

Program Name: Implementation of Outpatient Clinical Pharmacy Services: Award for A Pharmacist and Pharmacy Technician 2022

Brief Program Overview/Description: 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.

Funding Amount: The allowable award amount is based on program size. Applicants working at a care center with >100 patients in the CF patient registry may request up to \$190,000 over three (3) years to support the salary and benefits for a Pharmacist AND a Pharmacy Technician, plus twelve (12) percent indirect costs. Applicants working at a center with <100 patients in the registry may request funding of up to \$145,000 total spread out over a period of three (3) years, plus an additional twelve (12) percent indirect costs. Applicants working at a center with <50 patients in the registry may request funding of up to \$100,000 total spread out over a period of three (3) years, plus an additional twelve (12) percent indirect costs. Additional information can be found in Section III below.

Eligibility:

- Applicants must be U.S. Citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application)
- The principal investigator must be a CF center director, program director, or an associate director.
- 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.
- Please refer to Section IV below for additional eligibility requirements.

Key Dates:

Published	February 7, 2022 Updated April 7, 2022
Full Application Deadline	April 26, 2022*
Committee Review Date	Late May 2022
Notification to Applicants	June 2022
Earliest Start Date for Awarded Projects	July 1, 2022

Table of Contents

- I. About the Cystic Fibrosis Foundation
- II. Program and Award Overview
- **III.** Funding Amounts
- IV. Eligibility
- V. Mentorship Requirements
- VI. Goals of Research Currently of Interest to CFF/Priority Areas
- VII. Review and Award
- **VIII. Submission Information**
- IX. Letter of Intent Guidelines
- X. Full Application Guidelines
- XI. Other Information
- XII. Contact Information

^{*}We highly encourage all applicants to pre-register their profile, institution, contacts, and Title of their application at least two weeks prior to the application deadline. This will help to ensure the CFF Grants & Contracts Team is able to assist all applicants with any potential system-related queries prior to the Application Deadline.

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. Program and Award Overview

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. In a study conducted by Autry and colleagues, patients (pediatric and adult) whom enrolled in specialty pharmacy care services increased their weight (kg). (Autry E, Ferrante A, Ramsey PL, Kuhn RJ. Effect of a total care specialty pharmacy model on cystic fibrosis clinical outcomes. Pediatr Pulmonol. 2017;52(47):293-294.). Wright and colleagues demonstrated the time from when a prescription was written to filled was decreased by 9 days (p=0.028) when the prescription was filled at their health-system specialty pharmacy after incorporating a clinical pharmacist into the multidisciplinary CF care team. (Wright BA, Singh SB, Schultz JL, et al. Impact of pharmacy services on cystic fibrosis transmembrane conductance regulator modulator prescribing at a pediatric cystic fibrosis center. Pediatr Pulmonol. 2019;54(10):1591-1595.) The integration of a pharmacist and pharmacy technician as core members of the multidisciplinary CF care team resulted in a decrease in time from a positive *Pseudomonas aeruginosa* culture to the patient receiving inhaled tobramycin

by 6 days (p=0.005). (Burrus TE, Vogt H, Pettit RS. Impact of a pharmacy technician and pharmacist on time to inhaled tobramycin therapy in a pediatric cystic fibrosis clinic. Pediatr Pulmonol. 2021 Sep;56(9):2861-2867.

Thus, it is becoming increasingly clear that a pharmacist and a pharmacy technician can be vital members of the multi-disciplinary team caring for patients with CF.

Award Details:

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;
- Assess with patient/family the sustainability of the medication regimen and develop strategies to improve medication management; 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 pharmacy technician to optimize clinical pharmacy services.

III. Funding Amount

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

- 1) Pharmacist and Pharmacy Technician
 - a. >100 patients in the registry: A maximum of \$190,000 over 3 years to support the salary and benefits for a pharmacist AND a pharmacy technician, plus 12% indirect costs/
 - b. <100 patients in the registry: A maximum of \$145,000 over 3 years to support the salary and benefits for a pharmacist AND a pharmacy technician, plus 12% indirect costs.
 - c. <50 patients in the registry: A maximum of \$100,000 over 3 years to support the salary and benefits for a pharmacist AND a pharmacy technician, plus 12% indirect costs.

The applicant can choose to allocate the budget request as appropriate to their local circumstances. The CF Foundation recommends a 2:1 split of the award amount between the pharmacist and pharmacy technician. Additionally, the applicant may choose to allocate the funding as appropriate over the three-year period. For example, the first-year budget request for the pharmacist 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 (12%)	Total
Year 1	\$50,000	\$2,000	\$6,240	\$58,240

Year 2	\$50,000	\$2,000	\$6,240	\$58,240
Year 3	\$50,000	\$2,000	\$6,240	\$58,240
Option #2				
Year 1	\$30,000	\$2,000	\$3,840	\$35,840
Year 2	\$60,000	\$2,000	\$7,440	\$69,440
Year 3	\$60,000	\$2,000	\$7,440	\$69,440

IV. Eligibility

- Applicants must be U.S. Citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application)
- 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 followup, 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.

V. Mentorship Requirements

Not applicable to this RFA

VI. Goals of Research Currently of Interest to CFF/Priority Areas

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 pharmacy technician team to effectively deliver outpatient clinical pharmacy services.

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 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 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 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.

VII. Review and Award

All applications are evaluated by a CFF established review committee. Funding of awards is based on the priority score awarded to each application and the recommendations of the Committee. Relevance of the proposed project to issues in CF is also considered in determining awards. All awards are subject to observance of the regulations and policies of CFF related to that category of support and are contingent upon the availability of CFF funds.

CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion.

Chief reasons for assigning low priority scores to applications during review include the following:

- The proposed project/program does not meet the funding criteria in the policy statement for the award.
- The project/program description is unclear, lacks key details, and/or is not supported by sufficient documentation.

VIII. Submission Information

Applications deadline: Wednesday April 26, 2022 by 5:00 PM (Eastern)

Submit online through http://awards.cff.org (Refer to Section X 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. The CF Foundation reviews applications electronically, and only documents submitted online at http://awards.cff.org will be reviewed.

General Timeline:

Full Application Deadline	April 26, 2022*
Committee Review Date	Late May 2022
Notification to Applicants	June 2022
Earliest Start Date for Awarded Projects	July 1, 2022

*We highly encourage that you pre-register your profile, institution, contacts, and Title of your Application by this date. This will confirm that your submission at the Application Deadline, is without any system-related issue. It will also allow us to assist you on system-related queries, before the Application Deadline.

IX. Letter of Intent Guidelines

Not applicable to this RFA

X. Full Application Guidelines

Applications must be submitted online at http://awards.cff.org

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 awards.cff.org, the system will compile them into a single PDF file. You may preview this file by selecting "Application Full Print", as well as exporting the compiled PDF file.

To login, please visit: http://awards.cff.org

For all first-time applicants in the new Grants Management System, we ask that you pre-register to create a username and password for "http://awards.cff.org" and complete a profile prior to submitting an application. We also request that as you begin your application, you enter the title of your project, if available. If you are registered and cannot remember your password, click on the "Forgot Password?" link below the "Login" fields.

Once logged in, the award opportunities, including this Request for Applications (RFA), will be listed in the **Funding Opportunities** tab on the opening screen.

Locate the listing for the "Award for a Pharmacist and Pharmacy Technician - 2022" program. Click on the "Apply" 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 progress.

The following sections are displayed as tabs across the application screen. Click on each section and follow the directions. Click "Save" as you complete each section.

GENERAL

Enter the title of your project, and project start and end dates. Also, indicate whether this is a resubmission of an application that was reviewed previously.

CONTACT PROFILE

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, you may update your profile in this section. Once updated you must "Save and Validate" prior to returning to continue your submission.

Please note: This tab must be completed prior to being able to search for/locate relevant contacts in the next, CONTACTS tab.

If you are applying from an Institution (Organization), please select that option in the ('Type') dropdown menu. Then check that the Institution (Organization) is domestic. International institutions are not eligible for this award. Next, applicants must verify their institution by entering the Employer Identification Number (EIN) or Tax Identification Number (TIN) to search the system for the correct institution. If the EIN/TIN is not located, you may add the legal institution. Please also confirm if the project site is the same as the legal

institution. Institutional applicants then need to upload their institution's W-9 and Tax Status Letter.

If you are applying as an "Individual" not a part of an institution or organization, please upload your personal completed W-9. To download a blank W-9 form to fill out, please click here.

<u>Verification of Applicant Institution's Tax Status (upload as PDF documents):</u>

CFF's Grants and Contracts Office must have a copy of the individual applicant's W-9 form on file for the person who will be receiving the funds if awarded. Please make sure to sign and date the W-9 form. If the applicant is applying on behalf of, or through an organization, then a copy of the organization's W-9 and a copy of its 501(c)3 letter, or other documentation verifying its Federal tax status, are also needed. The CF Foundation's Grants and Contracts Office will not issue Award Letters to Awardees if these documents are not received and on file.

<u>International Applicants (if applicable):</u>

Not applicable to this RFA

CONTACTS

Please note: The INSTITUTION tab must be completed prior to adding internal contacts to ensure that the contacts are properly associated with the applicant institution.

Complete the required contact fields by searching by name for existing contacts at your institution for each role. If the desired institutional contact is not available in the system, you may select "Add Internal Contact" to create a basic contact profile in order to add the individual to your application.

Additional optional contacts <u>not</u> associated with the applicant institution may also be added. These contacts would be considered as additional contributors involved in the proposed research plan. These may include <u>consultants</u>, or <u>collaborators</u>. If the desired external contact is not available in the system, you may select "Add External Contact" to create a basic contact profile in order to add the individual to your application.

BUDGET

Select the "Edit Budget" button under the Budget tab and complete the relevant budget categories by filling in the applicable amounts for Period 1. Initial award commitments will be for one (1) year with the possibility of renewing for a second (extension) year. Continued support will be based upon achievement of the goals of the proposal, and the availability of CFF funds. The total budget request may not exceed \$190,000 (plus 12% indirect costs – see section III for more guidance).

Be sure to click "Save" prior to closing the budget window.

Please outline the anticipated budget for the proposed project/program. A budget justification will be required as an upload on the "Full Application Uploads" tab.

The following budget categories are offered under this program:

Salaries and Benefits – List the names and roles of all personnel involved in the project/program. 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 \$199,300. Organizational applicants can include fringe benefits of the personnel involved. Please see a brief example of a Salaries & Benefits section of a GMS budget below:



Applicant Jane Doe entered in 10% in the "% effort" box, and a "Institutional Base Salary/Stipend" of \$100,000. The GMS calculated a "Salary Requested" to be \$10,000.

Jane Doe was then able to manually edit the salary requested to the amount they actually want to request of \$4,000.



Travel - Describe the purpose of any relevant travel. Please note: expenses for travel outside the North American continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF Grants & Contracts Office. Registration fees associated with conferences should be listed under "Other 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.

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates to the corresponding attachment types within this section. Templates available for download include:

- Budget Justification
- Project Plan
- Other Support (NIH format)

Below are instructions specific to each template as well as additional information regarding other application components.

Budget Justification

Use this template to describe the nature of costs listed in the online Budget for each category:

- Personnel
- Travel
- Other Expenses

Project Plan

- 1) Provide a brief description of the patient population at the care center. (Maximum-half page).
- 2) Describe your plan to utilize a pharmacist and a pharmacy technician including:
 - i. How will you implement outpatient clinical pharmacy services?
 - ii. How your program will incorporate the new team member(s) into the multidisciplinary care team and the specific roles/tasks that might be offloaded, provided, and/or reallocated by adding a pharmacist and pharmacy technician?
 - iii. If the pharmacist and pharmacy technician is unfamiliar with CF, what training plan will you put in place to provide the basics needed for them to function effectively as a multidisciplinary team

member in the clinic? How additional person(s) with pharmacy expertise will support your multidisciplinary care team in providing care for your patients?

3) Describe your clinic and/or health system plan to obtain the necessary funding to sustain the pharmacist and pharmacy technician positions following this 3-year award (e.g. health system pharmacy or specialty pharmacy with or without 340b contract pricing) (Maximum-two pages)

Other Support (NIH format)

Complete and upload the Other Support form for all key project personnel, beginning with the Applicant/Principal Investigator. There is no page limitation. Information on other support assists CFF in the identification and resolution of potential sources of overlap. Scientific and budgetary overlap should be minimized. Commitment of an individual's effort greater than 100 percent, is not permitted.

Appendices

Appendices are restricted to the following category:

- 1. Resume/CV of Pharmacist and Pharmacy Technician
- 2. Statement of Qualifications

Validation and Submission

If applicants apply through an organization, once the applicant clicks "Sign & Submit to AIO" the application will be routed to be signed by the applicant and then sent on for final signature by their organization's AIO. After the AIO has signed the application, it will be submitted to CFF.

If applicants apply as an Individual, once the applicant clicks "Sign & Submit", the application will be electronically signed by the applicant and submitted to CFF.

To ensure the application is fully signed and submitted ahead of the Application Deadline for this program, please be sure to complete the application, and begin the Sign & Submit to AIO process in advance of the 5:00 PM EST deadline. The status of your application will display "Submitted" once fully signed, to indicate that your application has been received by CFF.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support:

Primary CF Foundation Grants and Contracts contact ewarnke@cff.org or 301-841-2667 Secondary CF Foundation Grants and Contracts contact nmohaghegh@cff.org or 301-841-2614

For programmatic questions:

CF Foundation Program Management contact Chris Dowd, cdowd@cff.org