Clinical Practice Controlled Substance Prescribing Workbook

Piedmont Area Health Education Center Practice Support (AHEC)

"Helping Practices Transform to Meet the Evolving Demands of Our Healthcare Systems."

> Sponsored by Piedmont AHEC Practice Support Team Revised 2/1/2023

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Where to Start?

In order to be compliant with the NC STOP Act, take the time to understand your practices current controlled substance prescribing behaviors. These behaviors may vary by prescriber, resulting in multiple workflows that can't be easily monitored.

The Greensboro AHEC Practice Support team developed this workbook to help your practice follow a systematic approach to:

- 1. Understanding the NC STOP Act and how it affects your practice.
- 2. Assessing your current controlled substances prescribing procedures and workflows.
- 3. Implementing changes that can help reduce confusion, complexity, and waste.
- 4. Ensuring the safety of your patients.

Examples of practice workflows, policies, and patient controlled substance treatment agreements are included. We encourage you to use these examples as starting points to develop documents that would best suit your practice.

This workbook does not suffice as a project management workbook; therefore, we encourage you to assign a point person in your practice to manage this project and ensure its completion.

In addition to using this controlled substance prescribing workbook, the Greensboro AHEC Practice Support team is available to work with you and help your practice assess workflows and develop policies and procedures related to this topic, or other areas within your practice.



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STOP Act Summary

During the summer of 2017, North Carolina Governor Roy Cooper signed House Bill 245, the STOP Act, into law. ¹ The STOP Act, which stands for the Strengthen Opioid Misuse Prevention Act, seeks to help curb epidemic levels of opioid drug addiction and overdose in North Carolina through several key provisions, including:

North Carolina STOP Act and Your Practice

- Strengthening oversight and tightening supervision on opioid prescriptions.
- Requiring prescribers and pharmacies to check the prescription database before prescribing opioids to patients.
- Instituting a five day limit on initial prescriptions for acute pain, with exemptions for chronic pain, cancer care, palliative care, hospice care, or medication-assisted treatment for substance abuse disorders.
- Saving lives through increased access to naloxone, which can reverse opioid overdose.
- Allow local governments to support needle exchange programs.

Education Requirements	Supervision Requirements	Prescribers	General Information
Physician must complete 3 hours per 3 year cycle of Category 1 Controlled Substance CME.	PAs/NPs working in pain clinics are require consultation with supervising physician prior to prescribing targeted controlled substances, when the therapeutic use is expected to or will exceed 30 days. If the prescription remains medically appropriate for the patient, the PA/NP shall consult with the supervising physician at least once every 90 days to verify its use.	Prescribers must electronically prescribe for all targeted controlled substances. Exemptions: Prescribers, other than a pharmacist, who's dispensing circumstances prevent e-prescribing (temporary technological or electrical failure) AND/OR Prescribers writing prescriptions to be dispensed by a pharmacy located on federal property (Must document the reason for both these exceptions within medical record).	Establishes prescribing limits for initial prescriptions of any targeted controlled substances • Acute pain-no more than 5 days' supply. • Post-operative pain - no more than 7 days' supply. Additional pain medications may be prescribed after subsequent evaluation/determination of need by the prescriber. • Prescribing limits do NOT apply to targeted controlled substances administered in hospitals, nursing homes, hospice facility, or residential care facilities.
PAs are required to complete 2 hours per 2 year cycle.		Prescribers can now use a streamlined process of creating delegate accounts in emergency departments in the NC Controlled Substance Reporting System (NC CSRS) ⁴ .	No Schedule II substance shall be dispensed more than 6 months after the date it was prescribed (written or electronically).
		Prescribers must review a patient's NC CSRS 12-month prescription history initially and then every 3 months thereafter as long as the targeted controlled substance remains part of the patient's treatment regimen. Use of prescriber's delegates is allowed/ encouraged.	Pharmacies are required to report targeted controlled substance prescriptions to NC CSRS by close of business the day after a prescription is delivered.
		Prescribers who observe prescribing limits are immune from civil liability and Board disciplinary action.	

Policy Assessment Workbook

What is your practices policy for prescribing controlled substances?

Whether your practice currently has a formal policy in place, an unwritten process, or no policy at all, you can follow these 12 steps below as a guideline to ensuring your practice has a robust policy in place.

1.	Assess your current policy.	Skip to h	iere		
	ls this policy written down?	YES	NO		
	Where is this policy kept?			Location:	
	Has this policy been reviewed/updated within the last year?	YES	NO	Review Date:	
	Does this policy reflect actual clinic workflows?	YES	NO S	Skip to Step 4	
	Has this policy been reviewed with staff within the last year?	YES	NO	Review Date:	
	Can you easily write down this policy?	YES	NO S	Skip to Step 2	
	Set deadline to write this policy.			Date:	
	Policy approved by management.			Date:	
	Policy reviewed with staff.			Date:	
	Policy will be reviewed at X frequency going forward.			Date:	

- Assemble a team to create a policy for prescribing controlled substances. (See page 9 for policy example)
 A diverse team helps to see the process from several different angles and to gain perspective to pieces of the process
 that are unfamiliar or overlooked. In addition, it fosters ownership and encourages buy-in.
 TeamMembers:
- 3. Establish a regular meeting with the team.

Regularly scheduled meeting helps keep the momentum going, and makes it easier for tasks to stay on track.

Meeting Date:		
-		

Frequency of Meetings:_

4. Write down the current process, limiting the process to 5-7 steps.

Define specific tasks, who is involved, and what the outcome of the task is. Defining the process with a team allows each member to see who the process stakeholders are and gain a better understanding of the process.

Defining a Process Example

1. Process The action steps that transform the inputs into outputs	Patient arrives to clinic for pain management.
2. Output The final product or service resulting from the process	Patient is able to talk to provider about their pain.
3. Customer The person, process, or organization that receives the output	Patient
4. Input The information materials, or service provided	Pain Scheduled appointment
5. Suppliers <i>Provides resources to the process</i>	Patient Front Desk Staff

Define your Practices' processes using the table below.

1. Process The action steps that transform the inputs into outputs	
2. Output The final product or service resulting from the process	
3. Customer The person, process, or organization that receives the output	
4. Input The information materials, or service provided	
5. Suppliers <i>Provides resources to the process</i>	

5. Observe the process in real time. (See page 7 for workflow examples)

Observing the process as it is happening or doing a walk-through where the work occurs allows you to confirm the process, and clearly see unnecessary steps and barriers.

Date of Observation: ______
Date of Observation: ______
Date of Observation: ______

6. Brainstorm potential gaps in your current process that could be making it burdensome or less-thanoptimal.

By this point, your team is familiar with the process, and there has likely been some discussion regarding roadblocks. More important than the barriers themselves is what is causing the barriers – the root cause.

Allow the team to brainstorm root causes, recording each person's idea – keep in mind no idea is too big, too small, too silly, or too haphazard at this point. All ideas should be welcome! It's helpful to record ideas on post-it notes or index cards, with one idea per post-it or card.

Next, the team should work together to sort the ideas into similar concepts or categories. Give a title to each category, and now you have an affinity diagram! The title of each category represents a gap in your current process.

Category 1 Gap: _____

Category 2 Gap: ___

Category 3 Gap: ____

7. The 5 Whys approach can be used to drill down to each gap's root cause. For each gap, you ask the question "Why?" five times (or as many times as it takes) until you get to an actionable root cause for the gap.

Here is an example: Gap: There are many patients who don't have their family history or personal history of substance abuse documented.

- Why?: Patients are not asked about family or personal history during their visit.
- Why?: The staff didn't know that they every patient should be asked.
- Why?: The staff didn't receive training on the controlled substance policy.
- Why?: Training requirements weren't updated when the policy was implemented.

Why?: Suzie normally updates the training requirements, but she was on vacation the week the policy was implemented.

Gap: _

- 1. Why? ____
- 2. Why? _
- 3. Why? ____
- 4. Why? _
- 5. Why? _

8. For each root cause, come up with one solution to test out.

A good way to eliminate root causes is to use a problem solving technique called Plan-Do-Study-Act, or PDSA.

• Using the root cause in the example from Step 7, let's look at what a PDSA may look like.

Plan:	Do:
Ensure there is a back-up for updating training requirements	Assign a staff member to be Suzie's back-up. Ensure the staff
when Suzie is on vacation.	member knows how to update training requirements.
Study:	Act:
Does Suzie's back-up know how to make the changes to training	We learned that it was helpful to ensure that training requirements
requirements if a new policy is updated? Did the task get done	would get updated even if Suzie wasn't at the office, but we didn't
while Suzie was on her vacation last week and a new policy was	really see a significant change in the number of patients with their
created?	history documented. We should try another PDSA.

Complete your Practices' PDSA using the table below.

Plan:	Do:
Study:	Act:

9. Implement any successful solutions into your current process.

When the solution trialed through a PDSA in effective is closing the gap and reducing barriers, you want to ensure it remains a part of your process and ultimately is recorded in the policy.

What are you keeping in place from your PDSA?:

10. Record the steps of the process in policy format.

Document each step of the process in policy format. Include who is responsible for completing each step and by when, and how often policy will be monitored.

Date Policy Will be Written:_

Frequency of Policy Review:_

11. Ensure ALL clinic staff are aware of and understands the new policy.

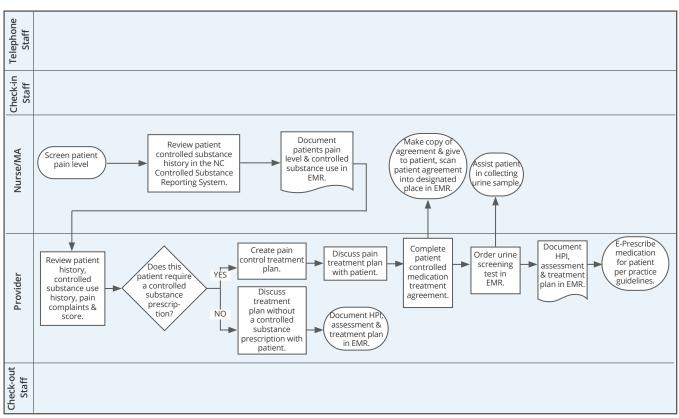
Date Reviewed Policy with Staff:_

12. Continue to search for ways to improve the process.

What Project Will You Start Working on Next?:_

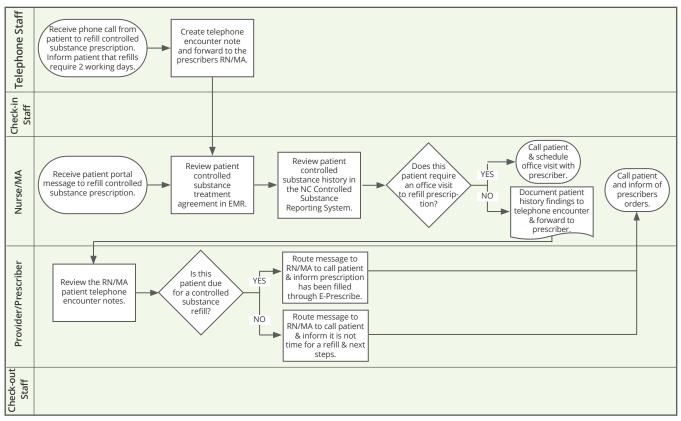
Start over @ Step 2 with new problem.

Contact a Practice Support Consultant to help plan or facilitate project improvement efforts in your clinic!



Initiating a Patient on a Controlled Substance Sample Clinical Workflow

Controlled Substance Prescription Refills Sample Clinical Workflow



CDC Recommendations for Prescribing Opioids for Chronic Pain Outside of Active Cancer, Palliative Care, and End-of-Life Care ⁵

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacological therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacological therapy and non-opioid pharmacologic therapy, as appropriate.

2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. Before starting and periodically during opioid therapy clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥90 MME/day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continue therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioid to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioids

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risks, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, high opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing as least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. Clinicians should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

ABC Practice Controlled Substance Prescribing Policy Treatment of Chronic Non-Cancer Pain with Long Term Opioid Therapy Sample

Policy:	Safe and effective treatment of chronic non-cancer pain (CNCP) with long-term opioids requires a team-based approach. These guidelines have been created to promote the cautious and selective prescribing of opioids while continuing to provide this treatment option for patients when the benefits outweigh the risks. In doing so we will promote the safety of our patients. For some existing patients, the most appropriate treatment plan may not conform to these guidelines. If desired, those cases can be referred to the Pain Advisory Board (PAB) for review and guidance on chronic opioid management.
Procedure:	1. Providers should prescribe opioids cautiously – using safer alternatives first and documenting what has been tried and failed. When opioids are indicated, providers should begin with low-dose, short-acting preparations and make the decision to extend treatment beyond a trial period after a careful evaluation of benefits, harms, and any adverse events.
	 2. For patients not currently receiving opioid therapy, providers can reduce risk of harm by carefully selecting patients who are candidates for long-term opioid therapy by doing a thorough risk assessment: Patients should be screened for depression.
	 Patients should be screened for alcohol and drug abuse.
	• The NC controlled substances reporting system should be consulted, urine drug screen considered, and controlled substance treatment agreement administered for patients being considered for long-term opioid therapy.
	3. Providers can reduce risk of harm by limiting use of high-risk drugs, doses, and drugs combinations.
	• A maximum total opioid dose of 100 mg morphine equivalent dose (MED) per day is suggested as the upper dosing limit for any one patient.
	 Methadone should only be prescribed by physicians knowledgeable of its pharmacokinetics. Fentanyl should be used by providers knowledgeable of its use and pharmacokinetics.
	• Providers are discouraged fom prescribing opioids to patients who are known to be taking chronic benzodiazepines (regardless of prescriber of benzodiazepines).
	Providers can consider prescribing Naloxone kits to patients at high risk for overdose.
	4. To ensure patient safety, once a provider decides to initiate long-term opioid therapy, this therapy should include the following:
	An identified prescribing primary care provider (PCP).
	• A meaningful assessment including complete history, physical, and work-up of the etiology of the pain. The diagnosis resulting in chronic pain should be documented on the problem list, in addition to the diagnosis "Encounter for Chronic Pain Management."
	Providers are encouraged to use the EMR dot phrase ".painmgmtoverview" to aid in documentation.
	5. Controlled substances should not be prescribed on the patient's first visit to the ABC practice. Providers are encouraged to request previous records and review them prior to prescribing opioids for new patients.
	6. A new provider assuming patient after another provider leaves should fully evaluate any patients on long-term opioids and may elect to continue with or modify the treatment plan.
	7. Providers on extended leave will partner with a covering provider to care for their patients with Control Substance Treatment Agreements. Covering Providers may elect to change a patient's regimen if necessary.
	 8. The ABC Practice will establish and maintain a Pain Advisory Board (PAB). This board will: Advise clinicians with any request regarding:
	o Behavior problems that impede relationships or efficiency of the practice.
	o Substance abuse, diversion, medication misuse.
	o Pharmacologic questions in the management of pain.• Server as an oversight body for the entire practice to assure:
	 Safe prescribing practices among the practice physicians.
	Timely updates and improvements in the practice as required.Regular review of controlled substance policy.
	9. Patients with a Controlled Substance Treatment Agreement may require treatment by other providers for acute pain. This should be limited to urgent situations (unexpected surgery, factures, etc.) ABC providers who prescribe a controlled substance in this situation should send a message to the patient's PCP.
Origination	Date: Department Review/Revision Date:

ABC Practice

Controlled Substance Treatment Agreement Sample

Patients must complete this contract befor	e doctors at ABC Pra	ctice will be willing to prescribe narc	otics for non-terminal patients.
Patient Name	DOB	MRN	
Diagnosis	PCP		
Treatment goals:			
Physical movement:			
Functional/Activities of daily living:			
Social activities:			
Medicine	Directions	Number_	per month
Pharmacy/Location		Telephon	e
Pharmacy/Location		Telephon	e
I agree to the following: I will only get prescriptions for controlled medicines I agree to tell any other doctors taking care of me al I will only use the pharmacy listed on this agreemer I will only ask for medicine changes at my office visi I understand that if my medicine(s) or prescription(: If I use up my supply of medicine early, I understand I agree to random urine drug tests and will provide I will not sell or share my medicines listed on this co I will not abuse alcohol or use illegal drugs which im I will go to any specialist, counseling, or therapy visi I will come to all of my doctor's appointment and bit	bout this agreement and t it. is. is) are lost or stolen, they w I that my doctor may not p a sample when asked. intract with anyone. cludes marijuana. t to help with my pain, sle	o tell my clinic doctor about any changes in m vill not be refilled early or another copy given give me extra medicine and that I may suffer s	to me – no exceptions.
The doctors at the ABC Practice will periodically util substances from another physiciar		Controlled Substance Reporting System og systems may also be utilized periodic	
Taking controlled substances, such as pain Memory and concentration problems Delirium and changed mental state Daytime hangover, fatigue, or grogginess Balance problems Falls and broken bones Car crashes Medicine addiction, dependence, or overdose Constipation These side effects may be more common after a dos	e change or with highe		
I understand that my doctor may stop, ch safety including but not restricted to: I am not showing progress towards achieving my lis I am not able to follow the requirements laid out in My medical issues change and the medication is no If I do not follow this agreement, the ABC Practice	ted goals this agreement. longer indicated, causing	too many side effects, or the risks outweigh t	he benefits.
I have read this agreement and it has been consequences of violating any of the terms		-	staff, and I fully understand the
Patient Signature		Printed Name	Date
Provider Signature		Printed Name	Date
Patient viewed Controlled Substances Video Pati	ent received copy of conti	act 🗌 Treatment Agreement Update Annu	Jally

Urine Drug Testing (UDT) Guidelines

Urine Drug Testing	No Urine Drug Testing
 Physician's predictions of UDT results are frequently inaccurate.⁶ Contextual evidence review found that urine drug testing can provide useful information about patients assumed not to be using unreported drugs.⁵ Experts agree that prior to starting opioids for chronic pain and periodically during opioid therapy, clinicians should use UDT to assess for prescribed opioids as well as other controlled substances and illicit drugs⁵ Because infrequent drug use is difficult to detect regardless of testing frequency, the benefits of frequent drug testing are greatest in patients who engage in moderate drug use.⁷ The frequency of UDT could be based on a risk assessment of the individual patient. High-risk patients require more frequent monitoring, whereas low-risk patients do not need to be monitored as frequently.⁶ 	 Many physicians work under the "truth bias"; that is, they have no reason to not believe their patients regarding narcotic use.⁶ Clinical evidence review did not find studies evaluating the effectiveness of UDT for risk mitigation during opioid prescribing for pain.⁵ Experts disagree on how frequently UDT should be conducted during long-term opioids therapy; however agreed that UDT at least annually for all patients was reasonable.⁵

Key UDT Recommendations for Practice 7				
Clinical Recommendation	Evidence Rating	References		
Immunoassay tests are the preferred initial test for urine drug screening.	С	10		
Positive results from an immunoassay test should be followed by gas chromatography/mass spectrometry or high-performance liquid chromatography.	С	10		
An extended opiate panel is needed to detect commonly used narcotics, including fentanyl (Duragesic), hydrocodone (Hycodan), methadone, oxycodone (Roxicodone, OxyContin), buprenorphine, and tramadol (Ultram).	С	10		
Appropriate collection techniques and tests of specimen integrity can reduce the risk of tampering.	С	15-17		

A=consistent, good-quality patient-orientated evidence; B=inconsistent or limited-quality patient-orientated evidence; C=consensus, disease-orientated, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to http://www.aafp.org/afpsort.xml

Reference List

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- General Assembly of North Carolina. House Bill 243 STOP Act, 2017. http://www.ncleg.net/Sessions/2017/Bills/House/PDF/H243v6.pdf Accessed September 25, 2017
- 3. "North Carolina Controlled Substance Act." Article 5 §90-90, §90-91, 1971.

http://www.ncga.state.nc.us/EnactedLegislation/Statutes/HTML/ByArticle/Chapter_90/Article_5.html

4. "North Carolina Controlled Substances Reporting System Act." (2005-276, s. 10.36(a).) Article 5E §90-113.70.

http://www.ncga.state.nc.us/enactedlegislation/statutes/html/byarticle/chapter_90/article_5e.html Accessed September 25, 2017

- 5. CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016. https://www.ncmedboard.org/images/uploads/article_ images/CDC-2016OpioidGuidelines.pdf Accessed September 25, 2017.
- 6. Owen, Graves T. DB. Urine Drug Testing: Current Recommendations and Best Practices. Pain Physician. 2012; 15:ES119-ES133
- 7. Standridge, John B. DB. Urine Drug Screening: A Valuable Office Procedure. American Family Physician. 2010. Mar 1;81(5):635-640

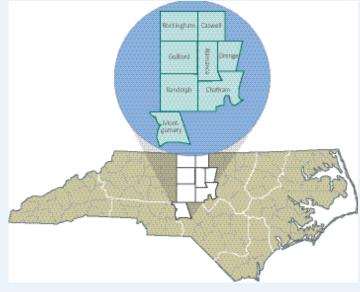
Other Resources

North Carolina Drug Control Unit https://www.ncdhhs.gov/divisions/mhddsas/ncdcu

Opioid Overdose Prevention Toolkit https://store.samhsa.gov/product/SAMHSA-Opioid-Overdose-Prevention-Toolkit/SMA16-4742 Step-by-step NC CSRS registration guide https://www.ncmedboard.org/landing-page/safeopioids The Piedmont AHEC has provided on-going practice support for ambulatory care clinics since 2010. We have helped practices achieve Meaningful Use, HEDIS and NCQA's Patient Center Medical Home recognition. Our vision is to help practices transform to meet the evolving demands of our healthcare system.

Practice Support offers expert consultation in many areas including but not limited to:

Quality Initiatives and Recognitions Electronic Medical Record Adoption/Changes and Implementation Panel Management Team-Based Care Models LEAN Practice Assessments and Operations Consultations Clinical Staff Training Patient Experience



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For more information on how to apply and contract with the GAHEC Practice Support Team, Contact us at piedmontahec.org

OR

Call 336-832-8025, and ask to speak to a member of the practice support team.