



PATIENTS FIRST PROGRAM GUIDE

A project of Americans for Safe Access



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Introduction

Patients First Certification (PFC) is a non-profit, third-party certification for the medical cannabis industry offered by Americans for Safe Access. As the only certification based on the new quality standards for medical cannabis products and businesses issued by the American Herbal Products Association, PFC is what patients, caregivers, health care providers, companies, and regulators can depend on to identify reliable, high-quality medical cannabis products and services.

ASA began work in 2011 to bring to the medical cannabis industry the experience and skills of the American Herbal Products Association (AHPA), the principal U.S. trade association and voice of the herbal products industry since 1982. AHPA has now issued standards for commercial medical cannabis companies to assure the quality, strength, and composition of medical cannabis products, as well as the reliability and quality of related services.

The first step in ASA's work with AHPA was to bring medical cannabis industry members from around the country together to form AHPA's Cannabis Committee to create a series of "recommendations for regulators." These recommendations provide standards to regulate the medical cannabis industry in the areas of 1) manufacturing, packaging and labeling; 2) analytics; 3) dispensary operations; and 4) cultivation. ASA's decade-long experience in drafting legislation, developing regulations, and educating and training medical cannabis providers, combined with AHPA's 30-year history of developing standards for the herbal products industry, provides the knowledge and expertise to evaluate the quality of medical cannabis products and distribution systems.

Because ASA is a non-profit organization, all proceeds from the PFC program fund activities beneficial to the medical cannabis industry and your business. Americans for Safe Access Foundation programs PFC supports include:

- Community Support and Patients' Rights Projects
- Think Tank and Policy Shop
- Local Grass Roots Development
- Outreach to Patients, Health Care Providers, Legislators and Regulators
- Scientific Research and Complementary and Alternative Medicine Projects

PFC includes employee training, compliance inspections, ongoing monitoring, an independent complaint process for customers, government relations and marketing support, and use of the PFC logo.

1. Participation in PFC will provide your company visibility in all PFC advertising and marketing programs to patients, caregivers, and health care providers.
2. Companies that successfully complete PFC will receive an identifying logo to be used on website, packaging and advertising.
3. PFC Certification provides discounted ASA trainings for staff, including Legal, Raid and Robbery Preparedness; Media and Spokesperson Training; and Trainings for Medical Cannabis Professionals.
4. Industry trade organization members will receive discounted certifications, as well as support for their organization. AHPA members and United Food and Commercial Workers Union contracted businesses also receive discounted certifications.
5. Certified companies will be listed as safe providers on ASA's PFC website, which reaches thousands of patients each month.
6. Participants will receive educational materials for patients, caregivers, health care providers, resellers, and regulators about the certification program.
7. Independent inspectors verify that AHPA standards are followed by your company to ensure patient safety and the quality and reliability of your products or services.
8. Certification demonstrates your commitment to your patients and reduces product risk and liability, as well as employer risk.
9. Your company can gain regulatory acceptance by verifying the reliability, consistency, and accuracy of your processes.
10. Participation in the certification program supports compliance and increases your company's readiness for government inspections.
11. PFC's complaint resolution program provides a third-party process to evaluate complaints, allowing you to identify, focus on and resolve legitimate quality and service issues.
12. Proceeds from the PFC program fund activities that benefit the medical cannabis industry, including education, legal services and research.

What is Third-Party Certification?

Third-party certification ensures that an independent organization has reviewed the manufacturing process of a product or management process of a service and has determined that the final product complies with specific standards for safety, quality, or performance. PFC certifies compliance with AHPA standards for medical cannabis products and services. This review typically includes comprehensive reviews of formulations and materials, independent testing, and facility inspections. Certified products typically exhibit the certifier's 'mark' on their packaging to help consumers make educated purchasing decisions. PFC requires annual inspections, unannounced random inspections, and product testing to ensure that certified companies continue to meet all AHPA standards after the

initial certification. Other nationally recognized certification programs include Good Housekeeping, NSF and ISO.

How Does PFC Help My Company?

PFC's government relations outreach program at the local and state level will increase awareness of the AHPA standards with relevant agencies. PFC and AHPA work with regulators and industry trade groups to coordinate the further development of medical cannabis industry standards. Regulators will increasingly recognize the PFC logo as an assurance that your company is committed to product safety and quality. ASA is dedicated to the adoption of mandatory standards for the medical cannabis industry nationally. Your participation in the PFC will ensure our outreach to your specific regulators gives your company an advantage.

Our patient outreach program will educate patients and caregivers to look for certified products. As a non-profit, third-party entity, ASA's credibility will enhance your company's reputation through participation in the PFC program. PFC's advertising and marketing program prominently features our certified companies and includes both traditional industry publications and unique channels, such as Complementary and Alternative Medicine outlets.

PFC means you'll have access to some of the industry's best technical experts, delivering consistent, personalized service with the highest levels of integrity. With PFC behind you, your patients and their health care providers can be confident your products and processes meet the highest levels of safety and quality available.

What are AHPA Standards?

Standards are established guidelines which provide a system of processes, procedures, and documentation to assure medical cannabis products have the quality, strength, composition, and identity they represent to possess, and the companies that distribute them are committed to quality.

AHPA's Cannabis Committee has developed standards in four areas:

1. Cultivation
2. Manufacturing, Packaging, Labeling, and Holding
3. Distribution
4. Analytics

Companies participating in PFC are required to comply with any AHPA standards revisions within three months of issuance. PFC will notify all certified companies as standards are updated.

Cultivation Certification Program

- Ensure the company is compliant with licensing and zoning requirements.
- Demonstrate the safety of products used in your cultivation process. As the first link in the medical cannabis supply chain, your cultivation facility is the first line of defense in ensuring product safety for patients.
- Certify medical cannabis product does not contain an unacceptable level of contaminants.
- Verify adherence to currently recommended Good Cultivation Practice for the medical cannabis industry.
- Determine the hazard, risk, and impact of the products used in your medical cannabis cultivation processes to ensure environmental, employee and patient safety.
- The certification process includes: document review, a label review to verify product and marketing claims, a contaminant review, testing to ensure there are no unsafe levels of contaminants, and a facility inspection.



Manufacturing, Packaging, Labeling and Holding Certification Program

- Ensure the company is compliant with licensing and zoning requirements.
- Verify the identity and quantity of ingredients declared on the product label.
- Demonstrate that the product does not contain undeclared ingredients.
- Certify the product does not contain an unacceptable level of contaminants.
- Verify adherence to currently recommended Good Manufacturing Practice for the medical cannabis industry.
- Determine the hazard, risk, and impact of the products used in your medical cannabis manufacturing processes to ensure employee and patient safety.
- The certification process includes: document review, a label review to verify product formulation and marketing claims, a formulation review to identify and quantify dietary ingredients declared on the product label, a contaminant review, testing to ensure there are no unsafe levels of contaminants, and a facility inspection.



Distribution Certification Program

PFC offers two levels of Distribution certification: Silver and Gold. The Silver level ensures a company is compliant with AHPA's distribution standards. Gold level certification is awarded when a company demonstrates that at least fifty percent of products it offers to patients are PFC certified.



- Ensure the company is compliant with licensing and zoning requirements.
- Demonstrate that the distribution company is committed to state and local compliant dispensing practices.
- Verify adherence to currently recommended Good Distribution Practice for the medical cannabis industry.
- Determine the hazard, risk, and impact of the processes used in your medical cannabis distribution company to ensure employee and patient safety.
- The Silver certification process includes: document review and a facility inspection.
- The Gold certification process includes: a label review to verify product formulation and marketing claims and testing to ensure there are no unsafe levels of contaminants in products provided to patients.

Analytics Certification Program

- Ensure the company is compliant with licensing and zoning requirements.
- Demonstrate the lab's commitment to accuracy and integrity.
- Verify adherence to currently recommended Good Laboratory Practice for the medical cannabis industry.
- Determine the hazard, risk, and impact of the processes used in your medical cannabis laboratory to ensure employee and patient safety.
- The certification process includes: document review, equipment and standards review, testing verification, and a facility inspection.



How to Become Certified

The certification process includes:

- **Application** – The PFC process begins when you provide a completed application to ASA. We will complete a confidential review of your business operations to determine appropriate inspections and testing.
- **Quote** – Using information from your Application, ASA will prepare a price quote and an estimate of time required for completing the certification process.

- **Contract** – The contract will list the responsibilities of all parties involved including financial obligations and acceptance of terms.
- **Preliminary assessment** (optional) – ASA will discuss expectations and procedures for the audit and question management about facilities and processes.
- **Documentation audit** – An offsite review of company documentation will determine if the company’s licensing and processes are sufficient to ensure adherence to standards.
- **Employee training** – Experienced ASA trainers will provide employee training required by the AHPA standards, as needed.
- **Facility audit** – Trained ASA field inspectors will conduct a confidential PFC standards audit and a facility inspection.
- **Product testing** – ASA will test for pesticides, molds, and contaminants when available, necessary and appropriate for certification.
- **Initial scoring and corrective recommendations** – Your company will receive the results of the PFC inspections and be given corrective actions to be taken, as needed.
- **Secondary audit** as needed
- **Certification** – The PFC Executive Committee will issue your company’s certification once the inspector verifies any required corrective actions were taken and compliance with APHA standards have been met.

How to Prepare for Certification

Your company is ready for certification after you’ve implemented good management practices based on AHPA standards, trained employees to become proficient with processes, and developed a sufficient evidentiary trail of documents that can be assessed.

ASA can provide PFC applicants with discounted training programs, as well as document preparation and advisory services to prepare for certification. Please contact ASA for additional information on supplemental services.

Preliminary Assessment

In many cases, a company seeking certification may request an optional preliminary assessment of their operations. This gives ASA an opportunity to identify, in advance, any weaknesses that may exist in the company’s management systems. A preliminary assessment gives the company sufficient lead time to correct deficiencies before the certification and assists ASA in planning for the certification. The scope of the preliminary assessment is determined by the company and may range from a review of documents to a full assessment. While the preliminary assessment is optional, it is recommended. Ultimately, it may save

time and expense by revealing deficiencies that, if corrected before the certification review, can save you the time and expense of follow-up actions.

Documentation Audit

Once you begin the PFC process, we will request copies of your management system documents. It is recommended you submit these documents as soon as possible so that needed corrections can be made prior to your final review and there are no delays to the certification process.

ASA will review your documentation to determine whether it meets all requirements of the AHPA standards.

Documentation should include at a minimum:

1. **Standards manual(s)** – outlining systems utilized to conform to AHPA standards;
2. **Operating procedures** – describing how to perform system functions;
3. **Work instructions** – defining specific job activities affecting the safety and quality of products and processes; and
4. **Quality documentation** – documents which demonstrate how quality is managed including records including charts, files, inspection and testing records, assessment results, and any other records of objective evidence.

If your documentation fails to meet AHPA standards, the deficiencies will be identified in a report, and you will need to take corrective action before certification is awarded. Once ASA has determined that your documented management systems are satisfactory, a facility audit will be scheduled.

Introductory Meeting

The first day of the audit, the PFC team will meet with company management and other staff and contractors directly involved in the company's management system. The meeting will include an overview of the audit process to give you clear expectations for the process. During this meeting, ASA will review the audit scope and objectives, confirm the audit schedule and resources, and review the procedures for identifying and reporting deficiencies. You will be required to provide a main point of contact to accompany the PFC team through the audit process.

Facility Audit

ASA will assign a qualified inspection and audit team to complete a full assessment of your facility and operations. The team will consist of one or more members,

depending on the size and purpose of your facility. PFC auditors have extensive experience in the medical cannabis and herbal products industries.

An audit agenda will be prepared for you prior to the arrival of the PFC team, including a daily schedule and any accommodation requests. It is the audit team's responsibility to verify whether your management systems are meeting all of the requirements of AHPA's standards.

Following the introductory meeting, the audit team will perform a facility walk-through to observe activities. Team members may obtain samples for testing, conduct private interviews with employees, inspect documents and records, observe work processes, and examine equipment. The objective of the facility audit is to compile evidence of technical competency, including statements, documented procedures, records and written policies which support observations.

If any deficiencies are found during the course of the audit, the team will bring them to your attention and record them on a corrective action report. A deficiency report will specifically describe in detail what deficiency was observed and the related standard or policy to which it relates.

Product Testing

PFC provides a wide range of comprehensive medical cannabis product safety testing, where available (services may be limited in some states). PFC's testing services help our certified companies establish product stewardship by confirming content and purity, identifying problems with contamination, and determining potential for human and environmental exposures to ingredients and by-products including potency, residuals, and microbiological. The program specializes in examining products and packaging to ensure public and patient safety. Testing services are provided by our certified labs conforming to AHPA's laboratory standards. Testing for certification is limited to necessary testing to meet AHPA standards but our certified labs can provide you additional services as requested.

Exit Meeting

Upon completion of the on-site audit, the PFC team will conduct an exit meeting. A summary review of the facility audit will be given to management. If any deficiencies were recorded, they will be described at this time and included in a facility audit report. You will be given a reasonable time period to take corrective action.

Corrective Action

Any and all deficiencies are given a reasonable time to correct; however, they must be corrected before certification can be granted. Your corrective action response

must include objective evidence that shows the necessary corrective actions have been completed. PFC may require a follow-up facility audit, limited to the area of concern, depending on the nature of the deficiency. Certification cannot be awarded until any and all deficiencies have been adequately corrected.

Final Review, Report and Appeal Process

Within 10 business days of the facility audit (if no deficiencies are found) or confirmation of completed corrective actions, PFC will issue a confidential report and certification decision. All documentation will be forwarded to PFC's Executive Committee, an independent decision-making body. The Executive Committee will review application materials and audit documentation and issue a decision on your certification. If the Executive Committee grants your company certification, you will be notified immediately, and your certification materials will be issued.

In the event that your application for PFC certification is denied, you may submit an appeal within 10 business days of the issuance of the decision. You will only be charged the direct costs related to the application and inspection process, you will not be charged the cost of certification. Appeal applications are available on the PFC website: AmericansForSafeAccess.org/PFC. ASA provides an independent Dispute Board including at least three members with sufficient knowledge and expertise to perform a review of your materials and reports and issue an impartial decision.

Certification

Certification materials include:

1. A certificate bearing PFC's certification logo
2. A PFC certification window decal
3. Educational and promotional materials for patients, health care providers, and regulators
4. PFC website links
5. Logo and advertising agreement
6. Model press release

You are encouraged to promote your certification and display the PFC certification logo in advertising, promotional literature, and printed collateral materials (i.e. letterhead, brochures, business cards, etc.) to inform patients, caregivers, health care providers, and regulators that your company has demonstrated technical competency and a commitment to health and safety standards and product/service quality and reliability.

At any time after certification has been granted, the review period begins, during which your company may be subject to random and unannounced audits and/or

product testing. An annual re-certification process is mandatory. Follow-up audits may require document submissions or an on-site visit. In the event a complaint is submitted to PFC regarding certified products or services, certified companies are required to respond within 5 business days of being contacted by the PFC Program Director.

How Much Does Certification Cost?

Each applicant has its own unique characteristics that will determine the cost of certification. Three key elements comprise the cost of certification: daily rate, overhead expenses, and travel expenses.

ASA will provide a PFC quote after a complete review of your application. This quote is an estimated cost and will include:

1. Fees for preliminary assessment (optional)
2. Fees for audits and certification review
3. Fees for travel and other expenses
4. Fees for review and complaint investigation

PFC is committed to providing your company with a quality certification program that adds value to your business. We are committed to providing the most qualified inspection and audit team at the lowest cost possible. The program's value drivers include:

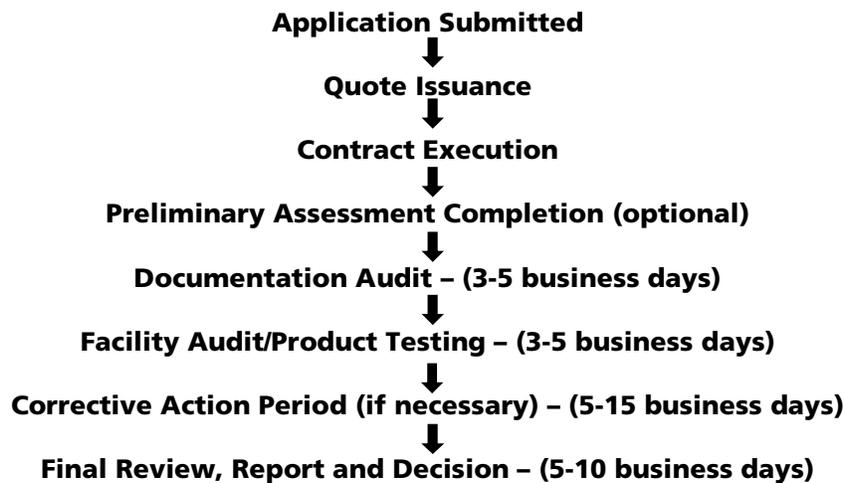
1. No application fee
2. Discounts for some trade association members, AHPA members, and UFCW contracted businesses.
3. No mandatory preliminary site visit
4. No hidden costs, overtime charges, or penalties for properly noticed schedule changes
5. Reimbursable expenses are charged at cost without mark-ups
6. Advanced off-site preparation is completed by PFC, reducing travel time required
7. Audits include a review of compliance with local and state regulations
8. Press release development by PFC outreach staff
9. Advertisement of your participation in all PFC ads

How Long Does the Certification Process Take?

The length of time required to complete the certification process depends on several variables, including: the type and size of the facility, number of employees, and complexity of operations. The amount of time it takes a company to achieve readiness for certification depends on the quality of management systems currently

in place. PFC provides optional advisory services to identify and resolve documentation and process deficiencies in advance of the audit process.

The speed of the certification process is dependent upon timely and complete responses from the applicant. A typical certification process will follow a timeline similar to the following:



Ongoing Review and Complaint Resolution

PFC will monitor your organization throughout the certification period. In the event AHPA releases updated standards, a review audit may need to be completed. PFC will notify certified companies of any standard updates and provide an explanation of actions required by your company to comply and the required timeframe. Additionally, if any third-party complaints require an investigation or a large number of complaints are received, a review audit may be necessary. PFC will evaluate and respond to all third-party complaints, verifying the legitimacy and severity of the complaint. Certified companies are required to respond to complaint inquiries by PFC within 5 business days.

PFC shall investigate complaints related to certified companies, misuse of the PFC logo by certified companies, or use of the PFC logo by non-certified companies. Failure to cooperate in a complaint investigation will result in the termination of PFC certification.

When filing a complaint, a Complaint Investigation Request provided by PFC must be completed and signed by the complaining party. Complaints will be sent directly to the program director, who will track all complaints and investigations. PFC will acknowledge receipt of the complaint, promptly investigate and validate the complaint, and take appropriate actions. PFC shall ensure the proper corrective actions are taken and notify the complainant of such actions. The certified company will be advised of the complaint at the appropriate time during the

investigation. PFC shall determine, together with the certified company and complainant, if the complaint and resolution should be made public.

When a complaint is made by a company, whether PFC certified or not, the complainant agrees to bear the cost of an investigation if the complaint is not verified. If the complaint is substantiated, the certified company shall be responsible for all costs of the investigation. Regulatory authorities and licensed health care providers are exempt from bearing the costs of any investigation costs. PFC shall not identify the complainant unless required to do so by law. If a complainant does not sign a Complaint Investigation Request, PFC will consider it an informal complaint and will investigate as needed, but has no obligation to investigate or respond.

About ASA and AHPA

Americans for Safe Access is committed to making PFC the nationally recognized non-profit, third-party dedicated to patient health and safety solutions for all medical cannabis stakeholders, including patients, health care providers, the medical cannabis industry, and government agencies. Founded in 2002, Americans for Safe Access is the largest organization of patients, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis. We engage a multifaceted strategy of public education, impact litigation, grassroots development and advocacy, media campaigns, and direct support services. See more at: AmericansForSafeAccess.org

The American Herbal Products Association has been the principal U.S. trade association of the herbal products industry since 1982. AHPA serves its members by promoting the responsible commerce of products that contain herbs used to enhance health and quality of life. AHPA chartered a Cannabis Committee in 2010 to meet the needs of its members that grow, manufacture, or distribute medical cannabis where it is allowed by state law, as well as those that market industrial hemp products. See more at: AHPA.org

For More Information

Jill Lamoureux

Patients First Program Director

720-335-1386

jill@safeaccessnow.org

PFC Confidential Complaint Investigation Request

Certified Company Information

Company Name	
Street Address	
City, State, Zip	

Complaint Description

<p>Describe in detail the specific complaint or action desired (attach additional sheets as necessary).</p> <p>Please include what requirements the company does not meet and attach any available objective evidence.</p> <p>Examples include: misuse of PFC logo, labeling errors, non-compliance with state or local regulations, etc.</p>	
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If this complaint form is signed, the complainant (other than regulatory agencies, patients, caregivers or licensed health care providers) agrees to bear all costs of the investigation if the complaint is unsubstantiated and deemed invalid. If this form is received unexecuted, PFC has no obligation to investigate or respond.

Name		Phone 1	
Title		Phone 2	
Organization		Email	
Signature		Date	

Completed Complaint Investigation Request forms should be emailed or mailed to the PFC Program Director: 1806 Vernon Street NW, Washington, D.C. 20009. Email: complaints@safeaccessnow.org



Patients First Certification Application

Business Trade Name _____

Business Legal Name _____

Mailing Street Address: _____

City: _____ State: _____ Zip: _____

Contact Name _____

Email _____ Phone: _____

A. FACILITIES to be Certified

Type of Certification Sought ¹	Number of Facilities	Other Information ²
Cultivation		Annual Yield (pounds):
Distribution (Dispensary/Delivery Service)		Annual Gross Income:
Manufacturing, Packaging, Labeling or Holding		Annual Gross Income:
Analytics Laboratory		Annual Gross Income:

1. AHPA has not yet released Cultivation, Manufacturing or Analytics standards. Certification is only currently available for Distribution (Dispensary/Delivery). Please list all certifications you are interested in, and you will be contacted as soon as the standards are available.

2. You may call us to report this information if you prefer not to list it.

B. PRODUCTS to be Certified

Please describe the types of products you cultivate, sell, manufacture, package, label or hold.

C. SERVICES to be Certified

Please describe the types of services you provide to your clients.

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D. LOCATIONS to be Certified

Name of Facility	City/State	Activities	Products	# of Workers

E. LICENSING

Please describe the state and local licensing or registrations relevant to your operations. Please note if no licenses are available for your operation.

F. MACHINERY AND INFRASTRUCTURE

Please describe the major machinery, software and infrastructure used in your operations.

G. SUBCONTRACTORS,

Please list any sub-contractors used in your operations including name and address and the activities they perform.

H. QUALITY CONSULTANT(S)

Please list any consultants, including name and address, used to develop your quality systems or operating procedures.

I. OTHER CERTIFICATIONS

Please list any certifications, past or present, your operation has received and the name of the certifying organization. If cancelled or no longer current, please describe why.

CONFIDENTIAL

THE UNDERSIGNED HEREBY ATTESTS TO HAVING COMPLETED THIS APPLICATION TRUTHFULLY AND TO THE BEST OF THEIR ABILITY:

Name: _____

Position: _____ **Date:** _____

All application information shall remain CONFIDENTIAL. Based on the information contained in this application, PFC will prepare a no-obligation offer for certification. PFC may require additional information to provide an offer.

Please submit the completed application for certification to Jill Lamoureux via email at jill@safeaccessnow.org or fax to (202) 618-6977.

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1806 Vernon Street NW, Washington, D.C. 20009
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