

TABLE 1—COST OF REGISTRATION—Continued

Affiliation	Through August 10, 2012	After August 10, 2012
Student Nonmember ¹	310	310

¹ Applicable nonmember rates.

Please visit PDA's Web site: <http://www.pda.org/pdafda2012> to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Wanda Neal (see *Contact*), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to "PDA." Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 200, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site: <http://www.pda.org/pdafda2012>.

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see *Contact*).

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA Joint Regulatory Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Regulatory Submission and Meetings

- Quality Risk Management Implementation
- Manufacturing in the Future
- Quality Systems
- Regulatory Considerations During Development
- Cell Therapy Innovations
- Life Cycle Management
- Process Validation
- Validation FDA Guidance
- Challenges of Contract Manufacturing Organizations
- Contract Agreements
- Drug Safety
- Emerging Active Pharmaceutical Ingredients (API) Regulations
- Investigations
- Emerging API Regulations
- User Fees
- Excipient Best Practices
- Good Manufacturing Practices
- Foreign Inspections Findings (Inspectional Readiness)
- Combination Products and Companion Diagnostics

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as outreach activities by Government Agencies to small businesses.

Dated: August 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-19295 Filed 8-6-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Document for Comment

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

ACTION: This is a Notice of Availability and request for comments on a draft

Agency Guidance ("Policy Information Notice" (PIN)). The draft PIN provides clarification on the sliding fee discount program and related requirements for federally-funded health centers and Federally Qualified Health Center (FQHC) Look-Alikes. The draft PIN, "Clarification of Sliding Fee Discount Program Requirements," is available on the Internet at <http://www.bphc.hrsa.gov/policiesregulations/policies/draftsforcomment.html>.

DATES: Comments must be received by the close of business on September 28, 2012.

ADDRESSES: Comments should be submitted to OPPDSFPIN@hrsa.gov by the close of business on September 28, 2012.

SUMMARY: HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Health Center Program. Therefore, we are requesting comments on the PIN referenced above. Comments will be reviewed and analyzed, and a final PIN, along with a summary and general response to the comments, will be published as soon as possible after the deadline for receipt of comments.

Background: HRSA provides grants to eligible health centers under Section 330 of the Public Health Service Act (PHS Act) to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. In 2011, grants helped fund approximately 1,200 health center grantees, which provided services at more than 8,500 health care delivery sites and served more than 20.2 million people. There are also approximately 100 FQHC Look-Alikes. As described in section 1861(aa)(4) and section 1905(l)(2)(B) of the Social Security Act, FQHC Look-Alikes do not receive Federal funding under Section 330 of the PHS Act. However, in order to receive the FQHC Look-Alike designation and benefits, FQHC Look-Alikes must meet the statutory, regulatory, and policy requirements for Health Centers Programs under Section 330.

A key requirement of the Health Center Program is for a health center to establish a "sliding fee discount

program” that includes a schedule of discounts for services, or “sliding fee discount schedule,” that ensures financial barriers to care are minimized for patients who meet certain eligibility criteria. All Section 330-funded health centers and FQHC Look-Alikes must utilize a sliding fee discount schedule that provides discounts to eligible patients based on their family size and income.

The purpose of this PIN is to provide clarification on Health Center Program sliding fee discount program requirements including: (1) A schedule of fees for services; (2) a corresponding schedule of discounts for eligible patients that is adjusted on the basis of the patient’s ability to pay (referred to as the sliding fee discount schedule, or SFDS for the purposes of this PIN); and (3) governing board-approved policies and procedures, including those around billing, collections, and waivers or reductions of any fees or payments required by the center for services that support the fee and discount schedules based on an individual’s ability to pay. When finalized, this PIN will supersede all other previous Health Center Program guidance and policy issued on this program requirement. However, please note that this policy does not supersede patient billing requirements resulting from a health center’s FQHC status under Titles XVIII and XIX of the Social Security Act (the Medicare and Medicaid programs), its implementing regulations, or policies.

HRSA’s Bureau of Primary Health Care is making this draft PIN available for comment. When providing comments, please be as specific as possible, and reference the section of the PIN and/or page number(s). Comments will be reviewed and analyzed, and a final PIN, along with a summary and general response to comments, will be published as soon as possible after the comment submission deadline. Comments should be submitted to OPPDSFPIN@hrsa.gov by the close of business on September 28, 2012.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at OPPDSFPIN@hrsa.gov.

Dated: July 31, 2012.

Mary K. Wakefield,
Administrator.

[FR Doc. 2012–19159 Filed 8–6–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Announcement of Requirements and Registration for “Stop Bullying Video Challenge”

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

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration’s (HRSA) Maternal and Child Health Bureau, located within the Department of Health and Human Services (HHS), announces the launch of the “Stop Bullying Video Challenge.” Bullying is unwanted, aggressive behavior among school aged children that involves a real or perceived power imbalance. The behavior is repeated, or has the potential to be repeated, over time. Bullying can affect everyone—those who are bullied, those who bully, and those who witness bullying. Bullying is linked to many negative outcomes including impacts on mental health, substance use, and suicide. The Federal Partners for Bullying Prevention is a Federal workgroup which is comprised of 9 departments, with 34 offices within those 9 departments, dedicated to preventing and ending bullying in schools and communities across the nation. HRSA and the Federal Partners are launching a video challenge that will encourage and motivate youth to prevent bullying.

The goal of the contest is to create an impact through accepting videos that demonstrate:

1. Peer-to-peer communication,
2. Positive messaging, and
3. Promotion of the

www.stopbullying.gov Web site. By using these guidelines, contestants will create relevant, youth-designed videos that stand to increase knowledge about bullying and how to prevent it.

DATES: Contestants can begin submission of tools on August 7, 2012, until the end of the submission period October 10, 2012. Judging will take place between October 11 and December 2, 2012. Winners will be notified and prizes awarded no later than December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Erin Reiney, MPH, CHES; Public Health Analyst, 301–443–5848.

AWARD APPROVING OFFICIAL: Mary K. Wakefield, Ph.D., R.N., Administrator, Health Resources and Services Administration.

SUPPLEMENTARY INFORMATION:

Eligible Entities

This video contest is open to U.S. middle and high school students aged 13–18 at the time of entry. Contestants may be individuals or groups (including but not limited to middle and high schools located in the U.S., and youth advocacy groups incorporated in and located in the U.S.). An individual, whether participating singly or in a group, must be a citizen or permanent resident of the U.S. If the contestant is under 18 years of age at the time of entry, the contestant must have permission from a parent or guardian, and an adult must complete and submit the contest entry form. Contestants/submitters must also have all the necessary permissions for individuals heard and/or seen on the submitted video. The permission of the parent or guardian of each person under the age of 18 who is seen or heard in the video is also required. Contestants in this category are encouraged to submit group entries. Employees and contractors of the Federal government are not eligible, nor are their immediate family members. The Contest is subject to all applicable Federal laws and regulations. Participation constitutes contestant’s full and unconditional agreement to these Official Rules, which are final and binding in all matters related to the Contest. Eligibility for a prize award is contingent upon fulfilling all requirements set forth herein.

Competition Submission Period and other Submission Requirements

Contestants must submit their videos between August 7 and October 10, 2012. Each contestant must complete and submit the required information on www.challenge.gov for the video entered into the Contest. Groups of more than one individual must submit a contest entry through a single designated individual or school within the group. Once a submission is made, the contestant may not make any changes or alter the submission until the judging is complete and winners announced. Contestants remain owners of the intellectual property rights of their submissions. Contestants must upload their video to YouTube as private. To do this, select “Privacy Settings,” mark video as private, enter the YouTube username “stopbullyinggov” in the box that appears below, then select “save changes.” Videos must be uploaded to YouTube in one of the following file formats: WebM, MPEG4, 3GPP, MOV, AVI, MPEGPS, WMV, or FLV.