Drug Enforcement Administration

Controlled Substances Act Online: New Applications

User Manual

Version 5.2
April 14, 2021

Change Control Page

New Version

Revision	Date	Section	Description	Author
1.0	10/9/2007	All	Initial Draft	Scott M. Roberts
2.0	12/28/2009	All	Update image headers to account for new website design.	Scott M. Roberts
3.0	7/10/2014	All	Updated screenshots	Scott M. Roberts
4.0	9/11/2014	All	Updated screenshots for Web 2.0	Scott M. Roberts
5.0	9.16.19	All	Separated into dedicated New and Renewal Manuals Updated for new online application Changed all references and acronyms for Office of Diversion Control to Diversion Control Division	Kevin Baker
5.1	2.19.20	1.3.1.6; 2.1.1; 2.2; 2.4; 2.9; B.2; B.3; C.0	1.3.1.6 - Added section 2.1.1 - Added EMS 2.2 - Added notation that not every business activity is available in every state 2.4 - Added notation that CS licenses will not appear if not required by that state 2.9 - Added section B.2, B.3 - Added appendix C.0 - Added new acronyms	Kevin Baker
5.2	4.14.21	SP; 1.3; 1.3.1.6; 2.2.1; 2.2.2; 2.8.1; 2.8.2; A.0; B.2	SP - Updated signatories 1.3 - Updated form order and business activity names to better reflect website 1.3.1.6	Amanda Blake

Revision	Date	Section	Description	Author
			- Deleted Emergency Medical Services (EMS) section 2.2.1; 2.2.2; 2.8.1; 2.8.2 - Clarified section headers 2.8.2 - Updated Tracking ID definition A.0 - Updated fees B.2 - Deleted EMS section	

Signature Page

Document Name: Controlled Substances Act Online: New Applications User Manual

Publication Date: April 14, 2021

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Preface

It is the reader's responsibility to ensure they have the latest version of this document. Questions should be directed to the owner of this document or the project manager.

This document was developed by the Information Systems Division, Diversion Technology Section.

Approval

Approval of this document is contingent upon the review of and signatures by the project and program managers and by specified members of TQD.

System Owner

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Table of Contents

1.0 Introduction

In 1970, the United States Congress created the Controlled Substances Act (CSA), legislation mandating that all entities manufacturing, distributing, dispensing, administering, and prescribing controlled substances must maintain an active registration within the Drug Enforcement Administration (DEA). All registrants must comply with all drug security, records accountability, and standards adherence requirements.

The New Application web form allows potential applicants the ability to apply online for a DEA registration. Note that applying does not guarantee approval. Every application is subject to a thorough investigation, which may end in a rejected application. Application fees are nonrefundable.

1.1 Basic Navigation

Do *not* use the browser's navigation buttons.

Use the buttons at the bottom of the page to navigate the application. Button functionality is as follows:

→ Proceed: proceed to the next page in sequence.

← Previous: return to the previous page.

⊘ Cancel: exit the application. Note that any progress made will be lost.

Required fields (indicated by an '*') must be filled out properly before clicking → Proceed.

Hover the cursor over a field's ? button to receive a description of that field.

1.2 Access

The New Application web form may be accessed by clicking the following link:

https://apps.deadiversion.usdoj.gov/webforms2/spring/newLogin

Note: the browser must support 128-bit encryption.

1.3 Form/Business Activity Selection

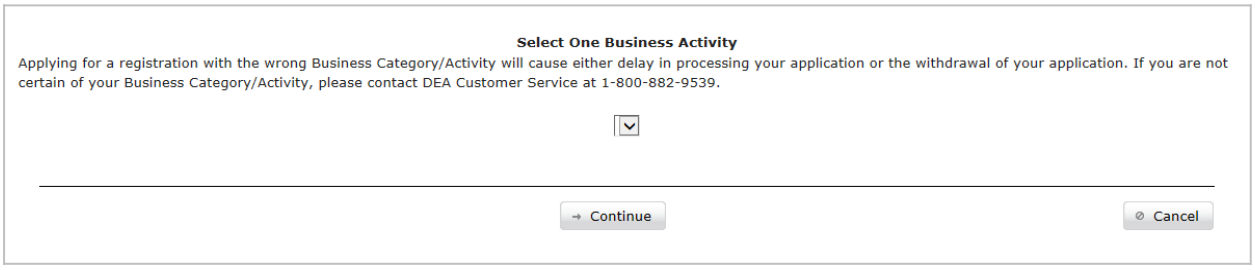


Figure 1: Select Business Activity

Choose one of the listed business activity categories. This will load a list of corresponding business activities into the drop-down box. See the following sections for a description of the available business activities. Go to section 2.0 for instruction on completing the application form.

1.3.1 Form 224

1.3.1.1 Practitioner

A **Practitioner** is defined as a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

1.3.1.2 Mid-Level Practitioner

A **Mid-Level Practitioner** (MLP) is an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. All business activities are authorized only to dispense controlled substances by the State in which they practice.

MLP – Ambulance Service: any individual that works for a ground ambulance vehicle service with the provision of medically necessary supplies and services including an Advanced Life Support (ALS) assessment or at least one ALS intervention.

MLP – Animal Shelter: any individual that uses controlled substances in the licensed care of animals within a private or state-run facility intended for the care of lost, abandoned, or surrendered animals.

MLP – Doctor of Oriental Medicine: any practitioner of non–traditional medicine of predominantly Eastern origin. This does not include general practitioners or any other business activity that specializes in traditional Western medicine.

MLP – Euthanasia Technician: any individual that employs pharmacological methods, including the injection of drugs and gases, in the euthanization of an animal.

MLP – Homeopathic Physician: any individual who prescribes controlled substances and listed chemicals in the practice of homeopathic medicine.

MLP – Medical Psychologist: any individual applying the application of psychological principles to the practice of medicine of both physical and mental disorders.

MLP – Naturopathic Physician: any individual who prescribes controlled substances in the course of alternative, or naturopathic, medicine.

MLP – Nursing Home: any private care facility providing residential accommodations with health care, especially for elderly people.

MLP – Nurse Practitioner: any Advanced Practice Registered Nurse (APRN) educated with the knowledge base and decision-making skills to treat medical conditions without the supervision of a doctor.

MLP – Optometrist: any medically trained individual licensed to deliver primary, secondary, and tertiary eye care.

MLP – Physician Assistant: any nationally- certified and state-licensed medical professional able to prescribe medication.

MLP – Registered Pharmacist: any individual with a license to practice the preparation, composition, and dispensation of drugs pursuant to a valid prescription.

MLP – Certified Chiropractor: any individual certified and licensed to diagnose and treat mechanical disorders of the musculoskeletal system and prescribe drugs related to such treatment

MLP – Assistant Physician: any individual licensed as a Physician Assistant (PA). PAs in Kentucky, Puerto Rico, and US Virgin Islands may not prescribe controlled substances.

1.3.1.3 Pharmacy

Retail Pharmacy: an entity permitted by the state in which it is located to prepare controlled substance orders for dispensing, pursuant to a valid prescription. Retail pharmacies should consult the Federal Register Notice and Pharmacy Manual before continuing. The links for both are provided below the drop-down menu.

Central Fill Pharmacy: a pharmacy permitted by the state in which it is located to prepare controlled substances orders for dispensing, pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such pharmacies shall be deemed “authorized” to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

1.3.1.4 Hospital/Clinic

This includes a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a

controlled substance in the course of professional practice, but does not include a pharmacy. This business activity is not for individuals. A physical location at which any combination of inpatient, outpatient, or emergency medical services are provided, based upon authority granted by the State in which it is located. This includes any school, which provides medical services to human patients in the process of teaching medicine. This does not include individual practitioners, incorporated or otherwise, licensed to practice medicine in a State.

1.3.1.5 Teaching Institution

A **Teaching Institution** is a physical location where medicine is taught under the authority of a State accredited college or university. This business activity is not for individuals. A physical location where inpatient, outpatient, or emergency medical services are not provided to human patients, but where medicine is taught under the authority of a State accredited college or university. This does not include individual practitioners, incorporated or otherwise, licensed to practice medicine in a State.

1.3.2 Active Military Only

1.3.2.1 Military Pharmacy

A **Military Pharmacy (PHARMACY – MIL)** is an entity permitted to prepare controlled substance orders for dispensing, pursuant to a valid prescription for the United States Military and its personnel.

1.3.2.2 Military Hospital

A **Military Hospital (HOSP/CLINIC – MIL**) is a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States Military to dispense a controlled substance in the course of professional practice. This does not include a pharmacy. This business activity is not for individuals. A physical location at which any combination of inpatient, outpatient, or emergency medical services are provided, based upon authority granted by the United States Armed.

1.3.2.3 Military Practitioner

A **Military Practitioner (MILITARY-PRACTICTIONER)** is a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States Military to dispense a controlled substance in the course of professional practice. This does not include a pharmacist, a pharmacy, or an institutional practitioner.

1.3.2.4 Military MLP

A **Military MLP (MLP – MIL)** is an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist who is licensed, registered, or otherwise permitted by the United States Military to dispense a controlled substance in the course of professional practice.

1.3.3 Civil Service Practitioner/MLP Assigned to Military Installations

1.3.3.1 Practitioner/DOD Contractor

A **Practitioner Contractor with the Department of Defense (PRACT-DOD CONTRACTOR)** is a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States and contracted with the DOD to dispense a controlled substance in the course of professional practice. This does not include a pharmacist, a pharmacy, or an institutional practitioner.

1.3.3.2 Military MLP/DOD Contractor

An **MLP Contractor with the Department of Defense (MLP-DOD Contractor)** is an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States and contracted with the DOD to dispense a controlled substance in the course of professional practice. All business activities are authorized only to dispense controlled substances by the State in which they practice.

1.3.4 Form 225

1.3.4.1 Manufacturer

Manufacturer: a business or facility that manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst

Manufacturer (Bulk): a business or facility that manufactures a drug or other substance in bulk quantity, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst

1.3.4.2 Importer

Importer: a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the controlled substance into the United States

Importer (C, I, II): any person who imports or who acts as an import broker for importation of List I and List II chemicals into the United States

1.3.4.3 Exporter

An **Exporter** is a regulated person, who as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the controlled substance out of the United States.

1.3.4.4 Distributor

Distributor: a business or facility who does not administer or dispense controlled substances but delivers a controlled substance or listed chemical to another entity registered with the DEA.

Chempack/SNS Distributor: a business or facility authorized to distribute self-centralized units placed in centralized locations with controlled substances (chempacks) from the Strategic National Stockpile (SNS) to enable first responders to quickly administer those lifesaving substances

1.3.4.5 Reverse Distributor

A **Reverse Distributor** includes individuals or businesses that perform a middleman service where controlled substances are collected from registrants and either returned to the manufacturer or arranged for disposal.

1.3.4.6 Researcher

Researcher (II-V): any individual who conducts diligent and systematic inquiry or investigation into controlled substances listed in schedules II-V

Researcher (I): any individual who conducts diligent and systematic inquiry or investigation into controlled substances listed in schedule I

1.3.4.7 Canine Handler

A **Canine Handler** is any individual who works with trained police dogs in the detection of illegally possessed controlled substances.

1.3.4.8 Analytical Lab

An **Analytical Lab** is a business or facility who analyzes controlled substances through analytical chemistry.

1.3.5 Form 510

1.3.5.1 Chemical Manufacturer

A **Chemical Manufacturer** is a business or facility who manufactures a listed chemical, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

1.3.5.2 Chemical Importer

A **Chemical Importer** is a regulated person, who as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

1.3.5.3 Chemical Exporter

A **Chemical Exporter** is a regulated person, who as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

1.3.5.4 Chemical Distributor

A **Chemical Distributor** is a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine or phenylpropanolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

1.3.6 Form 363

This form is for Narcotics Treatment Clinics (NTC). Every business activity in this category will participate in one or more of the following activities:

- **Maintenance**: anyone who dispenses for a period in excess of 21 days a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drug
- **Detoxification**: anyone who dispenses either short- or long-term a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug for the purposes of bringing the individual to a narcotic drug-free state within such period of time.
- **Compounder**: any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

The following business activities may be selected:

- Maintenance **(MAINTENANCE)**
- Detoxification **(DETOXIFICATION)**
- Maintenance and Detoxification **(MAINT & DETOX)**
- Compounder and Maintenance **(COMPOUND & MAINT)**
- Compounder and Detoxification **(COMPOUND & DETOX)**
- Compounder, Maintenance, and Detoxification **(COMP/MAINT/DETOX)**

2.0 CSA Registration
New Online Applications

The images found in the sections below are composites of every field available, regardless of business activity. They are intended for illustration purposes only and are therefore not true representations of what users will see when applying for registration. Many of the fields appear for individuals rather than businesses or for specific business activities and will be noted where appropriate.

2.1 First Steps

2.1.1 Pre-Acceptance Checklist

Select business activities must acknowledge the completion of a pre-application checklist before completing a new application. A sample of the checklist is available in appendix B.0.

List of Business Activities with Pre-Application Checklists:

- Practitioner
- Practitioner — Military
- MLP — Military
- Practitioner — DOD Contractor
- MLP — DOD Contractor
- Researcher I
- Emergency Medical Services

2.1.2 Statement of Understanding

All individual military practitioners must upload a Statement of Understanding (SOU) acknowledging that the DEA number provided to the applicant is to be used for official duty in the care of DOD beneficiaries, and may not be used for any other category of patient. Furthermore, the applicant must acknowledge that the DEA number assigned will be used for prescribing and administering only and that it must be surrender the DEA Registration upon separation from military service.

The SOU must be signed by the applicant and saved as a PDF for upload to DEA servers.

The following business activities must complete an SOU:

- Practitioner
- Practitioner — Military
- MLP — Military
- Practitioner — DOD Contractor
- MLP — DOD Contractor

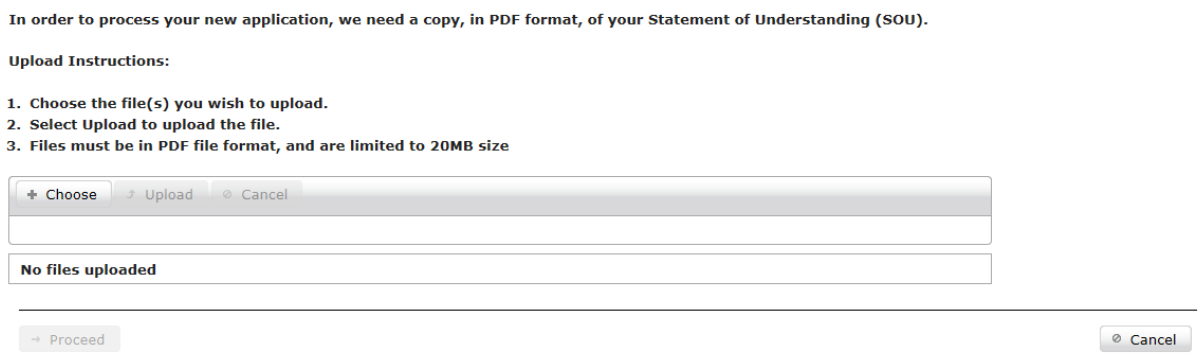


Figure 2: SOU, No Files Uploaded

Complete the following steps:

1. Select the Choose button.
    - A dialogue window will open. Navigate to and select one or more SOU files.
    - The SOU must be a PDF.
    - More than one file may be uploaded at once.

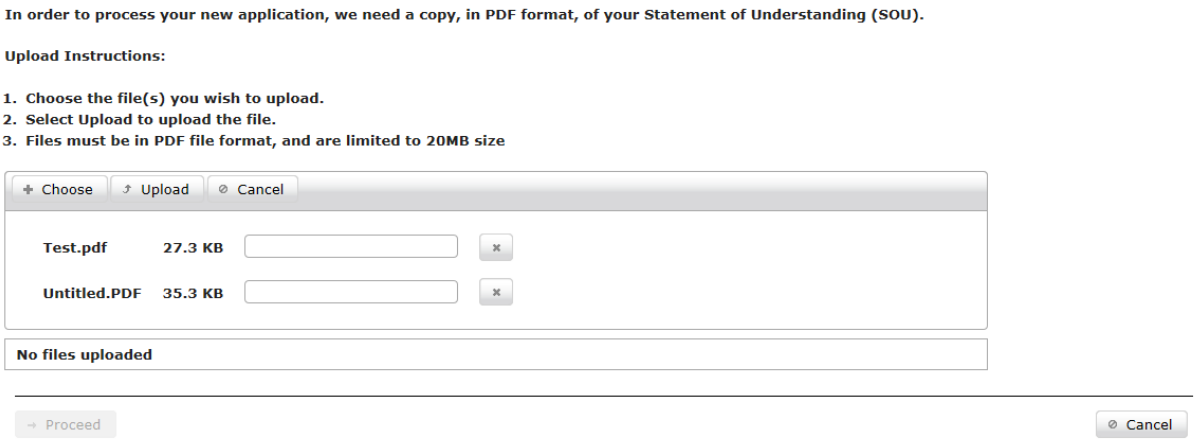
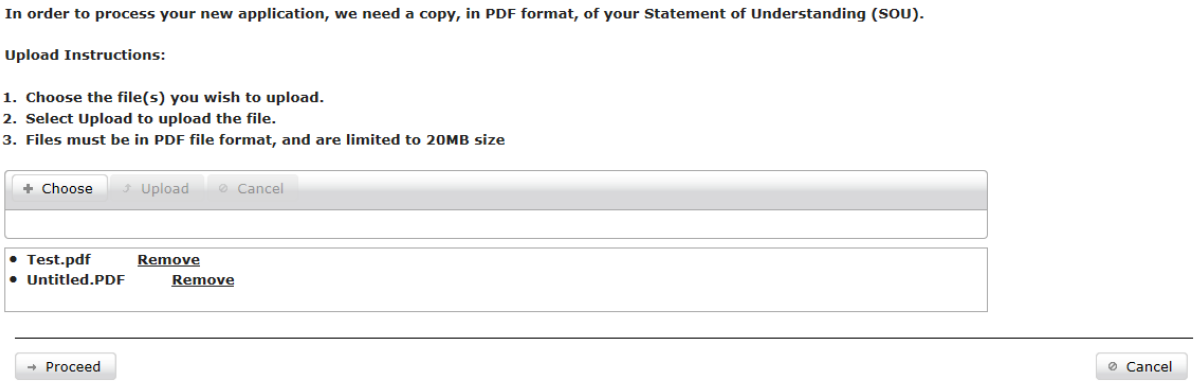


Figure 3: SOU, Files Selected

2. Click the Upload button.
    - PDFs may be removed before and after clicking the Upload button.



3. Click the Proceed button.

2.2 Personal Information

2.2.1 Personal Info - Page 1

The first page of the New Application Form requests personal information. Fill out all required fields, and continue to the next page by clicking the → Proceed button. Note that all entered information must be valid to proceed.

Note that clicking the ⊘ Cancel button will exit the online application, not just the current page.

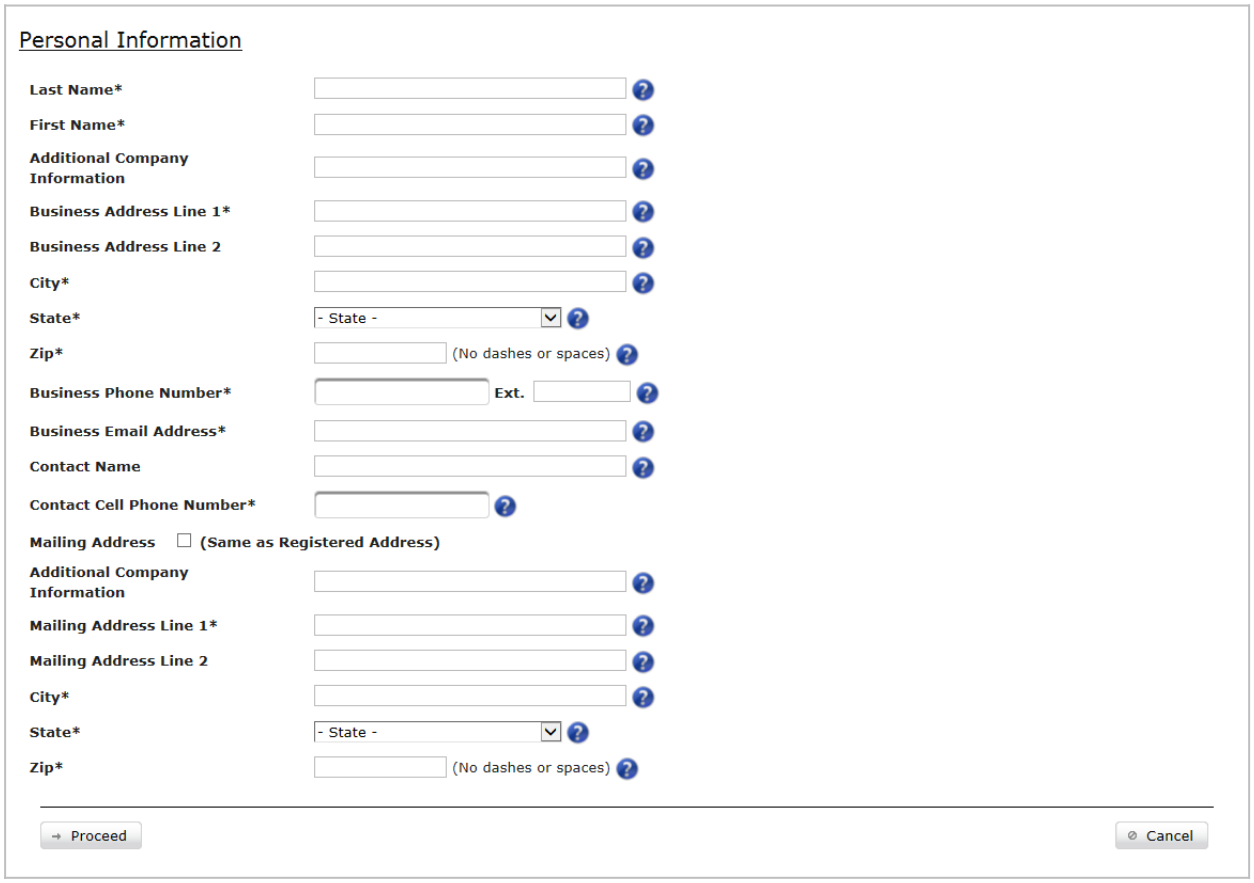


Figure 4: Personal Information, page 1

Note that fields marked with an asterisk (*) are required fields.

- **Last / Business Name**: for businesses and other facilities, the name of the business or facility; for individual practitioners, the last name of the practitioner. *This is a required field.*
- **First Name**: the first name, middle initial and medical degree of the individual practitioner. This field only appears when an individual practitioner is selected as the business activity (i.e.: practitioner, medical psychologist, optometrist, etc.). *This is only a required field for individuals.*
- **Additional Company Information**: any additional information concerning the registrant. This is usually a subdivision of the primary registrant or an individual doing business as the named registrant.

- **Business Address Line 1**: the physical address from which the registrant conducts business.
    - *This is a required field.*
    - The address must be between 2 and 60 characters.
    - Only valid addresses will be accepted.
- **Business Address Line 2**: any additional address information, such as suite and apartment numbers, if required.
- **City**: the city in which the registrant conducts business.
    - *This is a required field.*
    - The city must be between 2 and 35 characters.
    - The city must be valid for the entered state and zip code.
- **State**: the state in which the registrant conducts business, selected from the menu.
    - *This is a required field.*
    - The state must be valid for the entered city and zip code.
    - Note that not every business activity is available in every state.
- **Zip**: the registrant's postal code, plus four- (4) digit extension, if available.
    - *This is a required field.*
    - The zip code must be valid for the entered city and state.
- **Business Phone Number**: the registrant's telephone number, plus extension, if available.
    - *This is a required field.*
    - Valid formats: 1234567890 or (123) 456-7890
- **Business Email Address**: the registrant's email address.
    - *This is a required field.*
    - The email address must be no more than 60 characters
- **Contact Name**: the name of the business's or individual's primary contact.
- **Contact Cell Phone Number**: the business contact's cell phone number.
    - *This is a required field.*
    - Valid formats: 1234567890 or (123) 456-7890

The next fields contain the mailing information. Click the checkbox next to **Mailing Address (same as Registered Address)** if the mailing address is identical to the address entered in the above fields. The information will automatically be copied to the relevant fields. If the information is different, the following fields must be manually completed.

- **Additional Company Information**: any additional information concerning the registrant. This is usually a subdivision of the primary registrant or an individual doing business as the named registrant.
- **Business Address Line 1**: the physical address where the registrant may be contacted.
    - *This is a required field.*
    - The address must be between 2 and 60 characters.
- **Business Address Line 2**: any additional address information, such as suite and apartment numbers, if required.
- **City**: the city in which the registrant conducts business.

  - *This is a required field.*
  - The city must be between 2 and 35 characters
- **State**: the state in which the registrant conducts business, selected from the drop-down menu. *This is a required field.*
- **Zip**: the registrant's postal code, plus the four- (4) digit extension, if available. *This is a required field.*

2.2.2 Personal Info - Page 2

The Fee exempt checkbox is checked automatically for military business activities.

Note that clicking the Cancel button will exit the online application, not just the current page.

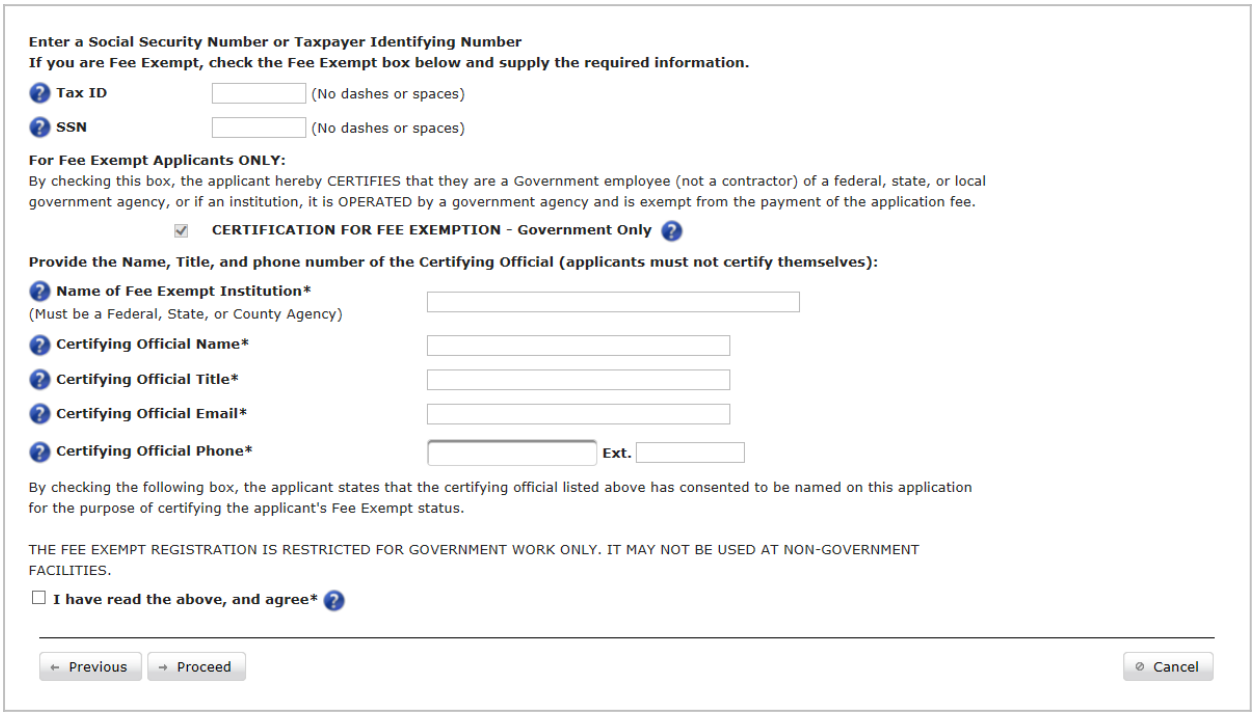


Figure 5: Personal Information, page 2

- **Tax ID**: the registrant's Federal Tax Identification number.
  - *This is a required field for businesses.*
- **SSN**: the Social Security Number (SSN) of either the registrant or the named contact.
  - *This is a required field for individuals.*
  - The SSN must be nine (9) characters.

The following fields are applicable and required for government applicants only. Non-government applicants may click the Proceed button to continue to the next page.

- **Certification for Fee Exemption**: indicates that the applicant is eligible for fee exemption. This should only be clicked by government authorities. The box will be checked automatically for all military applicants.
- **Name of Fee Exempt Institution:** the name of the registrant's organization. This field is applicable only when the Fee Exemption box has been checked. *This is a required field.*
- **Certifying Official Name**: the name of the individual at the facility authorizing the applicant for certification. This field is applicable only when the Fee Exemption box has been checked. *This is a required field.*
- **Certifying Official Title**: the certifier's title. This field is applicable only when the Fee Exemption box has been checked. *This is a required field.*

- **Certifying Official Email**: the certifier's email address. This field is applicable only when the Fee Exemption box has been checked. *This is a required field.*
- **Certifying Official Phone**: the certifier's phone number, as well as the extension, if available. This field is applicable only when the Fee Exemption box has been checked. *This is a required field.*

Once the Fee Exemption fields have been filled, applicants must acknowledge that they have read the following:

THE FEE EXEMPT REGISTRATION IS RESTRICTED FOR GOVERNMENT WORK ONLY. IT MAY NOT BE USED AT NON-GOVERNMENT FACILITIES.

Once applicants have checked the **I have read the above and agree** checkbox, click the → Proceed button to continue to the next page.

Note that if the application detects that the SSN entered is already in the system, a warning will display advising applicants to file a renewal application instead. However, it is possible to continue the application process with the entered SSN.

2.3 Business Activity/Schedules

Applicants request drug schedules on this page. At least one selected drug schedule must be selected to complete this section.

Note that clicking the Cancel button will exit the online application, not just the current page.

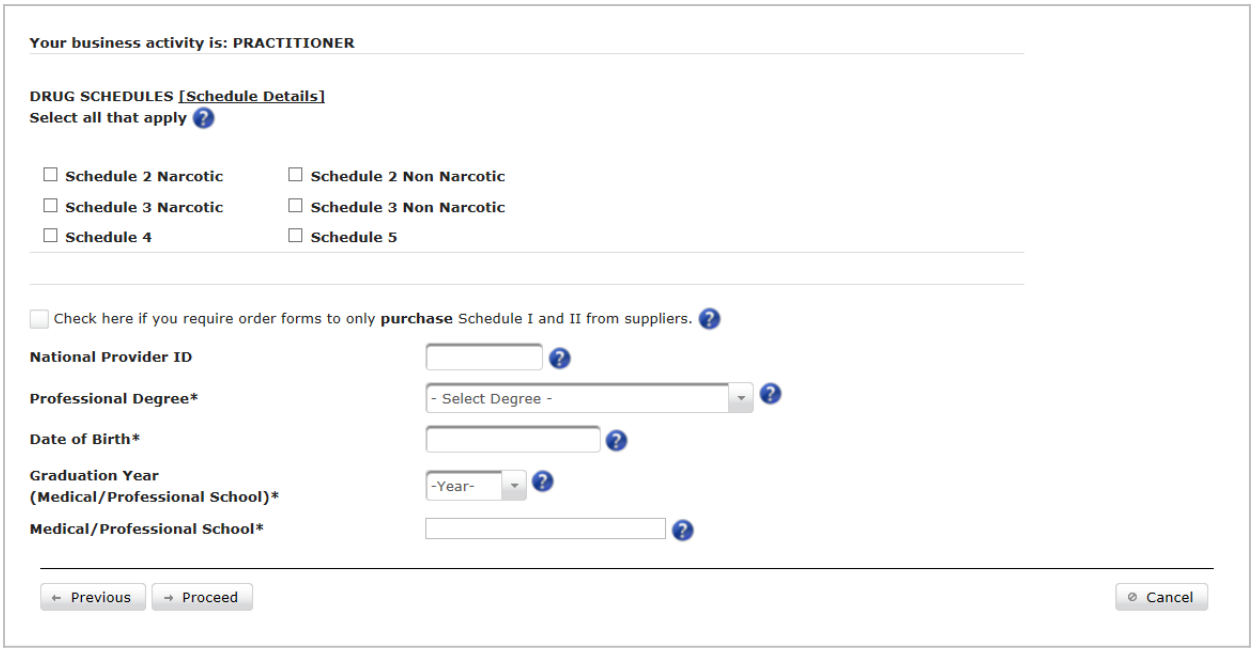


Figure 6: Business Activity/Schedule

- **Drug Schedules**: select one or more of the available drug schedules. Some checkboxes will be unavailable depending on the selected business activity.
    - *Note: individual fee exempt MLPs use the state license from the issuing state instead of the applicant's zip code to determine drug schedule eligibility. If no state license is available, it defaults to the state determined by the zip code.*
    - *Note: Schedules available to an MLP will vary based upon state eligibility and selected business activity.*
- **National Provider ID**: the registrant's National Provider Identification number (NPI). This field is required for any Form 224 business activity. *Note that NPIs must be entered in the correct format. Numbers must consist of ten (10) numeric characters and must not begin with a zero (0).*
- **Professional Degree:** select the applicant's degree from the drop-down menu. *This applies to Individuals only.*
- **Date of Birth:** enter the applicant's (individual's) date of birth. *This applies to Individuals.*
- **Graduation Year:** the year the applicant received a degree from medical school. *This applies to Individuals only.*
- **Medical/Professional School:** the medical school from which the applicant received a degree. *This applies to Individuals only.*

Applicants who propose to purchase Schedules I and II drugs from suppliers must check that checkbox.

Once the fields have been completed, click the → Proceed button to continue to the next page.

2.4 State Licenses

Applicants enter state license and state-issued controlled substance license information on this page. This page will be unavailable if a state license is not required for the selected business activity.

Note that clicking the Cancel button will exit the online application, not just the current page.

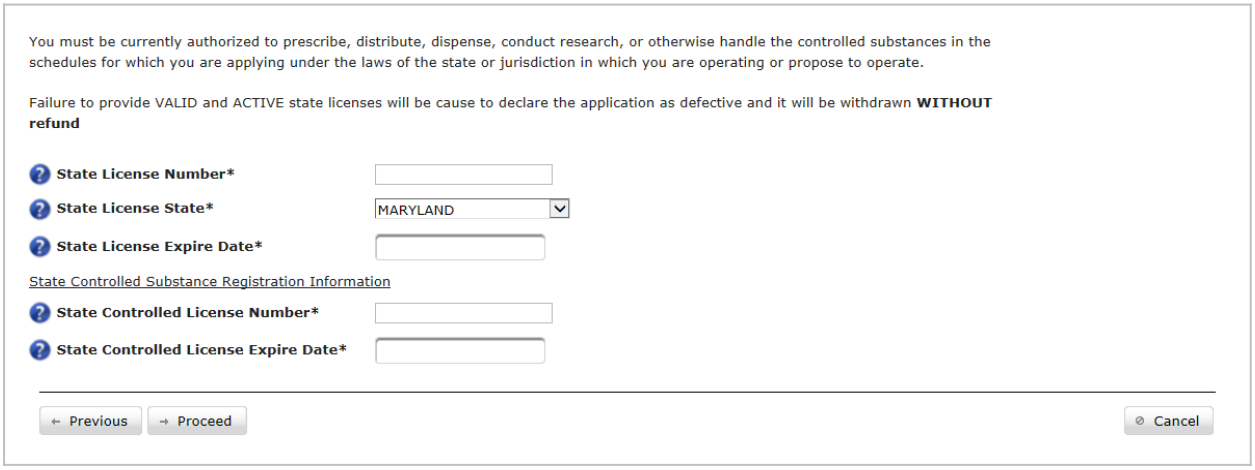


Figure 7: State Licenses

- **State License Number**: the license assigned to the registrant by the registrant's home state.
  - *This is a required field for Individuals.*
  - The license number must be between 2 and 20 characters
- **State License State**: select the state from the drop-down menu if either blank or different to the one previously selected. *This is a required field for Individuals.*
- **State License Expire Date**: the date on which the license is no longer valid. Click the field to bring up a calendar from which a new date may be selected. *This is a required field for Individuals.*
- **State Controlled License Number**: the Controlled Substance (CS) license number assigned to the registrant by the state in which said registrant conducts business.
- **State Controlled License Expire Date**: the date in which the CS license is no longer valid. Click the field to bring up a calendar from which a new date may be selected.

Note: the Controlled License fields are not required. However, the web application will issue a warning if the state for which a license is held requires the applicant to hold a controlled license number and no controlled license number is entered.

Once the information has been entered, click the Proceed button to continue to the next page.

2.5 Background Information

The next two (2) pages collect liability reporting information.

2.5.1 Liability Questions

The four (4) questions that all applicants must answer operate on the assumption that it is better to disclose potentially troubling controlled substance history to the DEA than to have that information be exposed during the requisite investigation.

Therefore, registrants are required to report whether any of the following are true:

- The applicant has been accused of a crime in connection with controlled substances.
- The applicant has connection with a person or entity that has been accused of a crime related to controlled substances.
- The applicant's controlled substance registration has been revoked.
- The applicant has connection with a person or entity whose controlled substance license has been revoked.

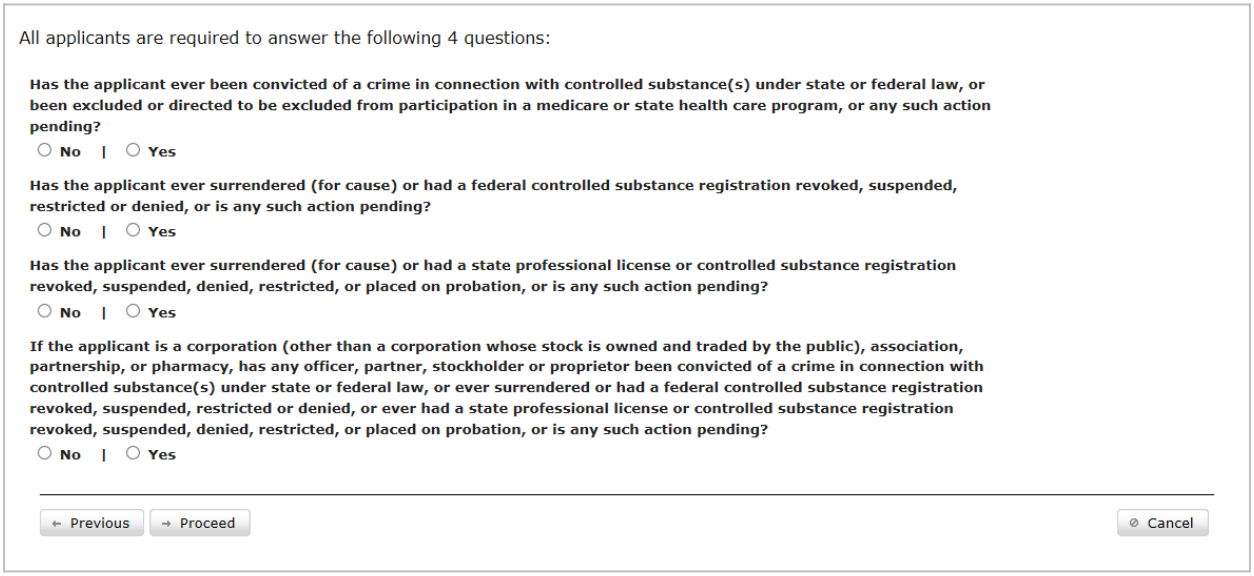


Figure 8: Liability Questions

If there are no liabilities to report, select the **No** radio button for every question.

Every question that can be answered in the affirmative should be marked with **Yes**.

If no liabilities were reported, click the → Proceed button to continue and turn to section 2.6. Otherwise, continue to section Error: Reference source not found.

Note that clicking the ⊘ Cancel button will exit the online application, not just the current page.

2.5.2 Liability Question Explanations

For every question answered **Yes**, an explanation must be provided to describe the date, location, nature, and result of the incident.

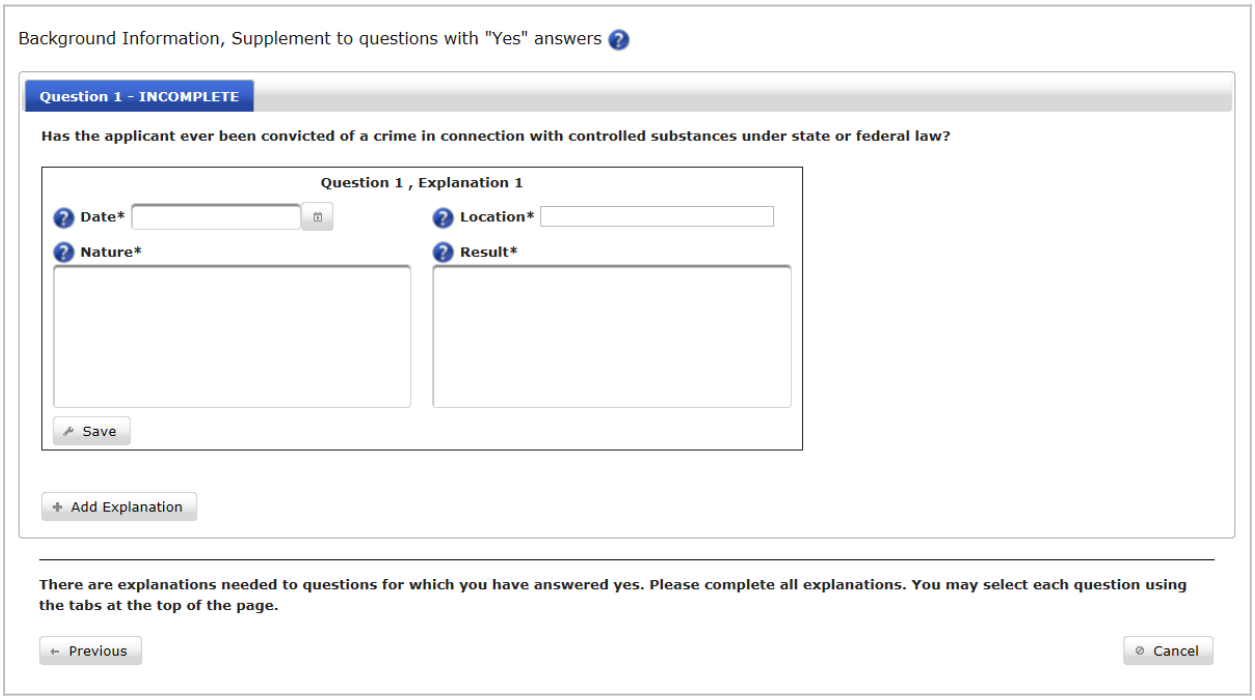


Figure 9: Liability Explanation

- **Date**: the date the incident occurred. Click the calendar icon ( ) to select the correct date from the displayed calendar.
- **Location**: the location in which the incident occurred
- **Nature**: a detailed description of the incident, including the events leading up to the incident, and the incident itself
- **Result**: the result of the incident as it applies to the applicant's standing as a DEA registrant.

After filling out the fields, click the Save button to save the incident data.

If more than one incident occurred that fits the current liability question, click the Add Explanation button.

Once every incident has been detailed and saved, the Proceed button will appear. Click it to continue to the next screen.

Note that clicking the Cancel button will exit the online application, not just the current page.

2.6 Select Drug Codes

Manufacturers must specify at least one (1) drug code for every drug schedule requested.

Note that clicking the Cancel button will exit the online application, not just the current page.

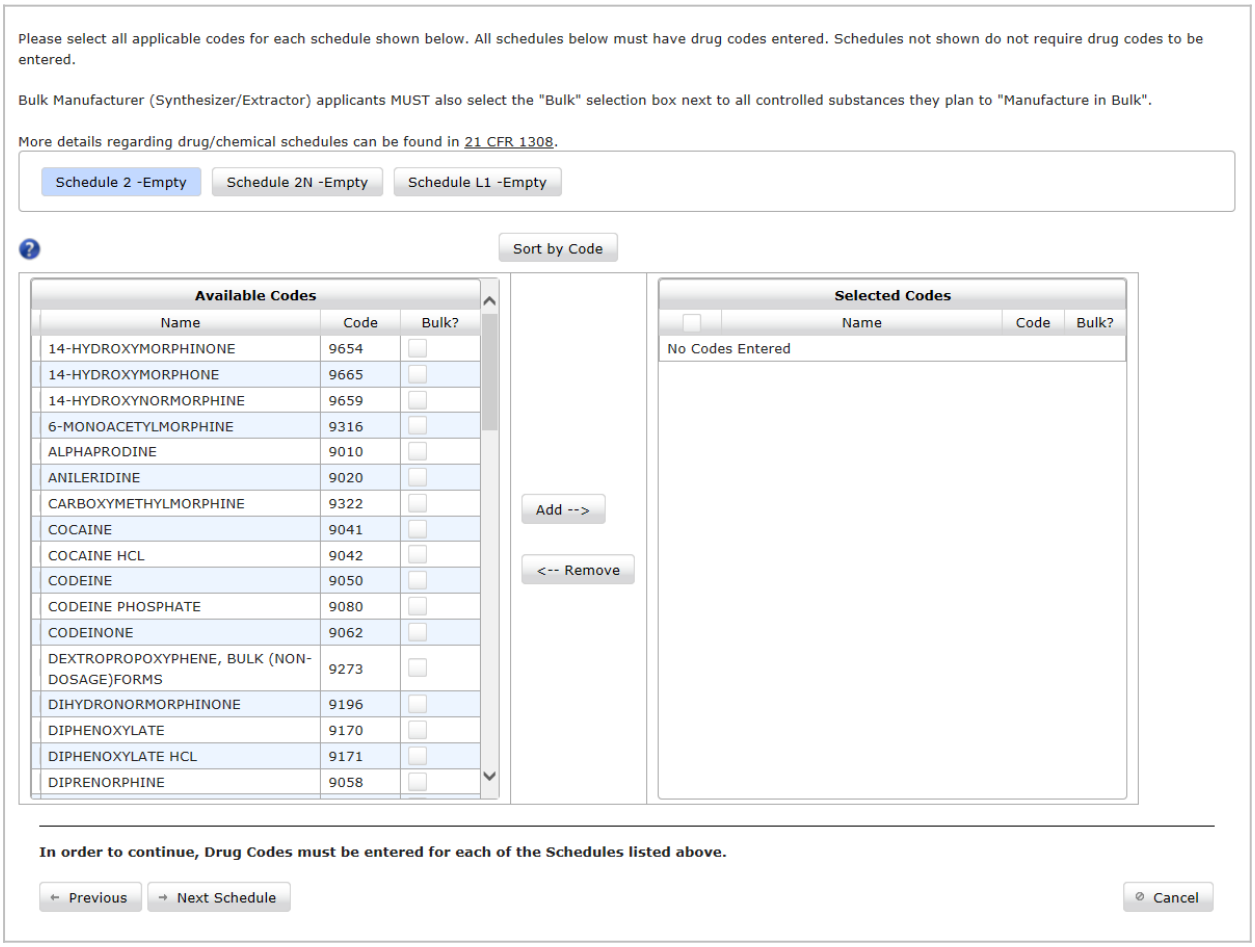


Figure 10: Select Drug Codes

Complete the following steps:

1. Select one (1) or more drugs in the **Available Codes** column.
    - Drugs are selected by clicking directly on the drug's name.
    - Drugs that will be manufactured in bulk must be indicated by checking the box in the Bulk? Column.
    - Click the button to sort the listed substances by drug code. The button will change to Sort by Code.
    - Click the Sort by Name button to sort the drugs by name.
2. Click the Add --> button.
    - Each selected drug will appear in the **Selected Codes** column.
    - The word "Empty" will be removed from the Schedule buttons.

- Remove mistakenly added drug codes by selecting the drug code and clicking the <-- Remove button.

3. Click the → Next Schedule button.
   - The word "Empty" will be removed from the schedule buttons when at least one drug code from that schedule has been added. For example, the Schedule 2N -Empty button will change to read Schedule 2N.
4. The → Proceed button will appear. Click it to continue to the next screen.

2.7 Manufacturer Details

Manufacturers must select specific tasks that agree with the overall Drug Schedules chosen. For example, manufacturers that request Schedule II must also choose at least one (1) activity (see below) in Schedule II.

No other business activities will see this page.

Note that clicking the Cancel button will exit the online application, not just the current page.

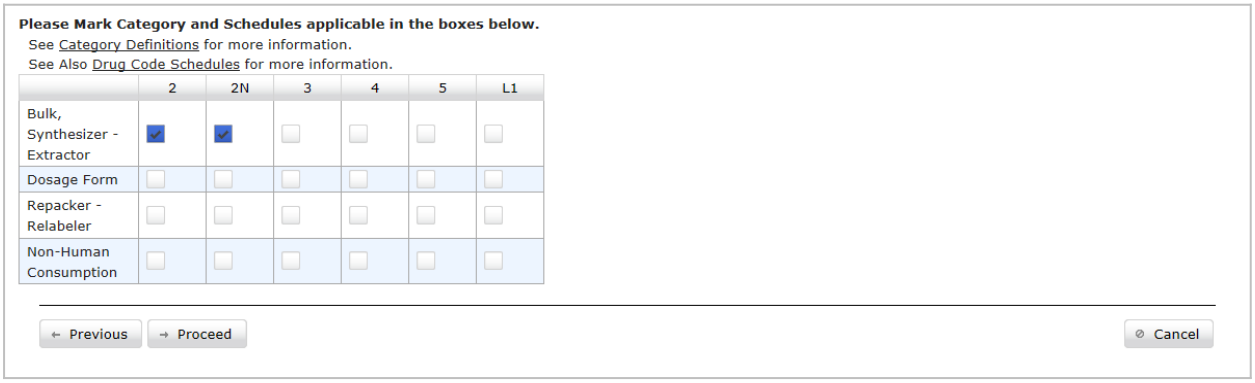


Figure 11: Manufacturer Details

- **Bulk, Synthesizer - Extractor**: select every drug schedule to be involved in the registrant's bulk synthesis and extraction process.
- **Dosage Form**: select every drug schedule to be involved in the registrant's dosage form manufacture process.
- **Repacker - Relabeler**: select every drug schedule to be involved in the packaging/repacking and labeling/relabeling process.
- **Non-Human Consumption**: select every drug schedule that will be manufactured for nonhuman consumption.

Click the Proceed button to continue to the next page.

2.8 Payment Information

2.8.1 Payment Info - Page 1

Unless fee exempt, all applicants must pay a non-refundable registration fee. The cost will vary depending on the selected business activity and will be indicated on the screen.

Fee exempt registrants will not see this page.

Note that clicking the Cancel button will exit the online application, not just the current page.

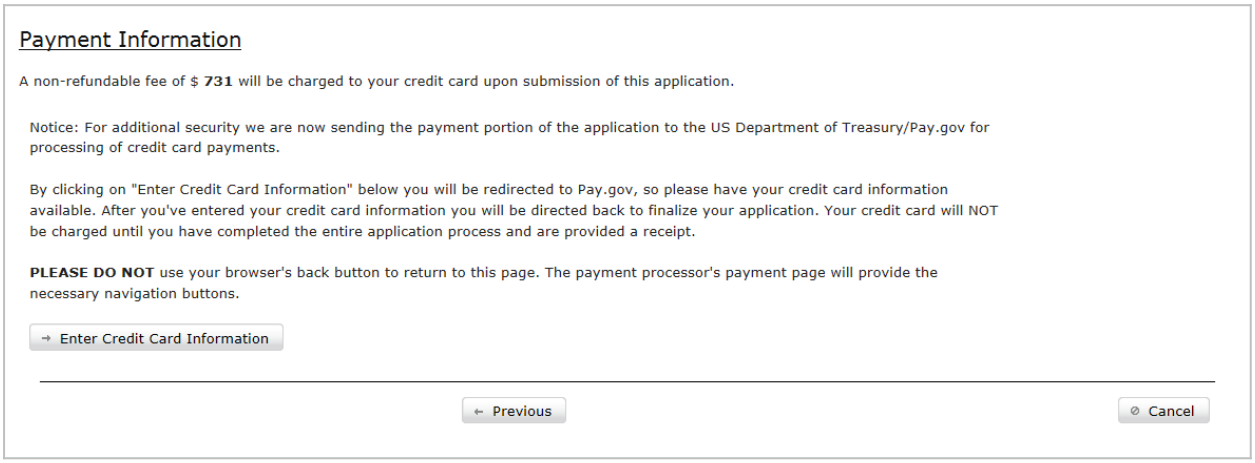


Figure 12: Payment Information

Click the Enter Credit Card Information button. The page will redirect to the pay.gov government payment site (see next page). Pay.gov is not owned or maintained by the Office of Information Systems, Diversion Control Division (SID) or the DEA.

2.8.2 Payment Info - Page 2

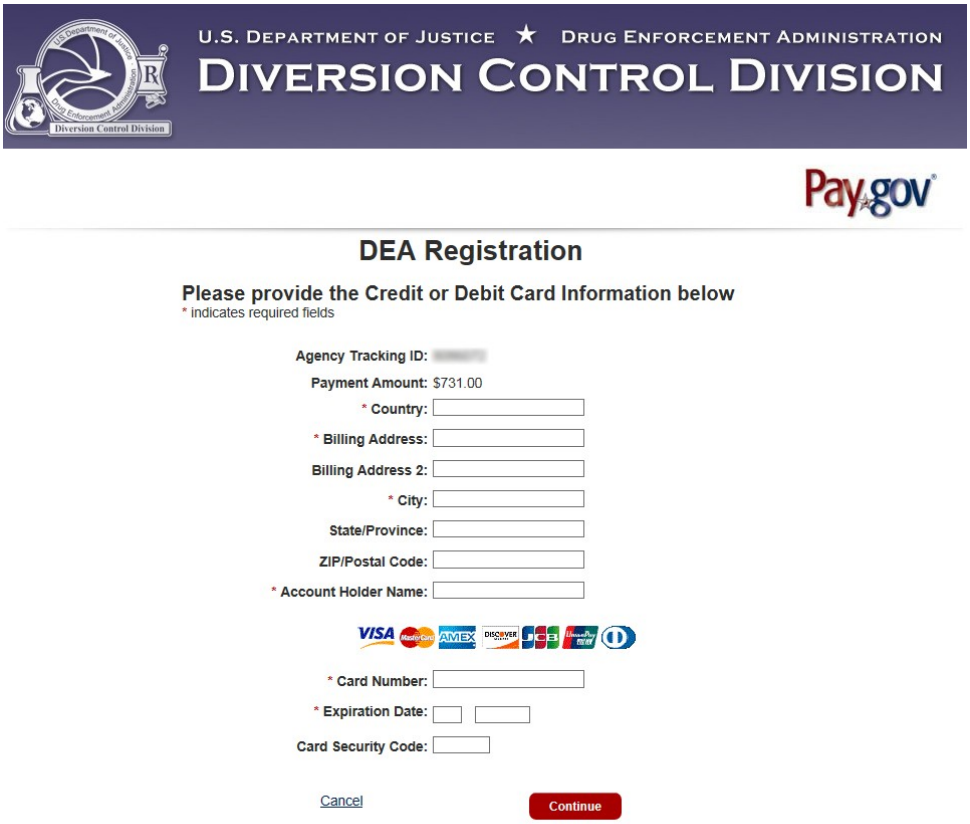


Figure 13: pay.gov

Enter the following information:

- **Agency Tracking ID**: the Tracking ID is a reference ID used by the system.
- **Payment Amount:** the amount charged to the applicant. *The amount is dependent upon the selected Business Activity and cannot be edited.*
- **Country:** the country in which the applicant resides
- **Billing Address:** the applicant's billing address
- **Billing Address 2:** the applicant's additional address information (apartment/suite numbers, etc.), if necessary
- **City:** the city in which the applicant resides
- **State/Province:** the state or province in which the applicant resides
- **Zip/Postal Code:** the applicant's postal code
- **Account Holder Name:** the name as it appears on the credit or debit card
- **Card Number:** the credit card number used to pay for the application fee
- **Expiration Date:** the date on which the entered credit card will expire
- **Card Security Code:** the three- (3) digit security code found on the back of the card

Click the Continue button.

Click the checkbox to confirm all payment information is accurate. Click the Continue button.

Pay.gov will return the applicant to the New Application web form.

Click Cancel to return to the web form without submitting payment.

Note that once the Continue button is clicked, the entered card will be charged. All application fees are non-refundable.

2.9 Review and Submit Application

Review the completed information, and submit the application (Figure 14, page 30).

Click any → Edit button to make changes to the application, if necessary.

The applicant may choose to answer the following question.

> *In the last 3 years, have you received any medical education training concerning the prescribing or dispensing of opioid substances? The DEA understands your response is strictly voluntary and not part of the application process.*

To submit the application, enter the name of one of the following in the **e-Signature** field:

- The applicant, if an individual
- A partner of the applicant, if a partnership
- An officer of the applicant, if a corporation, corporate division, association, trust, or other entity

Click the → Submit Application button.

Note that by signing the application, you agree that any information you provide is true and correct. Any information willfully falsified may be subject to legal actions imposed under 21 USC 843(d).

The certificate will be delivered as a PDF [Portable Document Format] file.

Note that clicking the ⊘ Cancel button will exit the online application, not just the current page.

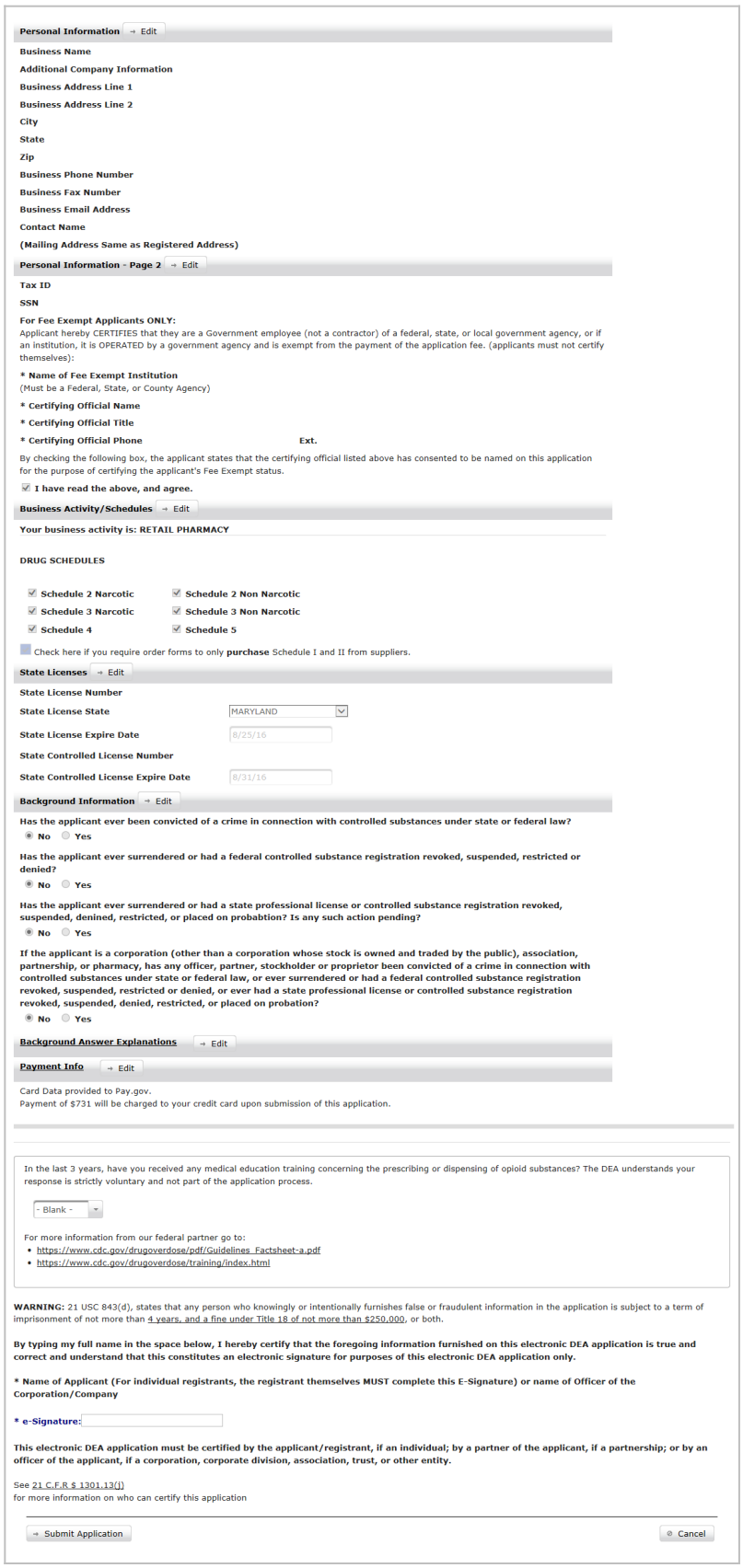


Figure 14: Review and Submit

2.10 Print Certificate and Receipt

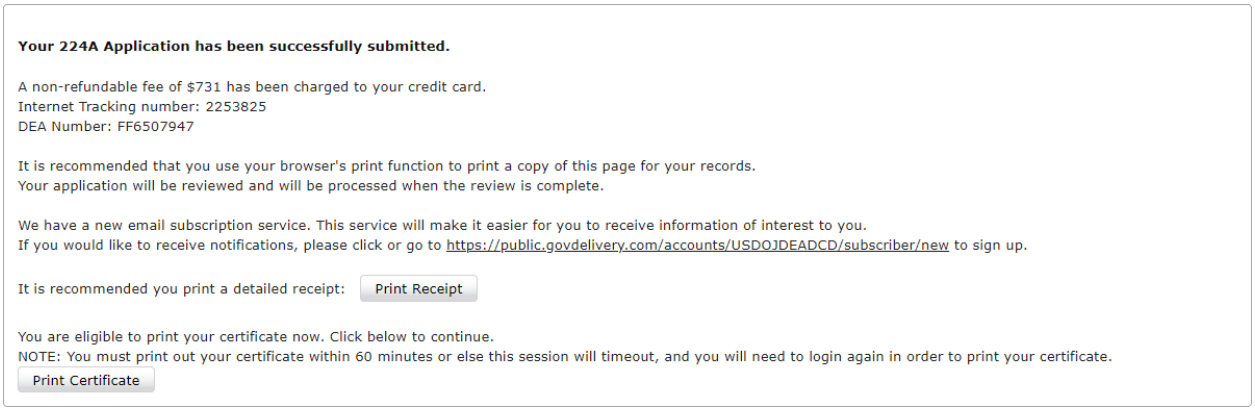


Figure 15: Certificate and Receipt

Once a submission is complete, the transaction receipt and new certificate may be printed. Note that these actions must occur within 60 minutes of reaching the screen above. The receipt and certificate will not be available after 60 minutes.

Click the Print Receipt button to print the receipt.

Click the Print Certificate button to print the certificate.

Appendices

A.0 Business Activity Table

Business Activity	Fee	Years Valid	Form Number	Description
Analytical Lab	$296	1	225	A business or facility who analyzes controlled substances through analytical chemistry
Canine Handler	$296	1	225	Any individual who works with trained police dogs in the detection of illegally possessed controlled substances
Central Fill Pharmacy	$888	3	224	A pharmacy permitted by the state in which it is located to prepare controlled substances orders for dispensing, pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user
Chemical Distributor	$1,850	1	510	A grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine or phenylpropanolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales
Chemical Exporter	$1,850	1	510	A regulated person, who as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.
Chemical Importer	$1,850	1	510	A regulated person, who as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.
Chemical Manufacturer	$3,699	1	510	A business or facility who manufactures a listed chemical, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.
Chempack/ SNS Distributor	$1,850	1	225	A business or facility authorized to distribute self-centralized units placed in centralized locations with controlled substances (chempacks) from the SNS to enable first responders to quickly administer those lifesaving substances

Business Activity	Fee	Years Valid	Form Number	Description
Compounder	$296	1	363	The business activity that engages in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program
Detoxification	$296	1	363	The business activity that dispenses, either short- or long-term, a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug for the purposes of bringing the individual to a narcotic drug-free state within such period of time
Distributor	$1,850	1	225	A business or facility who does not administer or dispense controlled substances but delivers a controlled substance or listed chemical to another entity registered with the DEA
Emergency Medical Services	$888	3	224	An organization that provides EMS only. This includes an organization that is governmental, nongovernmental, private, or volunteer-based; provides emergency medical services by ground, air, or otherwise; and is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.
Exporter	$1,850	1	225	A regulated person, who as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the controlled substance out of the United States
Hospital/Clinic	$888	3	224	A hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice but does not include a pharmacy
Hospital/Clinic — Military	$0	3	224	A military hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled

Business Activity	Fee	Years Valid	Form Number	Description
				substance in the course of professional military practice, but does not include a pharmacy
Importer	$1,850	1	225	A regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the controlled substance into the United States
Importer (C I, II)	$1,850	1	225	Any person who imports, or who acts as an import broker for importation of List I and List II chemicals
Maintenance	$296	1	363	The business activity that dispenses for a period in excess of 21 days a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drug
Manufacturer	$3,699	1	225	A business or facility who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst
Manufacturer (Bulk)	$3,699	1	225	A business or facility who manufactures a drug or other substance in bulk quantity, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst
MLP — Ambulance Service	$888	3	224	Any individual that works for a ground ambulance vehicle service with the provision of medically necessary supplies and services including an ALS assessment or at least one ALS intervention
MLP — Animal Shelter	$888	3	224	Any individual that uses controlled substances in the licensed care of animals within a private or state-run facility intended for the care of lost, abandoned, or surrendered animals
MLP — Physician Assistant	$888	3	224	Any individual licensed as a PA. PAs in Kentucky, Puerto Rico, and US Virgin Islands may not prescribe controlled substances.
MLP — Certified Chiropractor	$888	3	224	Any individual certified and licensed to diagnose and treat mechanical disorders of the musculoskeletal system, and prescribe drugs related to such treatment
MLP — Doctor of Oriental	$888	3	224	Any practitioner of non–traditional medicine of predominantly Eastern origin. This does not

Business Activity	Fee	Years Valid	Form Number	Description
Medicine				include general practitioners or any other business activity that specializes in traditional Western medicine.
MLP — DOD Contractor	$0	3	224	An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States and contracted with the DOD to dispense a controlled substance in the course of professional practice. All business activities are authorized only to dispense controlled substances by the State in which they practice.
MLP — Euthanasia Technician	$888	3	224	Any individual that employs pharmacological methods, including the injection of drugs and gases, in the euthanization of an animal
MLP — Homeopathic Technician	$888	3	224	Any individual who prescribe controlled substances and listed chemicals in the practice of homeopathic medicine
MLP — Medical Psychologist	$888	3	224	Any individual applying the application of psychological principles to the practice of medicine if both physical and mental disorders
MLP — Military	$0	3	224	An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States Military to dispense a controlled substance in the course of professional practice
MLP — Naturopathic Physician	$888	3	224	Any individual who prescribes controlled substances in the course of alternative, or naturopathic, medicine
MLP — Nurse Practitioner	$888	3	224	Any APRN educated with the knowledge base and decision-making skills to treat medical conditions without the supervision of a doctor
MLP — Nursing Home	$888	3	224	Any private care facility providing residential accommodations with health care, especially for elderly people
MLP — Optometrist	$888	3	224	Any medically-trained individual licensed to deliver primary, secondary, and tertiary eye care
MLP — Physician Assistant	$888	3	224	Any nationally-certified and state-licensed medical professional able to prescribe medication
MLP —	$888	3	224	Any individual with a license to practice the

Business Activity	Fee	Years Valid	Form Number	Description
Registered Pharmacist				preparation, composition, and dispensation of drugs pursuant to a valid prescription
Pharmacy — Military	$0	3	224	An entity permitted to prepare controlled substance orders for dispensing, pursuant to a valid prescription for the United States Military and its personnel
Practitioner	$888	3	224	A physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner
Practitioner — DOD Contractor	$0	3	224	A physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States and contracted with the DOD to dispense a controlled substance in the course of professional practice but does not include a pharmacist, a pharmacy, or an institutional practitioner
Practitioner — Military	$0	3	224	A military physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States Military to dispense a controlled substance in the course of professional practice but does not include a pharmacist, a pharmacy, or an institutional practitioner
Researcher (I)	$296	1	225	Any individual who conducts diligent and systematic inquiry or investigation into controlled substances listed in schedule I
Researcher (II-IV)	$296	1	225	Any individual who conducts diligent and systematic inquiry or investigation into controlled substances listed in schedules II-V
Retail Pharmacy	$888	3	224	An entity permitted by the state in which it is located to prepare controlled substance orders for dispensing, pursuant to a valid prescription
Reverse Distributor	$1,850	1	225	A person registered with the Administration to acquire controlled substances from another registrant or law enforcement for the purpose of return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or

Business Activity	Fee	Years Valid	Form Number	Description
				destruction
Teaching Institution	$888	3	224	A physical location where medicine is taught under the authority of a State accredited college or university

B.0 Pre-Application Checklist

B.1 Practitioner

Practitioner Pre-application Checklist

1. This form is for **NEW** applicants only. If you need to **renew** your DEA registration, please navigate to the registration renewal application.
2. A new application may take 4 to 6 weeks to process.
3. Registering as a practitioner requires a ***NON-REFUNDABLE*** fee of $731. If you are not sure you meet all the qualifications to obtain a DEA registration, or if you are unsure whether this is the correct application to complete, please do not continue. There is no prorated application fee and ***THE SUBSEQUENT WITHDRAWAL OF AN APPLICATION DOES NOT QUALIFY FOR A RETURN OF THE APPLICATION FEE***.
4. The applicant must be the only individual completing and certifying by E-signature that the information provided is accurate for purposes of this DEA application. There is an exception if the applicant files a power of attorney with DEA (Title 21 CFR § 1301.13(j)).
5. To register as a practitioner, you must currently hold one of the following degrees:
   a. DMD
   b. DDS
   c. MD
   d. DO
   e. DPM
   f. DVM
6. You must currently have a full state license in the state where you will register. A "temporary," "training," or "pro bono" license may be acceptable if that type of license represents full state authorization to handle controlled substances (i.e., administer, dispense, and prescribe). It is recommended you contact the local Registration Program Specialist for clarification on state law/regulations before you complete the application. ***A LACK OF STATE AUTHORIZATION DOES NOT ENTITLE YOU TO A RETURN OF THE APPLICATION FEE***.
7. Your current state license and the registered address you will provide in this application must be for the same state. If they are not, do not apply unless you are employed by a federal agency such as:

Bureau of Prisons	Centers for Disease Control and Prevention
Department of Homeland Security	Department of Justice
Federal Aviation Administration	Food and Drug Administration
Health and Human Services	Indian Health Services
National Aeronautics and Space Administration	National Cancer Institute
National Institutes of Health	National Institute of Mental Health
National Oceanic and Atmospheric Administration	Public Health Services
Department of Agriculture	United States Postal Service
Department of Veterans Affairs	U.S. Capitol Physician's Office
White House	

8. You must **currently** possess all required state authority to handle controlled substances for the state of your registered business/office address. Some states require a separate controlled substances license in addition to a medical, dental, or veterinary license. If you do not **currently** possess these credentials, do not apply until all state requirements are fulfilled.
9. The Controlled Substances Act requires a **separate** registration at "each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances ..." Be prepared to provide complete business address information. Your home address is acceptable **IF** it is the location of your professional practice.
10. You may be exempt from the application fee if you are a direct hire employee for a federal, state, or local government institution, or of a public university. The exemption will restrict the use of a DEA registration to government or university duties only. In accordance with Title 21 CFR § 1301.21(b), you must certify your status on the application. You may forfeit the fee exemption by not complying with this regulation. You may be required to provide evidence of government or public university employment.
11. Answers to liability questions are only relevant to your history with controlled substances.
12. A separate registration is required for **each state** where controlled substances will be administered*, prescribed, or dispensed*. However, additional registrations are required if a practitioner maintains supplies of controlled substances at multiple locations within that state.

    *Within the law there is an exception if you are a veterinarian.
13. Do not use this form if you have already mailed a paper application. Duplicate submissions may result in a duplicate collection of ***NON-REFUNDABLE*** application fees.
14. The application fee is ***NON-REFUNDABLE*** regardless of whether a registration is issued or not.
15. Federal laws and regulations applying to a practitioner holding a DEA registration may be found in the Practitioner's Manual
16. For additional questions or clarification, the following services are available:
    a. Contact a customer service representative at 1-800-882-9539
    b. Email DEA.Registration.Help@usdoj.gov
    c. Contact a Registration Program Specialist specific to your state

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☐ I have read and understood the information and agree to the terms outlined above.

Figure 16: Practitioner Checklist

B.2 Researcher I

Schedule 1 Researcher Pre-application Checklist

1. This form is for **NEW** applicants only who intend to handle Schedule I controlled substances for research purposes. If you need to **renew** your DEA registration, please navigate to the registration renewal application.

2. If your application is found to involve manufacturing activities not permitted under a researcher registration, your application may be denied. Some examples of manufacturing activities include the following:

   a. Activities to satisfy regulatory requirements such as FDA submissions or good manufacturing practice
   b. Activities related to production of material used for pilot, scale-up, and reformulation studies
   c. Activities related to product development including bioavailability, dosage formulation, stability, and validation studies

   For additional questions or clarification related to manufacturing activities please email ODESchedule@dea.usdoj.gov

3. Registering as a researcher requires a ***NON-REFUNDABLE*** fee of $244. There is no prorated application fee and ***THE SUBSEQUENT WITHDRAWAL OF AN APPLICATION DOES NOT QUALIFY FOR A RETURN OF THE APPLICATION FEE***.

4. The applicant must be the only individual completing and certifying by E-signature that the information provided is accurate for purposes of this DEA application. There is an exception if the applicant files a power of attorney with DEA (Title 21 CFR § 1301.13(j)).

5. You must currently possess all required state authority to handle controlled substances for the state of your registered business/office address. It is recommended you contact the local Diversion Field Office for clarification on state law/regulations before you complete the application. ***A LACK OF STATE AUTHORIZATION DOES NOT ENTITLE YOU TO A RETURN OF THE APPLICATION FEE***

6. You must currently possess appropriate institutional authority to conduct research with schedule I controlled substances.

7. You must separately identify each of the studies/projects, by Project Name, that are covered by this application. If your research involves one or multiple studies/projects you will need to provide information specific for each of these studies/projects. For a given Study/Project:
   A. Are you conducting human research? If YES:
      i. You must have Institutional Review Board (IRB) approval for clinical studies ***PDF FILE UPLOAD REQUIRED***
      ii. You must have an approved active Notice of Claimed Investigational Exemption for a New Drug (IND) (number) for clinical studies ***PDF FILE UPLOAD REQUIRED***
      iii. You must have a protocol* ,See Title 21 CFR § 1301.18 and 21 CFR § 1301.32 for the protocol requirements. ***PDF FILE UPLOAD REQUIRED***
   B. Are you conducting animal research? If YES:
      i. You must have approval from Institutional Animal Care and Use Committee (IACUC) for animal studies. ***PDF FILE UPLOAD REQUIRED***
      ii. You must have a protocol* ,See Title 21 CFR § 1301.18 and 21 CFR § 1301.32 for the protocol requirements. ***PDF FILE UPLOAD REQUIRED***
   C. Are you conducting research that does not use animals or humans? Examples of such research are: In-Vitro laboratory research that doesn't require institutional approval, research to develop analytical methods, and research to develop chemical synthesis procedures etc. If Yes:
      i. You must have a protocol* ,See Title 21 CFR § 1301.18 and 21 CFR § 1301.32 for the protocol requirements. ***PDF FILE UPLOAD REQUIRED***

   Protocols: If a given study/project has a consolidated research protocol, that covers all of the types of research being performed, then you only need to upload the consolidated research protocol once for that study/project. If study/project's research protocols have not been consolidated, then you will have to upload a dedicated research protocol for each type of research being performed.

   Note: Size limit for upload documentation is 10 MB

8. You must submit a **Curriculum Vitae for each of the investigator(s) working on each of the studies/projects** as part of the application process. See Title 21 CFR § 1301.18 and 21 CFR § 1301.32 for the protocol requirements.
   a. Curriculum Vitae of investigator(s) ***PDF FILE UPLOAD REQUIRED***

   Note: Size limit for upload documentation is 10 MB

9. Are you obtaining the Schedule I controlled substances that are mentioned in the research protocol from external sources?
   a. If YES, you will need to provide the DEA registration number(s) of the source(s) and validate their name and address. REQUIRED

10. You may be exempt from the application fee if you are a **CURRENT** direct hire employee for a federal, state, or local government institution, or of a public university. The fee exemption is not applicable for future employment. The exemption will restrict the use of a DEA registration to government or university duties only. In accordance with Title 21 CFR § 1301.21(b), you must certify your status on the application. You may forfeit the fee exemption by not complying with this regulation. You must include your email address that is associated with the fee exempt location. You may be required to provide evidence of government or public university employment.

11. Do not use this form if you have already mailed a paper application. Duplicate submissions may result in a duplicate collection of ***NON-REFUNDABLE*** application fees.

12. For additional questions or clarification, the following services are available:
    1. Contact a customer service representative at 1-800-882-9539
    2. Email DEA.Registration.Help@usdoj.gov
    3. Contact a Registration Program Specialist specific to your state

☐ **I have read and understood the information and agree to the terms outlined above.**

Figure 17: Researcher Checklist

C.0 Acronyms

Acronym	Description
ALS	Advanced Life Support
APRN	Advanced Practice Registered Nurse
CS	Controlled Substance
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DOD	Department of Defense
EMS	Emergency Medical Services
MLP	Mid-Level Practitioner
NPI	National Provider Identification
PA	Physician Assistant
PDF	Portable Document Format
SNS	Strategic National Stockpile
SSN	Social Security Number