



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

POLICIES AND GUIDELINES

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Application Deadline: December 3, 2018

I. ABOUT THE CYSTIC FIBROSIS FOUNDATION

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.

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). Two studies by Zobell et al, document the benefits of a CF pharmacist and integrated CF pharmacy team. In the first published study ranging from 2014 to 2016, the dedicated CF clinic pharmacist and integrated CF pharmacy team both demonstrated significant improvements in the likelihood of monthly dornase alfa adherence (OR = 2.36, p<0.001 and OR = 2.82, p<0.001, respectively). (Zobell JT, et al. Impact of pharmacy services of cystic fibrosis medication adherence. *Pediatr Pulmonol*. 2017; 52:1006-1012. In the second study, the date range was extended to 2017, the dedicated CF pharmacist and integrated CF pharmacy team continued to show significant improvements in the likelihood of monthly dornase alfa adherence (OR = 1.86, p<0.001 and OR = 2.25, p<0.001, respectively), as well as a significant decrease in odds of monthly hospitalizations by improving adherence (OR = 0.418, p<0.001) and significant negative relationship between adherence and hospitalizations (Pearson correlation coefficient -0.37, p<0.018). (Zobell JT et al. Impact of pharmacy services on cystic fibrosis medication adherence: Update. *Pediatr Pulmonol*. 2018; 53:694-695. Thus, it is becoming increasingly clear that a pharmacist and/or a pharmacy technician can be vital members of the multi-disciplinary team caring for patients with CF.

III. IMPLEMENTATION OF OUTPATIENT CLINICAL PHARMACY SERVICES AWARD OVERVIEW

Current CFF Center Accreditation guidelines recommend having a pharmacist as a member of the CF Center multidisciplinary team. The 2016 CFF Strategic Investment Committee 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 (RFA) is to provide seed funding and travel support 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:

- Ensuring safe, appropriate, cost effective therapy;
- Assessing drug dosing, drug-drug interactions, drug allergies, adverse drug reactions;
- Advising on CF and non-CF medication therapy;
- Providing drug information and/or counseling to patients and/or caregivers;
- Serving as liaison between CF clinic, hospital or institution, community practitioners, and payers;
- Assessing medication adherence and develop strategies to improve adherence; and
- Evaluating and assisting in ensuring access to medications.

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 clinical pharmacy services.

General Guidelines and Eligibility:

- The principal investigator must be a CF center director, program director, or an associate director.
- 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.
- 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.
 - Year 1 Progress Report should provide specific details on the contributions by awardee to implement outpatient clinical pharmacy services and follow-up.
 - Year 2 Progress Report: In addition to the contributions of the awardee, plans for program sustainability should be described.
 - Year 3 Final Report
- Funding for Year 2 and year 3 is contingent upon progress documented in the annual reports.
- 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.

IV. 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.

Recent clinical studies have demonstrated the importance of having a pharmacist and/or pharmacy technician team to effectively deliver outpatient clinical pharmacy services. It is therefore recommended that applicants consider applying for both the pharmacist and pharmacy technician option, however, applications for a pharmacist only position or a pharmacy technician only position will be considered.

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.

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.

V. REVIEW AND AWARD

To apply for the Award for a pharmacist and/or a pharmacy technician, programs will need to complete an application form, budget, budget justification, and other supporting documents as outlined in Section #7. The pharmacist and/or pharmacy technician do not have to be identified at the time of the application. Applications will be reviewed by a peer review committee.

Applicants may apply for one of the following three awards:

- **Option 1 (Recommended):** 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.
- **Option 2:** Salary and travel support for a pharmacist. This may be most appropriate for programs without any outpatient pharmacist presence in the outpatient clinic.
- **Option 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.

Applications will be reviewed by a CFF ad hoc review committee. Funding decisions are based upon the availability of funds, responsiveness to the RFA and eligibility.

VI. SUBMISSION INFORMATION & GENERAL TIMELINE

Application Deadline: Monday, December 3, 2018 at 5:00 PM (Eastern)

Submit online through proposalCENTRAL: <https://proposalcentral.altum.com/>
(Refer to Section VII of these guidelines for specific submission instructions.)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at proposalCENTRAL will be reviewed. Late applications will not be accepted, and the deadline will not be waived.

General Timeline

Application Deadline _____	December 3, 2018
Committee Review _____	mid-February 2019
Applicant Notified _____	late February 2019
Award Letters Issued _____	early March 2019
Award Start Date _____	April 1, 2019

VII. APPLICATION GUIDELINES

Applications must be submitted online at proposalCENTRAL: <https://proposalcentral.altum.com/>

Documents should be typed using:

- Font: Times New Roman 12 or Arial 11
- Margins: No less than a half inch on each side

Note: When all the documents have been uploaded to proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence.

First-time applicants must register to create a user name and password for proposalCENTRAL and will need to complete a profile online before applying. If you are registered and cannot

remember your password, click on the “**Forgot Your Username/Password?**” link below the “**Application Login**” fields.

Award opportunities, including this Request for Application (RFA), are listed on the opening screen, but you must be logged in first to see them.

Select the gray tab labeled “**Grant Opportunities**” found in the upper right-hand side of the page.

Click on the light blue “**Filter by Grant Maker**” button to the left and scroll down to locate Cystic Fibrosis Foundation in the list.

Locate the listing for the “**Implementation of Outpatient Clinical Pharmacy Services**” program. Click on the “**Apply Now**” button in the column on the far right to open the application form.

Applicants may stop at any point but must click the “**Save**” button before exiting in order to save their work. When logging in to continue, click on the blue tab, “**Proposals**”, and then the “**Edit**” button.

- 1. Title Page:** Enter the title of your project as “**Award for a Pharmacist and/or Pharmacy Technician**”. Please indicate using the drop-down selection if the application is for Option 1: Pharmacist and Pharmacy Technician; Option 2: Pharmacist; or Option 3: Pharmacy Technician. Also, indicate if this is a resubmission of a previous proposal.
- 2. Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #7. Templates available include: Budget Detail, Budget Justification, Current Circumstances and Plans, and Appendix.
- 3. Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the “**Permissions**” column, use the pulldown menu to select the type of access you wish to give. Please note that only delegates who are granted “**Administrator**” rights can submit applications on behalf of the applicant. Check the “**Auto Notify**” box and then “**Save**”.
- 4. Applicant/PI:** If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, click the “**Edit Professional Profile**” button and follow the instructions. If a profile was not completed, enter the required information and click “**Save**”.
- 5. Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator’s (PI) institution will be preloaded as Lead Institution. If a profile was not completed, enter the required information and click “**Save**”. Be sure to use the full legal name of the institution.

6. **Budget Summary:** Fill in the start and end date and applicable amounts for each year of support requested by completing the online fields (Period 1, 2 & 3). Please follow below budget guidance for completing this section. **Note: The Budget Detail and Budget Justification templates downloaded in Section #2 need to be completed and uploaded in Section #7 for each year of the award.**
7. **Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above, in PDF format, as well as the additional upload only requirements. Complete the fields for the attachment type/description, select the attachment type from the drop-down menu, choose the file to be uploaded, and click “**Upload and Continue**” or “**Upload and Return**”. Do this for each attachment.
- A. **Budget Detail and Budget Justification (separate templates available for download)**
Fill out the Budget Detail and Budget Justification templates for each and all years of support requested. In the space provided on the templates, indicate the year or period as well as start and end dates for the proposed budget period. (Be sure the amounts entered in the Budget Detail match the amounts entered in the online budget summary in Section #6 above).

Budget Detail

Personnel - List the names and positions of all relevant personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of \$189,600. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

Travel – List the names and positions of all relevant personnel whom would be attending the Annual NACFC conference, unless prior written approval from CFF has been obtained. Travel expenses may not exceed \$2,000 per year. Registration fees associated with the NACFC conference are included in this \$2,000 limit and should be listed separately under “Other Expenses”. Travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses.

Other Expenses – If registration for NACFC is being requested please complete this section of the online budget summary and in the budget detail template.

The budget may be for up to three (3) years for each of the three award options described above:

- 1) Option 1: Pharmacist and Pharmacy Technician
 - a. >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]

- b. <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]
 - c. <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]
- 2) Option 2: Pharmacist only
- a. >100 patients in the registry [Maximum \$150,000 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]
 - b. <100 patients in the registry [Maximum \$105,000 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]
 - c. <50 patients in the registry [Maximum \$75,000 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]
- 3) Option 3: Pharmacy Technician only
- a. >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]
 - b. <100 patients in the registry [Maximum \$52,500 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]
 - c. <50 patients in the registry [Maximum \$32,500 over 3 years to support the salary and benefits for the pharmacist, plus 8% indirect costs]

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.

Option #1	Direct Costs	Travel and Registration Fees	Indirect Costs (8%)	Total
Year 1	\$50,000	\$2,000	\$4,160	\$56,160
Year 2	\$50,000	\$2,000	\$4,160	\$56,160
Year 3	\$50,000	\$2,000	\$4,160	\$56,160
Option #2				
Year 1	\$30,000	\$2,000	\$2,560	\$34,560
Year 2	\$60,000	\$2,000	\$4,960	\$66,960
Year 3	\$60,000	\$2,000	\$4,960	\$66,960

Budget Justification

Describe costs listed in the Budget Detail. Use major categories, such as Personnel, Travel, and Other Expenses. Justify all items and make sure amounts and figures listed in

the narrative are consistent with those listed in the Budget Detail(s).

B. Current Circumstances and Plans (template available for download)

- 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:
 - a. How they will implement outpatient clinical pharmacy services
 - b. How they program will incorporate the new team member(s) into the multidisciplinary care team and the specific tasks that might be offloaded, provided, and/or reallocated by adding a pharmacist and/or pharmacy technician.
 - c. 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.
 - d. 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)

C. Verification of Applicant Institution's Tax Status (upload as PDF documents)

The CFF Grants and Contracts Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution's W-9 and IRS documentation verifying the organization's Federal tax status. Awards are not issued prior to having these documents on file with the CFF Grants and Contracts Office.

D. Appendix (optional, upload as PDF documents)

If the individual who will serve as the pharmacist and/or pharmacy technician is known at the time of submission, as supporting documents, please submit the resume/CV and statement of qualifications.

8. PI Data Sheet: Fill in the required fields, save and exit.

9. Print Face Page: Follow the prompts on the screen to generate and print a Face Page. The Face Page will be populated automatically with data entered in the online application (applicant's name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official and uploaded in Section #7. Co-Principal Investigators, if any, are not expected to sign the Face Page. No hardcopy is required.

10. Validate: Upon completing the application, click on the “**Validate**” button. Attend to any omissions/errors if prompted onscreen, and then click “**Validate**” again.

11. Submit: Click on the blue button with white lettering . CFF will not receive your application unless the “**Submit**” button is clicked.

Confirmation: Applicants will receive an e-mail confirmation from proposalCENTRAL (not from CFF) that the Application was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure that your submission was submitted and processed.

For technical support with the online application:

proposalCENTRAL 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

VIII. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: Monday, December 3, 2018 at 5:00 PM (Eastern)

Applications must be submitted online at proposalCENTRAL: <https://proposalcentral.altum.com/>

Face Page, which includes:

- Signatures
 - Principal Investigator (Co-PI's are not required to sign)
 - Program Co-Director, if applicable
 - The Official authorized to sign on behalf of the Awardee Institution
- Applicant/PI information (online)
- Complete Institution and PI Contact information, including correct mailing address (online)

Supporting Documents:

- Budget Detail for each year – (upload)
- Budget Justification for each year – (upload)
- Current Circumstances and Plans – (upload)
- Signed Face Page
 - Principal Investigator and Authorized Institutional Official signatures required – (upload)
- Verification of Applicant Institution's Tax Status – (upload)
 - W-9 (U.S. applicants)
 - Federal (IRS) tax status letter
- Optional – (upload if applicable)
 - Resume/CV
 - Statement of Qualifications