Implementation of Outpatient Clinical Pharmacy Services: Award for A Pharmacist and/or Pharmacy Technician

POLICIES AND GUIDELINES

June 1, 2016
I. IMPLEMENTATION OF OUTPATIENT CLINICAL PHARMACY SERVICES
The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis (CF) and provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care. Current CFF Center Accreditation guidelines recommend having a pharmacist as a member of the CF Center multidisciplinary team. The CFF Strategic Investment Committee recently recommended developing outpatient pharmacy services at CFF-Accredited Care Centers and Affiliate programs.

This Award is designed to facilitate development and implementation of outpatient clinical pharmacy services at CFF-Accredited Care Centers and Affiliate programs throughout the U.S. The focus of this Request for Applications is to provide seed funding and travel support for a pharmacist and/or a pharmacy technician to implement outpatient clinical pharmacy services which includes but is not limited to: 1) ensuring safe, appropriate, cost effective therapy 2) assessing drug dosing, drug-drug interactions, drug allergies, adverse drug reactions 3) advising on CF and non-CF medication therapy 4) providing drug information and/or counseling to patients and/or caregivers 5) serving as liaison between CF clinic, hospital or institution, community practitioners, and payers.

For those programs that have an established outpatient clinical pharmacy service, this award is not intended to replace the support already in place. However, CFF will consider an application from such programs to secure additional funding for a pharmacist and/or pharmacy technician to optimize the service.

II. BACKGROUND
A wide range of medications are utilized on both an acute and chronic basis to manage cystic fibrosis. Medication regimens often include oral antibiotics, aerosolized antibiotics, aerosolized mucolytics, pancreatic enzymes, and insulin (Rowe, S.M. et al., Cystic fibrosis. N Engl J Med, 2005. 352(19): p. 1992-2001). Due to the complexity of the disease and medication management, a multi-disciplinary team approach to care is recommended by the Cystic Fibrosis Foundation (CFF) for patients with CF (Yankaskas, J.R., et al., Cystic fibrosis adult care: consensus conference report. Chest, 2004. 125(1 Suppl): p. 1S-39S.). According to the European, UK, and Australian Standards on of care for patients with CF, the pharmacist is considered primary members of the multi-disciplinary CF care team. (Kerem, E., et al., Standards of care for patients with cystic fibrosis: a European consensus. J Cyst Fibros, 2005. 4(1): p. 7-26.; Standards for the Clinical Care of Children and Adults with cystic fibrosis in the UK, Cystic Fibrosis Trust 2011; Bell, S.C. et al. Cystic Fibrosis Standards of Care, Australia, Cystic Fibrosis Australia 2008). Sterner-Allison published a single center’s experience regarding pharmacist’s involvement in CF care at Emory University (Sterner-Allison, J.L., Management of adolescent and adult inpatients with cystic fibrosis. Am J Health Syst Pharm, 1999. 56(2): p. 158-60.). The authors reported that pharmacist were involved in a broad range of patient care activities ranging from patient education to therapeutic drug monitoring. Anstead and colleagues demonstrated that 52% of their adult patients were unable to access >1 medication prescribed by their CF provider. Ninety-eight percent of these patients were able to access their prescribed medication(s) via pharmacist & pharmacy technician as CF team members (Anstead, M., et al. Identifying and overcoming barriers to adherence at an adult cystic fibrosis center by the addition of a pharmacist. Pediatr Pulmonol, 2014. Abstract 511: p. 402). In a survey conducted by Bhakta et al., 100% of the CF center directors that do not have a dedicated CF pharmacist believe one would add value to the multidisciplinary team. (Bhakta, Z., et al. A Survey of the Pharmacist’s Role at Provided Care at U.S. Cystic Fibrosis Foundation (CFF) – accredited Centers. Pediatr Pulmonol, 2013. Abstract 518: p. 396) Thus, it is becoming increasingly clear that a pharmacist (and a pharmacy technician) can be key members of the multi-disciplinary team caring for patients with CF.
III. PHARMACIST AND/OR PHARMACY TECHNICIAN ROLE DESCRIPTION

The overall purpose of this Award is to promote the development and implementation outpatient clinical pharmacy services at CFF-Accredited Care Centers and Affiliate programs throughout the U.S.

We envision that funding will be used to secure a pharmacist and/or a pharmacy technician who will be responsible for the development and implementation of outpatient clinical pharmacy services which includes but is not limited to: 1) ensuring safe, appropriate, cost effective therapy 2) assessing drug dosing, drug-drug interactions, drug allergies, adverse drug reactions 3) assessing access and adherence to drug therapy regimens 4) advising on CF and non-CF medication therapy 5) providing drug information and/or counseling to patients and/or caregivers 6) serving as liaison between CF clinic, hospital or institution, community practitioners, and payers.

Specific tasks would include the following:

- Development
  - Development of a clearly elucidated strategy to provide outpatient clinical pharmacy services within the CFF-Accredited Care Center or Affiliate program.

- Implementation
  - The pharmacist and/or pharmacy technician must become integral members of the outpatient multidisciplinary care team.

- Assessment
  - Development of a clear plan to assess the impact of the aforementioned outpatient clinical pharmacy services.

a. Eligibility

Award for a pharmacist and/or a pharmacy technician must go towards salary support and travel for a pharmacist and/or pharmacy technician who will focus on providing outpatient clinical pharmacy services to the CFF-Accredited Care Center and Affiliate program.

b. Qualifications

Some training and expertise in cystic fibrosis care and treatment (e.g., completion of the ACPE-Accredited CF 101 Webinar, acceptance to or completion of CFF Mentorship or Mentee program) is preferred, but not mandatory.

The Award for a pharmacist and/or a pharmacy technician is available to all CFF-accredited Care Center and Affiliate programs:

- Smaller centers with pediatric and adult programs that share components of the multi-disciplinary team should consider applying for one pharmacist and/or pharmacy technician for the entire center.
- Centers with distinct pediatric and adult care teams should consider applying for an award at the program level, i.e. if both programs are interested in implementing the outpatient pharmacy services, then consider submitting two separate applications.

c. Requirements

1. The principal investigator must be a CF center director, program director, or an associate director.
2. Supported personnel will commit to providing outpatient clinical pharmacy services. He/she will collect data on the impact of the clinical pharmacy services provided and indicate in the patient registry on the annual form that the patient has been assessed by the pharmacist. Subsequent assessments and follow-up, provision of interventions, and their outcomes will be documented in the annual progress reports.
3. Sites receiving Awards will submit an annual progress report to document progress and fulfillment.
of award requirements including documentation of the clinical pharmacy services provided and compilation of data on subsequent assessments, interventions, and outcomes.

a. Year 1 Progress Report should provide specific details on the contributions by awardee to implement outpatient clinical pharmacy services and follow-up.

b. Year 2 Progress Report: In addition to the contributions of the awardee, plans for program sustainability should be described.

c. Year 3 Final Report

4. Funding for year 2 and year 3 is contingent upon progress documented in the annual reports.

d. Review Process

To apply for the Award for a pharmacist and/or a pharmacy technician, programs will need to complete an application form, budget, and budget justification. The pharmacist and/or pharmacy technician do not have to be identified at the time of the application. Award applications will be peer reviewed.

Applicants may apply for one of the following three awards:

1. Salary and travel support for a pharmacist. This may be most appropriate for programs without any outpatient pharmacist presence in the outpatient clinic.

2. Salary and travel support for a pharmacist and a pharmacy technician. This is another option for programs without any outpatient pharmacist presence in the outpatient clinic. As indicated this award splits the salary and travel support between the pharmacist and the pharmacy technician.

3. Salary and travel support for a pharmacy technician. This may be most appropriate for centers that already have a sustainable model for outpatient pharmacist support and see the value in adding a pharmacy technician to assist the pharmacist.

IV. SUBMISSION INFORMATION

APPLICATION DEADLINE: AUGUST 1, 2016 at 5:00pm (Eastern)

Online submission at ProposalCENTRAL: https://proposalcentral.altum.com/

CFF reviews applications electronically, and only the documents submitted online will be reviewed. The Face Page (system-generated upon submission of the application) must be signed and emailed to grants@cff.org by the same deadline. Late applications will not be accepted.

General Timeline

Application Deadline........................................August 1, 2016
Review by CF Foundation....................................early October 2016
Applicant Notified...............................................mid October 2016
Award Letters Issued.........................................late October 2016
Start Date.........................................................November 1, 2016

V. APPLICATION COMPONENTS

There are a total of four (4) required attachments and one (1) optional set of attachments in the application. Templates are provided for download on proposalCENTRAL in Section 2: Download Templates & Instructions. Completed templates should be uploaded in Section 8. At the top of each page, type the Principal Investigator’s name.

a. Face Page

The Face page is populated automatically with data entered (applicant’s name, institution, title of
application, etc.) in the online application. After you hit the “Validate” button for your completed application, you will be able to download the Face Page. The Face Page must be signed by the Principal Investigator and Authorized Institutional Official. Scan and email the signed Face Page to grants@cff.org by the deadline. No hardcopy is required.

b. Budget
Budget and budget justification for up to 3 years for each of the three award options described above:

1. Pharmacist:
   i. >100 patients in the registry [Maximum $150,000 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]
   ii. <100 patients in the registry [Maximum $105,000 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]
   iii. <50 patients in the registry [Maximum $75,000 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]

2. Pharmacist and pharmacy technician:
   i. >100 patients in the registry [Maximum $120,000 over 3 years to support the salary and benefits for the pharmacist AND maximum $60,000 over 3 years to support the salary and benefits for the pharmacy technician, plus 8% indirect costs]
   ii. <100 patients in the registry [Maximum $90,000 over 3 years to support the salary and benefits for the pharmacist AND maximum $45,000 over 3 years to support the salary and benefits for the pharmacy technician, plus 8% indirect costs]
   iii. <50 patients in the registry [Maximum $60,000 over 3 years to support the salary and benefits for the pharmacist AND maximum $30,000 over 3 years to support the salary and benefits for the pharmacy technician, plus 8% indirect costs]

3. Pharmacy technician
   i. >100 patients in the registry [Maximum $75,000 over 3 years to support the salary and benefits for the pharmacy technician, plus 8% indirect costs]
   ii. <100 patients in the registry [Maximum $52,500 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]
   iii. <50 patients in the registry [Maximum $32,500 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]

Travel and Registration Fees: In addition, up to $2,000 per year may be requested for travel and registration fees to attend the Annual NACFC unless prior approval from CFF has been obtained. Travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses.

The applicant can choose to allocate the budget request as appropriate to their local circumstances. For example, the first year budget request for the pharmacist (option #1 above) could be $30,000 for planning with a hire or adjustment in FTE later in year 1, and then a higher amount ($60,000) requested for years 2 and 3. Alternatively, a center may already have an individual identified for the pharmacist and/or pharmacy technician role and choose to budget $50,000 equally over 3 years or $150,000. The table below illustrates just two examples.

<table>
<thead>
<tr>
<th>Option #1</th>
<th>Direct Costs</th>
<th>Travel and Registration Fees</th>
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<td>Year 1</td>
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<tr>
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<td>$2,000</td>
<td>$4,160</td>
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<tr>
<td>Year 3</td>
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<td>$4,160</td>
<td>$56,160</td>
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<tr>
<td><strong>Option #2</strong></td>
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</table>
c. **Current Circumstances and Plans:**
   1. Provide a brief description of the patient population at the care center. (Maximum-half page)
   2. Describe what your current staff is doing to implement outpatient clinical pharmacy care services. How would a pharmacist and/or a pharmacy technician improve your implementation of outpatient clinical pharmacy care services at your center or program? (Maximum-one page)
   3. Describe your plan to utilize a pharmacist and/or a pharmacy technician including:
      i. How they will implement outpatient clinical pharmacy services.
      ii. If the pharmacist and/or pharmacy technician is unfamiliar with CF, what training plan will you put in place to provide the basics needed for them to function effectively in the clinic.
      iii. How additional person(s) with pharmacy expertise will support your multidisciplinary team in providing care for your patients.
   4. Describe your plan to sustain this position(s) following this 3-year award. (Maximum-two pages)

d. **Verification of Applicant Institution’s Tax Status**
   Per Internal Revenue Service (IRS) stipulations for grant-making organizations, CFF’s Grants and Contracts Office must have a copy of the Applicant Institution’s current W9 and 501(c)3 letter, or other documentation verifying its Federal tax status, on file. CFF’s Grants and Contracts Office will not issue Award Letters to Grantees if these documents are not on file.

e. **Optional:**
   If the individual who will serve as the pharmacist and/or pharmacy technician is known at the time of submission, please submit the resume/CV and statement of qualifications. Upload the resume/CV as a supporting document.

VI. **ONLINE APPLICATION INSTRUCTIONS**

**DEADLINE: August 1, 2016 by 5:00 pm (Eastern)**

a. **Registration and Log In:** If you are a first time user, register at proposalCENTRAL, https://proposalcentral.altum.com. If you have registered before, and cannot remember your password, click on the “Forgot Password” button.

   - Select the gray tab labeled **GRANT OPPORTUNITIES.**
   - Locate **Cystic Fibrosis Foundation** in the list.
   - The **APPLY NOW** button will be visible next to the program name: “Implementation of Outpatient Clinical Pharmacy Services” Click on that button to begin.

b. **Start and Continuation:** Application Sections are listed in the gray menu box to the left of the screen. The sections need not be complete sequentially. Click the red **SAVE** button after completing each section.

   Enter your project title as **“Award for a Pharmacist and/or Pharmacy Technician”**

   You may stop at any point in the application, each time remembering to SAVE your entries, and return to continue, revise, and upload until you have actually hit the SUBMIT button.

   When you log in to continue, click on the blue tab, **MANAGE PROPOSALS**, and then the Edit button next
to your application’s title. Do not start a new application.

c. **Designating Access to Another:** Complete Section 3 online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the full name and email address and in the Permissions column, then use the pulldown menu to select the type of access you wish to give.

d. **Final Steps**

1. **Validate:** Upon completing your application, click on the blue VALIDATE button on the main screen. Attend to any omissions/errors as prompted onscreen, if prompted, and validate again.
2. **Print face page:** After validation, follow the prompts to print the system-generated face page.
3. **Submit:** Click on the gray button with blue lettering. CFF will not receive your application until and unless you have submitted it. You will receive an email confirmation from proposalCENTRAL (not from CFF) that your application has been successfully uploaded. This email will be your only acknowledgment. If you do not receive it, please contact proposalCENTRAL immediately to ensure that the application is properly submitted.
4. **Sign, scan and email the face page** to grants@cff.org by the deadline date, November 9, 2016. The Program Director, as well as the authorized institutional official must sign it. No hard copy is necessary.

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For technical support with the online application:
Proposal CENTRAL at pcsupport@altum.com or 800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

For program/content information:
CFF Grants & Contracts at grants@cff.org or 301-841-2614