MEDICAL EDUCATION GRANTS: FREQUENTLY ASKED QUESTIONS

WHICH GUIDELINES AND/OR REGULATIONS DOES THE ALLERGAN MEDICAL EDUCATION DEPARTMENT ADHERE TO?

Allergan’s grant approval process is in full accordance with the recommendations and guidance of the Office of Inspector General (OIG), Pharmaceutical Research and Manufacturers of America (PhRMA), Advanced Medical Technology Association (AdvaMed), the Accreditation Council for Continuing Medical Education (ACCME), “National Physician Payment Transparency Program: OPEN PAYMENTS” (commonly known as the “Sunshine Act”) and internal Allergan compliance policies.

WHAT IS ALLERGAN’S MEDICAL EDUCATION GRANT PROCESS?

Allergan’s Medical Education grant process is the process by which Allergan is able to consider support for independent medical education activities.

All medical education grants must be requested through the Allergan Medical Education Department website at www.allerganmededgrants.com. There is no manual process for grant submissions separate from the online system.

Allergan employees outside of Allergan’s Medical Education Department and Allergan’s Grant Review Committee have been removed from the educational grant review and approval process to ensure that Allergan only provides independent educational grants based on scientific and educational merit of the proposed activity.

DOES AN ORGANIZATION HAVE TO BE AN ACCREDITED CME/CE PROVIDER TO RECEIVE GRANT FUNDING?

Allergan considers grant requests for both accredited and non-accredited medical education; however, a preference will be given to accredited educational activities. Please note that requests for accredited activities that do not meet the accreditation or certification standards of ACCME, AOA, AAFP, AMA, and ADA CERP and/or are associated with a TI, it is preferred that all grant requests are submitted by the following, but are not limited to: Teaching Institution’s Central CME Office, COPE administrator, CE Provider, Patient Advocacy or Association/Society Group.
WHAT ACTIVITIES ARE CONSIDERED FOR FUNDING?

Allergan Medical Education is committed to supporting independent educational activities in specific therapeutic areas that foster increased understanding of scientific, clinical or healthcare issues and that serve to improve patient care.

All grants are awarded at Allergan’s sole discretion. Approval of grant funding is never related to or conditioned upon past prescriptions or purchases of Allergan products. Furthermore, Allergan does not offer or provide educational grants to encourage or to reward the prescription, purchase, order or recommendation of Allergan products.

Grants are awarded to support medical education activities, scientific conferences, development of health care publications, and other legitimate educational and scientific activities. Grant proposals must identify specific activities, or a series of activities, that occur over a specified period of time for which funding is requested. Eligible grants may include:

- **Live educational programs** that are advertised and open to a broad audience. A broad audience is defined as one which extends beyond the employees of a single institution or practice group.
- **Educational publications and other types of enduring materials** (e.g. CD-ROM/DVD, printed material, online educational activities, etc.) that are available to a broad audience beyond employees of the requesting institution
- **Fellowships**
- Programs from organizations whose mission is to improve patient care and health outcomes, such as **Patient Support or Patient Advocacy Groups**

WHAT TYPES OF GRANTS ARE GENERALLY NOT CONSIDERED FOR FUNDING?

Allergan will NOT provide medical education grants for the following:

- Grants to individual physicians or group practices
- Grants that are intended to directly and commercially promote Allergan products
- Funding for activities that have already occurred
- Research grants, including Investigator Initiated Trials and Research Fellowships. For information on Investigator Initiated Trials, please contact Allergan’s Global Medical Affairs at www.allerganresearchgrants.com or call 714-246-4188.
• Charitable Contributions. Please contact your Allergan representative for questions regarding charitable contributions. If you seek funding for a charitable contribution exceeding $5,000, you may contact the Allergan Foundation at www.allerganfoundation.org.

• Capital campaigns/building funds/equipment

• Service contracts

• Entertainment (e.g., holiday parties, recognitions/retirement dinners, etc.)

• Capital or operating expenses (e.g., office or computer equipment, staff, medical library resources etc.)

• Grants that seek funding only for promotional exhibits or display space

• Travel fellowships

• Journal Clubs

• Textbooks

WHAT IN-KIND PRODUCTS MAY I REQUEST THROUGH A MEDICAL EDUCATION GRANT?

Allergan may only provide in-kind product in connection with an educational grant if the activity is conducted by an ACCME-accredited provider and/or if it is an independent medical education activity conducted for the education of residents, fellows or other physicians in training. The following products may be requested:

• Botox® Cosmetic vials

• Botox® Therapeutic vials

• Juvéderm® Ultra XC and Ultra Plus XC syringes

• Juvéderm® Voluma XC syringes

• EMG Needles

• Anatomical Models (for Neurosciences only)

WHEN ARE GRANT REQUESTS ACCEPTED?

Grant requests are accepted and approved throughout the year. Requests for grant funding must be submitted at least eight (8) weeks before the scheduled activity start date.
WHAT IS ALLERGAN’S STANDARD GRANT REVIEW/PROCESSING TIME?

Review times vary from grant to grant; however, our normal grant processing time is a minimum of 8 weeks.

HOW CAN I FIND THE STATUS OF MY GRANT REQUEST?

Log into the Grant Management System for the current status of each request you have submitted.

HOW TO ACCESS YOUR LEGACY GRANT:

Enter your User ID from the former grant management system and enter the following (password is case sensitive): **Password1**

If you require assistance, please contact our Grants Help Desk at (866) 257-0272.

For technical assistance with the grant management system, please call us toll-free at 866/257-0272 or email us at vtsupport@envisionpharma.com

WHEN CAN WE EXPECT PAYMENT ONCE THE GRANT HAS BEEN APPROVED?

You can expect a check approximately four (4) weeks after Allergan has received the signed Letter of Agreement. All parties (i.e., Provider and Educational Partner, if applicable) must sign the Letter of Agreement in order for payment to be issued.

WHAT IS A “REQUEST FOR ADDITIONAL INFORMATION” AND HOW MUCH TIME DO I HAVE TO RESPOND?

A Request for Additional Information is made when additional information is needed to consider your grant request. The request will be sent via email to the contact listed in the grant request. If the Allergan Medical Education Department has not received the requested information within 10 business days of the follow-up request, the grant request will be declined.

MAY ALLERGAN FIELD REPRESENTATIVES ASSIST WITH SUPPLEMENTAL DISTRIBUTION OF INVITATIONS?

A provider may request Allergan’s support in the supplemental distribution of invitations associated with a medical education activity for healthcare professionals. The provider must request in writing Allergan’s assistance with the distribution of any materials at the
time the organization submits their grant request (there is a section in the grant application template that records your request for assistance). Allergan representatives may not be the primary method of distribution of invitations. Allergan is unable to assist with more than a 30% subset of the total amount of invitations to be distributed by the provider.
WHAT DO I DO IF THE SCOPE OF MY ACTIVITY CHANGES AND I WOULD LIKE TO REQUEST ADDITIONAL GRANT FUNDING?

Requests for additional funding must be submitted and approved by Allergan before the activity commences. In order to request additional funds, please submit a new grant request and identify the following:

- Reference to the original grant request ID# and activity title
- Reason for request for additional funding
- Amount of additional funding
- Updated, detailed budget

WHAT IF I HAVE MY OWN LETTER OF AGREEMENT?

All programs supported by an Allergan Medical Education grant must abide by the Letter of Agreement issued by Allergan. If you have any questions on the agreement terms, please contact the Allergan Medical Education Department at 866-257-0272.

WHAT IS RECONCILIATION?

At the conclusion of your Allergan-funded activity, the grant recipient is required to submit information detailing the audience reach, outcomes level, use of funds, and other pertinent information to verify the grant award was used in the manner in which it was intended. Upon activity conclusion, you will receive an email notification that the activity reconciliation is due. If we do not receive reconciliation within 90 calendar days of the activity end date, you will be prevented from submitting grant requests until the reconciliation is received. Allergan reserves the right to request receipts to support the activity expenses specified in the grant reconciliation.

NATIONAL PAYMENT TRANSPARENCY ACT

On February 8, 2013, the Centers for Medicare and Medicaid Services (CMS) published the final rule to implement section 6002 of the Affordable Care Act. CMS is now calling this the “National Physicians Payment Transparency Program: OPEN PAYMENTS.” This is also commonly known as the “Sunshine Act”

This final rule requires pharmaceutical and medical device manufacturers to report to CMS payments and transfers of value made to:

- Any physician licensed in the United States and/or
• A specific list of Teaching Institutions (TI) as designated by CMS

Beginning August 1, 2013, in order to comply with this new regulation, Allergan began capturing all payments and other Transfers of Value made to physicians and TIs. In addition, these payments and other Transfers of Value will be submitted to CMS annually. CMS intends to make this information publically available annually.

CMS has established a public website called “National Physician Payment Transparency Program: OPEN PAYMENTS” and can be viewed at: http://go.cms.gov/openpayments.

PLEASE CONSIDER THE FOLLOWING CRITERIA WHEN APPLYING FOR A GRANT:

• For activities that meet the accreditation or certification requirements and/or standards for Continuing Education by the Accreditation Council for Continuing Medical Education (ACCME), American Osteopathic Association (AOA), American Academy of Family Physicians (AAFP), American Medical Association (AMA), American Dental Association Continuing Education Recognition Program (ADA CERP), only buffet or box meals for attendees may be supported as food and beverage expense, and there will be no reporting requirements.

• For activities that are accredited by ACCME, AOA, AAFP, AMA, ADA CERP and are associated with a U.S. TI, only buffet or box meals for attendees may be supported as food and beverage expense, and the total grant payment (i.e., monetary and in-kind contribution) must be reported to the TI.

• For activities that do not meet the accreditation or certification requirements and/or standards of ACCME, AOA, AAFP, AMA, ADA CERP, all indirect payments (faculty honoraria, travel, meals) to all Covered Recipients associated with this activity must be reported. If Allergan funds were applied to Covered Recipient attendee meals, only box or buffet meals may be supported, AND reporting is required if less than 50 attendees were present. Additionally, it is preferred that grant requests be submitted by the following but not limited to: COPE Administrator, CE Provider, Patient Advocacy or Society Group.

• For activities that do not meet the accreditation or certification standards of the ACCME, AOA, AAFP, AMA, ADA CERP, and are associated with a TI, the total grant payment (i.e., monetary and in-kind contribution must be reported to the TI). Additionally, all indirect payments (faculty honoraria, travel, meals) to all Covered Recipients associated with this activity must be reported. If Allergan funds were applied to Covered Recipient attendee meals, only box or buffet meals may be supported, AND reporting is required if less than 50 attendees were present. It is preferred that grant requests are submitted by the TI’s Central CME Office.
WHAT WILL I BE RESPONSIBLE FOR REPORTING ON THE RECONCILIATION AS A RESULT OF THE “NATIONAL PHYSICIAN PAYMENT TRANSPARENCY PROGRAM: OPEN PAYMENTS” (COMMONLY KNOWN AS THE “SUNSHINE ACT”)?

Beginning August 1, 2013, in order to comply with this new regulation, Allergan began capturing all payments and other transfers of value made to physicians and TIs. In addition, these payments and other transfers of value will be submitted to CMS annually.

Grants that have received funding from Allergan, either fully or partially, whose activity end date was after August 1, 2013, may be required as part of the recent regulation to complete an additional reconciliation template in the grant management system including but not limited to, milestone payments, buffet or box meals for less than 50 attendees, and/or in-kind product provided after August 1, 2013.

Once the grant management system has been updated and you are notified that you can complete the new reconciliation process, the following will apply:

- For activities that meet the accreditation or certification requirements and/or standard for continuing education of one of the following: ACCME, AOA, AAFP, AMA, ADA CERP, there will be no additional reporting requirements.

- For activities that do not meet the accreditation or certification requirements and/or standards of ACCME, AOA, AAFP, AMA, ADA CERP, all indirect payments (faculty honoraria, travel, meals) to all Covered Recipients associated with this activity must be reported. If Allergan funds were applied to Covered Recipient attendee meals, only box or buffet meals may be supported, AND reporting is required if less than 50 attendees were present. The following information is required to be reported to Allergan within 90 calendar days of the activity end date including but not limited to:
  - Covered Recipient (CR) type: physician or TI
  - CR Full name
  - Complete business address
  - National Provider Identifier Number (NPI) and/or license number
  - Specialty (if applicable)
  - Form of payment or transfer of value (TOV)
  - Nature of payment or TOV

For questions regarding the “National Physician Payment Transparency Program: OPEN PAYMENTS” (commonly known as the “Sunshine Act”), please visit: http://go.cms.gov/openpayments. This website provides helpful information including an overview of the program, a description of how the program works, fact sheets for
physicians and teaching institutions, and a Frequently Asked Questions link available at: 

You may also contact Allergan Customer Support at: 877-509-5442 (7:00 A.M. to 4:00 P.M. Pacific Time) or www.allergancustomersupport.com.

Other resources are listed at the end of the document for your reference and review.

**TECHNICAL**

**CORRECTING THE INTERNET EXPLORER SETTINGS**

If you are using Internet Explorer, it may be necessary to alter your download settings in order to see the PDF printout. If nothing happens when you click “Print,” please follow the instructions below:

1. Select and click on “Internet Options” from the “Tools” menu
2. Select the tab called “Security” and then the “Custom Level”
3. Scroll down to the “Downloads” section and make sure all three options (Automatic prompting for downloads; File download; Font download) are set to “Enable,” then click “OK”

**HOW DO I SAVE AN APPLICATION?**

A successful save will display a message on the screen stating the application has been saved, and the system will provide you with a temporary tracking number.

Once in the system, you will see a list of selections below your login name on the left side of the webpage.

- You can locate a saved application by either clicking on “Task List” or “All My Applications.” Note: If you have applications pending, they will be listed as tasks waiting for you. You will be able to view those applications under the “Task List” tab.
- Within the “Actions” column, there are links called “Complete Grant” or “View Grant”
- Click on the link to view your application
- You may click on “Tracking Number” to open the entire application
**HOW DO I PRINT OR REFRESH MY APPLICATION?**

You may generate a PDF of your entire application at any time. The “Print” icon is located in the “Application Toolbar” next to the “Save” and “Submit” buttons.

**HOW DO I ATTACH A DOCUMENT?**

1. Click on the “Attachments” tab at the top of the webpage
2. Click the paperclip icon to attach a required document of click the “Post New” to attach an additional attachment
3. A pop-up window will display, click “Browse” to locate your attachment
4. Click “OK” to save your attachment or “Cancel” to go back to the previous screen
5. Required attachments are identified by an asterisk (*)

**WHAT IF MY NEEDS ASSESSMENT, AGENDA, BUDGET, ETC. DO NOT FIT INTO THE ALLOTED SPACE?**

Documentation may be uploaded at the end of the Grant Request Form prior to submission.

**WHAT FILE FORMAT MUST I USE FOR MY ATTACHMENTS?**

Allergan prefers all documentation to be provided in PDF files.

**LOCKOUT CONFIGURATIONS**

- User accounts will lock out after five (5) invalid login attempts
- You may contact Grant Management System support by clicking on the “Contact Us” link on the left side of the homepage screen
- Select “Technical Support” in the “Address to” field
- Select your subject and provide a message

**LOCKOUT AFTER FAILED ATTEMPTS**

If you are locked out of the system after (5) failed login attempts, you will need to request a new password.
After receiving a new password, close all open browser windows, re-open and try again. You may also need to clear any cached pages from your browser. Please follow the instructions below if you continue to receive a “Failed Login” message.

1. On the browser menu, click on “Tools”
2. Click on “Internet Options”
3. On the “General” tab under “Browsing History” click on the “Delete” button
4. Mark the box for “Temporary Internet Files” and click the “Delete” button once again
5. Click “OK”

IT IS IMPORTANT THAT YOU USE THIS “PRINT” BUTTON AND NOT THE PRINTING FUNCTION OF YOUR WEB BROWSER

- You may refresh the page at any time after you have clicked on “Save”
- “Save” and “Submit,” as well as the “Print” icons, are located on the right-hand side of the Application Toolbar
- The “Refresh” icon is located on the right-hand side of the Application Toolbar

WHOM SHOULD I CONTACT IF I HAVE ANY QUESTIONS?

You may contact the Allergan Medical Education Department at 866-257-0272 or via email at IR-AGNMedEd@allergan.com.