tools, including posting information on our public shortages Web sites and sending targeted notifications to specialty groups. Are there other communication tools that FDA should use or additional

information the Agency should share to help health care professionals, manufacturers, distributors, patients, and others manage shortages more effectively? Are there changes to our public shortage Web sites that would help enhance their utility for patients, prescribers, and others in managing shortages?

5. What impact do drug and biological product shortages have on research and clinical trials? What actions can FDA take to mitigate any negative impact of shortages on research and clinical trials?

6. What other actions or activities should FDA consider including in the strategic plan to help prevent or mitigate shortages?

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: February 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Current Traumatic Brain Injury State Implementation Partnership Grantees; Non-Competitive One-Year Extension Funds

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Non-Competitive One-Year Extension Funds for Current Traumatic Brain Injury (TBI) State Implementation Partnership (H21) Grantees.

SUMMARY: The Health Resources and Services Administration (HRSA) will issue funding for a non-competitive one-year extension for the State Implementation Partnerships (H21) awards to current grantees whose awards are scheduled to end in fiscal year (FY) 2013. Up to \$250,000 per

grantee will be awarded over a one-year extended project period.

The HRSA TBI Program was initially authorized by the Traumatic Brain Injury Act of 1996 (Pub. L. 104–166) and was most recently reauthorized by the Traumatic Brain Injury Act of 2008 (Pub. L. 110–206). Under this authority, the HRSA TBI Program is charged with improving access to rehabilitation and other services for individuals with traumatic brain injury and their families. The TBI State Implementation Partnership Grants support activities that complement existing state infrastructure to provide needed services following TBI. Through comprehensive and periodic needs and resources assessments, activities

supported by grant funds are aligned with the highest priority areas as determined by providers, individuals with TBI and their families, advocates, and other stakeholders. Recipients of grant funds are expected to modify infrastructure in such a way that improvements in service delivery will be sustained beyond the grant period. As part of this charge, grantees must specifically have or develop the following four core components:

(1) A Statewide Advisory Board consisting of members of the community, and representatives of other state agencies with an interest in TBI, such as State Departments of Health, Rehabilitation, Human Services, Education, Transportation, or Labor.

This board should also have strong representation from individuals with TBI and/or family members; and also organizations that serve individuals with TBI; and other service providers, medical and non-medical;

(2) A designated state agency that takes responsibility for carrying out activities of the grant;

(3) A statewide needs and resources assessment; and

(4) A comprehensive Statewide Action Plan for assisting individuals with TBI and their families to increase access to needed services and supports.

SUPPLEMENTARY INFORMATION: Grantees of record and intended award amounts are:

<i>Grantee/organization name</i>	<i>Grant number</i>	<i>State</i>	<i>FY2012 authorized funding level</i>	<i>FY2013 estimated funding level</i>
Alabama Department of Rehabilitation Services	H21MC06738	AL	\$245,100	\$245,100
Arizona Department of Economic Security	H21MC06754	AZ	249,915	249,915
Idaho State University	H21MC07735	ID	250,000	250,000
Indiana Vocational Rehabilitation Services	H21MC06756	IN	249,739	249,739
Iowa Department of Public Health	H21MC06748	IA	250,000	250,000
Massachusetts Rehabilitation Commission	H21MC06737	MA	250,000	250,000
Michigan Department of Community Health	H21MC06747	MI	250,000	250,000
Missouri Department of Health and Senior Services	H21MC06740	MO	250,000	250,000
Nebraska Department of Education	H21MC06758	NE	250,000	250,000
Health Research, Inc./New York State Department of Health	H21MC06742	NY	249,909	249,909
North Carolina Department of Health and Human Services	H21MC06746	NC	250,000	250,000
State of Ohio Rehabilitation Services Commission	H21MC06771	OH	248,500	248,500
Tennessee Department of Health	H21MC06739	TN	250,000	250,000
Virginia Department of Rehabilitative Services	H21MC06763	VA	250,000	250,000
West Virginia University	H21MC11468	WV	250,000	250,000
Oregon State Department of Education	H21MC06769	OR	249,999	249,999
Texas Health & Human Services Commission	H21MC16375	TX	250,000	250,000

Amount of the Award(s): Up to \$250,000 per grantee over a one-year project period. CFDA Number: 93.234
Current Project Period:

• All grants in this cohort except Texas: 4/1/2006–3/31/2013 (competing continuations awarded 4/1/2009)

• Texas: 4/1/2006–8/31/2013 (competing award 9/1/2009)

Period of Additional Funding:

• All grants in this cohort except Texas: 4/1/2013–3/31/2014

• Texas: 9/1/2013–8/31/2014

Authority: Public Health Service Act, Title XII, Section 1252 (42 USC 300d–52) as amended by the Children's Health Act of 2000, sec.1304, Pub. L. 106–310, as further amended by the Traumatic Brain Injury Act of 2008, sec. 6(a), Pub. L. 110–206.

Justification: The Maternal Child Health Bureau (MCHB) within HRSA has determined, through assessment of its State Implementation Partnership (H21) grants, that a series of services are commonly identified as “needs” via state-conducted assessments and as such are common programmatic activities pursued under the auspices of

H21 grants. MCHB proposes a one-year extension of the current grant cohort to allow time to refine the focus of the H21 program, defining these common activities, crafting appropriate performance measures, and securing clearance to collect uniform data on these activities that demonstrate the impact of this program on the target population.

In the interest of continuing to align the structure of the program with the needs of this population, and therefore fulfilling our legislative charge, the TBI Program proposes this course of action: To align the next grant competition with demonstrated areas of need, to capture uniform data on the impact of this program, to provide for sufficient fiscal resources to continue programmatic activities, and to maintain MCHB programmatic support with the least disruption to the state, community, affected constituencies who are currently receiving assistance and services from these grantees, and the grantees themselves.

In general, the project period for 17 TBI State Implementation Partnership grantees would end March 31, 2013, and a robust competitive process would have taken place in December 2012. MCHB does not believe the idea of conducting a competition at this time is appropriate or cost effective. Therefore, MCHB proposes to extend the project period of these grants into FY 2014. Awards will be subject to the availability of funds.

FOR FURTHER INFORMATION CONTACT:

LCDR Donelle McKenna, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 13–61, Rockville, Maryland 20857 or email dmckenna@hrsa.gov.

Dated: February 5, 2013.

Mary K. Wakefield,

Administrator.

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