

Alabama Board of Medical Examiners

Controlled Substance Prescribing in Collaborative/Supervisory Relationships: Roles and Responsibilities



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MISSION OF THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS AND MEDICAL LICENSURE COMMISSION

"The Alabama Board of Medical Examiners and the
Medical Licensure Commission of Alabama
are charged with protecting the health and safety of the
citizens of the state of Alabama."

William M. Perkins
Executive Director

Alabama Board of Medical Examiners

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What's NEW?



LICENSEE GATEWAY



NEW QACSC/LPSP
PROTOCOLS



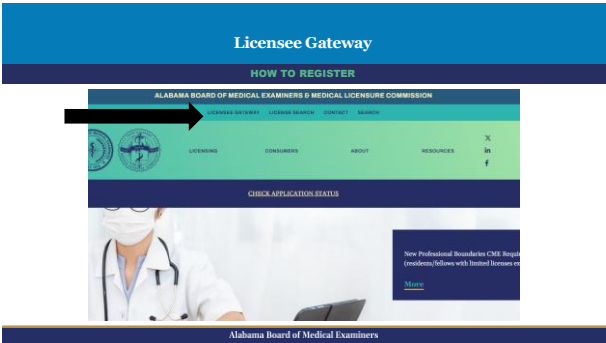
MANDATORY QA FOR
CONTROLLED PRESCRIBING

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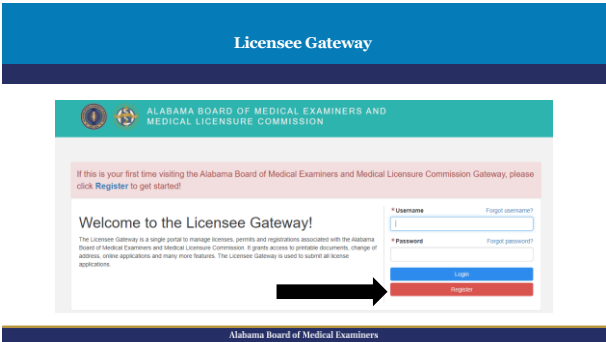
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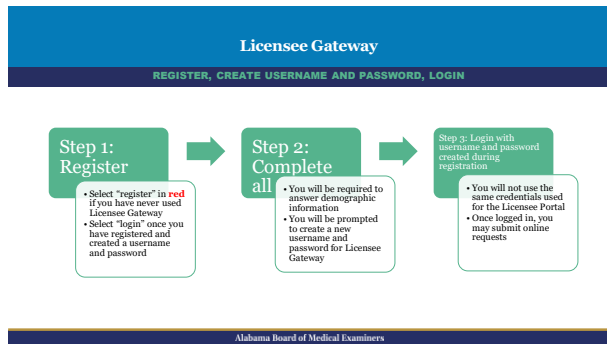
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Prescriptions and Medication Orders by CRNPs, CNMs, and PAs

May not sign prescriptions for controlled substances without a QACSC and a DEA.

- May call and/or write a verbal order for a controlled substance provided....
- Collaborating physician has approved the medication and either signed the Rx or given a verbal order which is written in the medical record
- The CRNP/CNM/PA verbal order must be signed by the physician within 7 business days

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Controlled Substance Prescribing

Define separate policies in your practice for prescribing legend drugs and controlled drugs

Check Medical Staff Bylaws and facility policies prior to writing inpatient orders for Controlled Substances-some are now requiring a QACSC for inpatient prescribing

You will need a QACSC and your own DEA if writing prescriptions for discharge that will be filled at an outside pharmacy

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Code of Alabama 20-2-260

• An APP authorized to prescribe.... shall not prescribe, administer, or dispense any controlled substance to:

- ❖ his or her own self
- ❖ spouse
- ❖ child
- ❖ parent

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Where Do I Find the Rules?

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Important Chapters:

- 540-X-7 Assistants to Physicians
- 540-X-8 APN: Collaborative Practice
- 540-X-12 QACSC (PAs)
- 540-X-17 Weight Loss Rules
- 540-X-18 QACSC (CRNPs)
- 540-X-19 Pain Management
- 540-X-20 LPSP (all)

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**Qualified
Alabama
Controlled
Substance
Certificate**

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Obtaining a QACSC



Eligibility Requirements to obtain a QACSC



Collaborative Agreement(s) or Registration Agreement(s) with Final Approval by the ABN/BME totaling at least 12 months in the State of Alabama- Waiver for the PAs



Attended the controlled prescribing seminar presented by the Medical Association State of Alabama to obtain the 12 AMA PRA Category 1 credits offered (Register at www.albme.gov)



Send in application for QACSC within one (1) year of completing the prescribing course. Application must be approved by the Board. The Board meets once a month

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The 12 months of collaboration/supervision is a cumulative total. It does not need to be completed with a single physician, nor must it be with the physician for whom you are applying with for the QACSC.

Statute requires this for CRNPs/CNMs.

PAs that have worked in a supervising relationship with a physician for 3 years in another state and held a DEA for 1 year may apply with the waiver for this requirement

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Where do I find the Applications?

www.albme.gov



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Next step: Click on FORMS or Application Forms

A QACSC is specific to each collaborative practice agreement.



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Forms

- + NEW: Prescribing Protocols for QACSC and LPSP* and Quality Assurance Plan Forms (Required)
- *NOTE that all QACSC protocols also apply to LPSPs
- + Initial QACSC Application for CRNPs/CNMs Application and Instructions
- + Additional QACSC Application for CRNPs/CNMs Application and Instructions
- + QACSC Covering Physician Agreement-NP (How to add coverings to QACSC)

Fees (Non-Transferable/Non-Refundable)

- + Initial QACSC: \$110
- + Additional QACSC: \$60
- + QACSC renewal: \$60

Print receipts at the Licensee Gateway.

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Initial QACSC versus Additional QACSC



The Initial QACSC is the FIRST QACSC that you apply for and receive. The fee is \$110.00 and includes a PDMP fee.



The Additional QACSC is ANY SUBSEQUENT QACSC that you may apply for after you have been issued the Initial QACSC. The fee is \$60.00.



*If you apply for an Initial QACSC and withdraw the application or are not granted approval, then you will be required to pay the \$110.00 initial fee again.

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Which license do I apply for first?

A) QACSC

B) DEA

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Which license do I apply for first?

A) QACSC- you must have the QACSC License number to apply for the DEA

B) DEA

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If you work for the VA, you have independent practice and may write controlled substances without a collaboration/registration/QACSC/LPSP provided you have a DEA and ZERO prescriptions will be filled outside the walls of the VA.

If a single prescription gets filled at an outside pharmacy, you must have a collaboration/registration agreement and a QACSC!

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Applying for the DEA

- **Do not apply** for the DEA until you have approved for and been issued a QACSC-the DEA costs \$888 and is non-refundable!
- Apply for DEA Registration at www.deadiversion.usdoj.gov and then send a copy of the certificate to the BME or upload into your Licensee Gateway-please email us, the system DOES NOT notify us!
- Your QACSC status will be "Active Pending DEA" until we receive a copy of the DEA. You cannot print your certificate or renew the QACSC for the next calendar year with this status!

You are not authorized to sign a prescription for a controlled substance in Alabama without both the QACSC and the DEA

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Do I Need Multiple QACSCs?



- APP works with the physician in his/her primary practice site Monday thru Friday.

On the weekends, they also work together at the ER in their town. Does the APP need a QACSC for each site?

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Answer: **NO**



- If **all** practice sites are listed on the Collaborative Practice/Registration Agreement and the physician can walk into any listed site and see patients and records, only one QACSC is required.
- *If APP works at Urgent Care on the weekends under a different collaborating/supervising physician, then 2 QACSCs would be required. One for each physician/site.
- **If a PA has multiple registration agreements with the same physician, the PA may be required to have a QACSC for each registration agreement.

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**Controlled
Substances
for Weight
Reduction...
Can I
Prescribe?**

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540-X-17-.03 Schedule III, IV And V Controlled Substances for Weight Reduction:

(1) Only a doctor of medicine or doctor of osteopathy licensed by the Medical Licensure Commission of Alabama may order, prescribe, dispense, supply, administer or otherwise distribute a controlled substance in Schedule III, IV or V to a person for the purpose of weight control, weight loss, weight reduction, or treatment of obesity, except that a Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife may prescribe non-controlled drugs for such purpose. If a Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife prescribes non-controlled drugs for weight reduction or the treatment of obesity, the prescriber shall comply with the guidelines and standards of this Chapter which apply to MDs and DOs.

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540-X-17-.02 Schedule II Controlled Substances.

"A physician shall not order, prescribe, dispense, supply, administer or otherwise distribute any Schedule II amphetamine or Schedule II amphetamine-like anorectic drug, or Schedule II sympathomimetic amine drug or compound thereof or any salt, compound, isomer, derivative or preparation of the foregoing which is chemically equivalent thereto or other non-narcotic Schedule II stimulant drug, which drugs or compounds are classified under Schedule II of the Alabama Uniform Controlled Substances Act, to any person for the purpose of weight control, weight loss, weight reduction or treatment of obesity."

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(2) A written prescription or a written order for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity **shall be signed by the prescribing physician on the date the medication is to be dispensed, or the prescription is provided to the patient**

If an electronic prescription is issued for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity, the prescribing physician **must sign and authorize the transmission of the electronic controlled substance prescription** in accordance with federal law and must comply with all applicable requirements for Electronic Prescriptions for Controlled Substances

Such prescriptions or orders **shall not** be called in to a pharmacy by the physician or an agent of the physician

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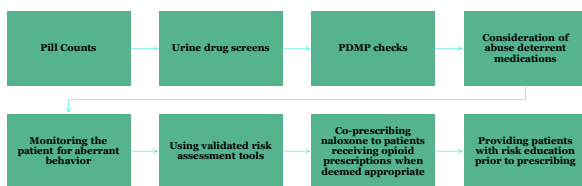
(3) The prescribing/ordering physician shall be present at the facility when he or she prescribes, orders or dispenses a controlled substance for a patient for the purpose of weight reduction or treatment of obesity

Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §34-24-53 History: New Rule: Filed December 16, 2011; effective January 20, 2012. Amended: Filed June 18, 2015; effective July 23, 2015. Amended: Published August 31, 2020; effective October 15, 2020

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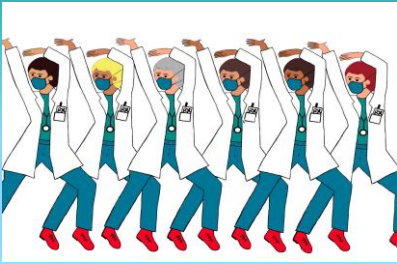
Risk Mitigation Includes:



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NEW Prescribing Protocols!!



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What are the QACSC & LPSP Protocols?

The Protocols govern how you prescribe controlled medications!



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NEW!! QACSC Protocols (Schedule 3-5)

- APP may initiate a 30-day supply with 2 refills (not to exceed 90 days) or an initial 90-day supply with physician approval
- If physician initiates, and the patient is well-maintained, the APP may prescribe a 30-day supply with 2 refills (not to exceed 90 days total). A 90-day supply is permissible for reissue if established on a 90-day supply from the physician.
- The decision to continue therapy after ninety (90) days must be made in collaboration with the approved collaborating physician following the physician's evaluation of the patient and consultation with the QACSC holder. The medical decision-making, evaluation, and consultation must be documented in the medical record. If approved by the collaborating physician, the QACSC holder may issue subsequent prescriptions in compliance with this protocol.
- The physician must conduct an in-person evaluation of any patient receiving ongoing treatment with controlled substances at least once every twelve (12) months. This evaluation is required to ensure that all prescriptions are issued for a legitimate medical purpose and within the usual course of professional practice. At the time of the evaluation, any controlled substance prescriptions must be reissued or refilled exclusively by the physician, using their own Alabama Controlled Substances Certificate (ACSC) and Drug Enforcement Administration (DEA) registration.

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QACSC Protocols Continued

- May have on site a more restrictive prescribing protocol which is specific to the individual practice, but it may not be more permissive than this stated protocol
- A QACSC holder may make a verbal order for a controlled substance in Schedules III-V under the circumstances stated in this protocol.
- A QACSC holder is not authorized to dispense controlled substances in any Schedule. For the purposes of this protocol, "dispense" is defined as ordering a controlled substance to be dispensed or distributed from a dispensary located in the facility where the QACSC holder practices to a patient for off-premises consumption or administration
- The QACSC holder may sign for samples of those controlled substances in Schedules III-V approved in the QACSC holder's Formulary for office use as is normal and customary for that practice specialty

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Limited Purpose Schedule 2 Permit

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Limited Purpose Schedule 2 Permit (LPSP)

Requirements	Important
Current /Active QACSC	Covering physicians must first be on the QACSC
Current/Active DEA	LPSP will terminate along with the QACSC if the Collaborative Agreement Terminates
Submit Application to include the drug groups need for your practice	Long-Acting Schedule 2 medications are historically only approved for Hospice/ Palliative Care under the umbrella of Hospice/ Oncology/ Rehab clinical practices/ nursing homes
Submit explanation for the need of each drug group requested	Not just the drug name

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Helpful Hints

Historically, the Board will not approve Hydrocodone Cough Preps for children under the age of 18 or for chronic cough.	Historically, the Board will not approve ADHD medications for: Hypersomnia (IH), obstructive sleep apnea, or Binge-Eating Disorder.
ADHD medications are historically approved for ADD/ADHD only.	Historically, the Board will not approve ADHD meds for urgent care. Only primary care.

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APPs may now request to treat Narcolepsy with stimulants
IF:

- 1) Medications are FDA approved for Narcolepsy
- 2) The patient has undergone a sleep study and received a diagnosis of Narcolepsy by a physician
- 3) The practice site has been approved by the Board of Medical Examiners

(This may require individual review)

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LPSP Protocols Continued

- The physician must conduct an in-person evaluation of any patient receiving ongoing treatment with controlled substances at least once every twelve (12) months. This evaluation is required to ensure that all prescriptions are issued for a legitimate medical purpose and within the usual course of professional practice. At the time of the evaluation, any controlled substance prescriptions must be reissued or refilled exclusively by the physician, using their own Alabama Controlled Substances Certificate (ACSC) and Drug Enforcement Administration (DEA) registration.
- Cannot dispense controlled substances in any schedule
- Can always have on site a more restrictive prescribing protocol specific to the individual practice, but it may not be more permissive than these stated protocols
- Quality Assurance is REQUIRED every quarter on BME mandatory forms for all schedules

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Long-Acting Schedule 2 Medications

- For **long-acting Schedule II** controlled substances, the initial dose and any subsequent escalation of the dose must be written by the physician with the APP writing maintenance doses only. **NO CHANGE!**
- Long-acting Schedule II medications may only be prescribed for patients in Hospice/Palliative Care; Nursing Home/ Rehabilitation Facilities; or Oncology. **NO CHANGE!**
- These specific specialties/locations **must be approved and listed** on the collaborative/registration agreement.

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In a nutshell:

- Schedules 2-5 –the APP may initiate the first 90 days (30 days with 2 refills/or 90-day supply with physician approval QACSC; 30 days with 2 reissues LPSP)
- After initial 90 days prescribed by APP, if schedule 2/2N, the physician must physically see the patient before the APP can reissue
- Every 90 days, there must be documented collaboration with the physician for the APP to continue the Rx and every 90 days thereafter
- The APP can write the prescriptions 11 months out of the year
- Once per year, at a minimum, the physician must physically see the patients receiving continuous controlled substances and write the Rxs under their own ACSC and DEA. (Telemedicine may be utilized if law requirements are met)
- QA is required quarterly on mandatory forms

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After receiving approval from the BME, you will need to **update** the DEA with the new approved drug schedules to include 2 and/or 2N



You cannot utilize the LPSP until this has been completed, and you have received the updated DEA certificate



Scan/email or upload a copy of the updated DEA certificate once received

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May I Apply for the QACSC and the LPSP at the Same Time?

What If I Only Need an LPSP to Write Stimulants?

If you have a current Alabama DEA registration, you may apply for the QACSC and the LPSP at the same time



If this is your initial QACSC, you must wait to apply for the LPSP until AFTER you have received the DEA and the BME has made the QACSC "Active"



You cannot have an LPSP without a QACSC, therefore, you must first receive the QACSC and subsequently the DEA before applying for the LPSP

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What If I Need to Add a Drug Class?

APP requested ADHD Medications, Hydrocodone Cough Preps and Hydrocodone Combinations on LPSP application.

- APP needs to **add** Oxycodone IR medications.



APP may submit a request for an **LPSP Expansion**. This may be done at any time for no additional fee. The request will still go before the Board of Medical Examiners for review and approval.



If the expansion request is for **ADHD Medications**, the DEA will need to be updated to reflect the addition of **2N** medications.

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Quality Assurance for Controlled Prescribing



QA for Controlled substance prescribing is now required

Data can be compiled by office staff and reviewed by physician/CRNP/CNM

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Quarterly Quality Assurance Documentation Required

- *As part of the approved collaborative practice agreement, the collaborating or covering physician shall conduct and document a quarterly quality assurance review of the QACSC/LSP holder's-controlled substance prescribing practices. This review may include an evaluation of the my RX report through the Alabama Department of Public Health's Prescription Drug Monitoring Program (PDMP)*
- **REQUIRED FORMS ARE LOCATED ON OUR WEBSITE** www.albme.gov and include:
 - 1. QA Plan for Controlled Prescribing
 - 2. QA Tool for Quarterly Review
 - 3. Summary of Findings and Recommendation for Change Form
 - 4. Adverse Event Form

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Quality Assurance Plan

10% Required Quarterly

Provide who will compile the data

Sign and Date

Must be readily retrievable at the practice location!

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Electronic Prescribing

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Scheduled 2 and 2N Medications

Cannot be verbally
called into a pharmacy

Must either be written
or sent in electronically
“Electronic
Prescription for
Controlled Substances”
(EPCS)

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EPCS: Why is This Important?

*EPCS is one and the same as a practitioner physically signing a prescription
*Do not send a controlled medication via EPCS unless you are physically
registered appropriately with your own signature

*If you do not have an LPSP and DEA, you should never send in a controlled
medication for another prescriber via EPCS

*If you have an LPSP and DEA, but you are not authenticated by the DEA-
required process, you should also never send in a controlled medication via
EPCS

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What if the Pharmacy says I am not authorized to write controlled substances?

- Medicaid does require that you submit a copy of your DEA certificate directly to them.
- Prescribers of controlled substances are mandated to re-register their DEA License every three years. To ensure your DEA is on file at Medicaid, upload a copy of the provider's DEA Registration Certificate to the Medicaid Interactive Web Portal or fax to (334) 215-7416 with the barcode cover sheet that is provided in the Interactive Web Portal at the end of the Enrollment Updates request. Please be sure to include the provider's name, NPI number, and license number on the certificate. Medicaid will apply the DEA to all service locations based on the provider's NPI and license number. Melissa.gill@gainwelltechnologies.com
- Call and speak with a pharmacist about a specific patient with a medication that was denied. Ask specifically for the reasons why. Many times, it has to do with the pharmacy not being able to access your QACSC and DEA information through their third-party vendors (This is usually the case!!)
- Make sure you have added the appropriate schedules to your DEA!
- It can be an insurance issue where they are denying the medication because there is something specific that needs to be addressed as far as being a credentialed provider for that specific insurance company
- Go to our website at www.albme.gov; Click on "Licensee Search"; Search for Licenses; Enter your first and last names only; Click Search. Please click on your name to view the details that we have listed for your QACSC and/or LPSP. Make sure all of this is appropriate

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Prescription Drug Monitoring Program (PDMP)

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PDMP: Registration

1

Register

- Register as a **Prescriber Delegate-Licensed** if you do not have personal controlled prescribing certificates but are a licensed LPN, RN, NP, or PA

2

Register

- Register as a **Prescriber Delegate-Non Licensed** if you are not a licensed health care professional (example: office administrator, medical assistant)

3

Register

- Register as a **Nurse Practitioner or Physician Assistant** if you are a Nurse Practitioner or Physician Assistant and you have your own state controlled prescribing certificates and DEA



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Information Needed When Registering for the PDMP

Email address	DEA Number	NPI Number	State License Number (QACSC)
Last 4 digits of SSN	Health Care Specialty	Primary contact phone number	Cell phone number
Email associated with your collaborating/supervising physician's PDMP account			

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Training Videos Available on the
PDMP Website:
www.alabamapublichealth.gov/pdmp/

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Prescription Drug Monitoring Program (PDMP)

Upon receipt of the QACSC and DEA you are **required** to register for the Prescription Drug Monitoring Program at <https://alabamapmpaware.net/login>

PDMP allows you and the Collaborating/ Supervising physician to check your prescribing on a regular basis

Always contact the pharmacy if you see any errors when you review the PDMP

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The \$29.95 is for the prescription, ma'am, and the \$15.00 surcharge is a little gift for our handwriting expert!

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Example of How a Prescription Gets Logged Into the PDMP Under the Wrong Prescriber

Both the physician and the NP are listed on the prescription pad

The prescriber does not circle their name nor indicate who is the actual prescriber

The pharmacy cannot read the illegible signature on the prescription

Prescription gets logged into the PDMP under whomever the pharmacy personnel entering the information chooses or logs it under who wrote the previous prescription

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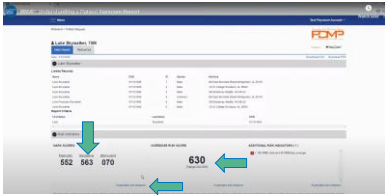
PDMP CONTRACT AGREEMENT



- Agree to check current patients and/or potential patients of your practice only
- Privacy Statement: Any person who intentionally obtains unauthorized access.....shall be guilty of a Class C Felony
- **Unlawful Disclosure: Any reproduction or copy of the information is privileged and confidential.....not subject to subpoena or discovery in civil proceedings**

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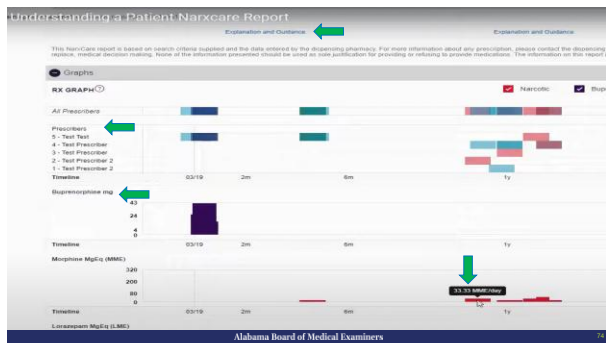


- This report reveals **Risk Indicators** and will show how many prescriptions are active in a specific drug type
- The **Risk Score** should be used to trigger discussion and draw awareness to the presence of significant PDMP data
- It should be used to guide decision making. **It should NOT be used as a single factor in clinical decisions.**
- **Explanation & Guidance** offers excellent information!

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How Often Do I Need to Check the PDMP?

****Nursing homes, hospice prescriptions, treatment of active malignant pain, intra-op are EXEMPT**

- For prescriptions totaling less than 30 MME/day or 3 LME/day, practitioners are expected to use the PDMP in a manner consistent with good clinical practice
- MME greater than 30/day or LME greater than 3/day requires a PDMP check at least twice annually
- MME greater than 90/day or LME greater than 5/day requires a PDMP check with every prescription written on the same day that it is written

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PDMP Contact Information

Password Reset/ Creating an Account/ Technical
Support: #1-855-925-4767

Deactivated Account/ Not Tech Support/ Other Questions:
#1-877-703-9869

For questions regarding linking or deleting the collaborating physician:

Vicki Walker: vicki.walker@adph.state.al.us
Rachel Kiefer: rachel.kiefer@adph.state.al.us

For general PDMP questions:
• #334-206-6226
• 1-800-703-9869 or 1-800-925-4767

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Highest Ranking States for Prescribing Opioids in 2023 CDC

Highest opioid dispensing rates per 100 persons in 2024:

- 1) Arkansas (68.8)
- 2) **Alabama (68.5)**
- 3) Mississippi (61.4)
- 4) Louisiana (59.2)
- 5) Tennessee (58.6)

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The overall national opioid dispensing rate declined steadily from a rate of 46.8 opioid prescriptions per 100 persons in 2019 to a rate of 35.4 opioid prescriptions dispensed per 100 persons in 2024.

While this is great news, we are still **second highest** in the nation for dispensing opioids

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Lowest States in the Nation for Dispensing Opioids in 2023 CDC

Lowest dispensing rates per 100 persons in 2024:

- 1) Hawaii (21.0)
- 2) California (22.4)
- 3) New Jersey (23.7)
- 4) New York (24.1)

**We are dispensing 44.4- 47.5 per 100 persons higher!

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Prescription Requirements

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DR. T. W. JACKSON
Manchester, Ga. Telephone 110
Office Hours: 10 to 11 a. m.—2 to 4 p. m.

Name: L. B. Buchanan

R Codine sul gr IV

Ans. A. gr XXX

5 cc op na IV

5 gr. auc every 4 hours if

needed for pain

HAVE THIS FILLED AT
CITY DRUG COMPANY
THE GREAT STORE
MANCHESTER GEORGIA

Date: T. W. Jackson M. D.

217829 JUN 18 1942

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RENEWALS: QACSC, LPSP, and DEA

- Any QACSC and/or LPSP obtained during the calendar year must be renewed annually before 12/31 for the next calendar year
- Renewals for the QACSC and/or LPSP are processed **online** only between **10/01-12/31** in the Licensee Gateway
- The fees are \$60.00 for each QACSC and \$10.00 for each LPSP
- Obtain **4 AMA PRA Category 1 credits** every 2 years through a **Board approved** course/courses
- DEA renewals are processed on the DEA website: www.deadiversion.usdoj.gov every 2-3 years. The DEA will send one email reminder 30 days in advance. The fee is \$888. Please send the BME a copy



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Renewal is Required for Both the QACSC and LPSP

- ✓ QACSC is renewed **FIRST**.
- ✓ Cannot renew with an Active Pending DEA status
- ✓ Cannot renew LPSP until QACSC is renewed
- ✓ **If you fail to renew the QACSC or the LPSP, you will not have the ability to write controlled substances after December 31st!**
- ✓ You may print your renewal receipt and certificate in the Licensee Gateway



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December or January Issue

If this is your **FIRST** (Initial) QACSC and your application is approved in December, the QACSC will be issued **JANUARY 2**

***The DEA takes 2-4 weeks to receive.** If the DEA is not received in time to renew the QACSC by December 31, you could incur late fees/penalty fees

Any **Additional QACSC or LPSP** license issued in November or December will have to be renewed by **December 31** to remain active for the following year!!

*December approvals for Additional QACSC and/or LPSP will be given the option to issue January 2 –avoids renewal fee but delays use of the license as it cannot be used until issued

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If the QACSC is Not Renewed by December 31, it Will EXPIRE....



If the **QACSC** is reissued between **January 1- January 31**, a **LATE FEE of \$75.00** will be added to the **\$60** renewal fee

A paper renewal form must be completed after January 31

If the **QACSC** is reissued **after** January 31, and **NO PRESCRIBING** has occurred, a **PENALTY FEE of \$110.00** will be added to the **\$60** renewal fee

If the **QACSC** is reissued after January 31, and there is evidence of prescribing, a **PENALTY FEE of \$150.00** will be added to the **\$60** renewal fee

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If the LPSP is Not Renewed by December 31, it Will EXPIRE....



If the **LPSP** is reissued between **January 1 – January 31**, a **LATE FEE of \$50.00** will be added to the **\$10** renewal fee

A paper renewal form must be completed after January 31

If the **LPSP** is reissued **after** January 31, and **NO PRESCRIBING** has occurred, a **PENALTY FEE of \$95.00** will be added to the **\$10** renewal fee

If the **LPSP** is reissued after January 31, and there is evidence of prescribing, a **PENALTY FEE of \$125.00** will be added to the **\$10** renewal fee

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Make sure to complete your evaluation! Without it, you will not receive your CME credits from the Medical Association!

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Questions?

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