A Toolkit for

Establishing Clinical Pharmacy Services:

The Feasibility, Implementation, Performance and Sustainability Assessments

A Case Demonstration Employing Chronic Pain Services

Developed by The North Carolina Association of Pharmacists

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DISCLAIMER:

This toolkit was completed in 2019. While it is not a comprehensive list of all chronic pain related resources, it is based on a thorough investigation of the literature and expert clinical opinion in this area of practice. The NC Association of Pharmacists (NCAP) and Pfizer neither recommend nor endorse any of the websites, materials, or information. Please be advised that links provided are available for use at the discretion of Pharmacists and other healthcare professionals to help implement a broad array of clinical services, including those specific to improving chronic pain management. All registered names or brands referenced in this document remain their respective owners' property and are only included for identification purposes.

This implementation toolkit was developed through a collaboration between the NCAP and Pfizer (with financial support provided by Pfizer Inc). All content related to policy, billing, financial viability, activities and sustainability in this toolkit were created independent of Pfizer. NCAP is pleased and excited to launch this informative, dynamic, and illustrative tool. Our hope is it will provide the blueprint you need to create sustainable services that improve patients' lives in both your practice and your community.

Letter from the Executive Director
The North Carolina Association of Pharmacists

Given a choice about how to spend their time, most pharmacists would answer “taking care of patients”, rather than resolving insurance claims, handling audit data, or pouring over inventory or financial reports. Pharmacy owners or directors often describe success as knowing their employees feel valued, and that the services they offer make a difference in the lives of patients and the community they serve.

Pharmacists are recognized, by patients and others, as “the medication experts”; yet their clinical prowess has historically been underutilized. The ever-increasing costs for both healthcare services and prescription medications, as well as our nation’s chronic disease burden and primary care provider shortage heightens the importance and need for pharmacist-provided clinical services for patients in all practice settings.

The profession of pharmacy, as most think of it, has been disrupted. We simultaneously face a number of external forces, challenges and opportunities. The traditional product-based pharmacy operation, as a sole modality for conducting business, is rapidly dying. As product reimbursement margins continue to narrow, and as models of care transition away from fee-for-service towards value-based care, it has never been more important for pharmacists and pharmacies to collaborate and diversify revenue streams by providing and expanding clinical services. Specifically, pharmacies will need to establish services designed to generate value for patients, prescribers and other healthcare team members, alike.

There is nothing simple about healthcare reform, but ‘reform’ at its core, means ‘change’; and although those who embrace elements of change are likely to survive, it will be those who innovate and truly adapt that will thrive in a reformed healthcare era. Simply speaking it is up to pharmacists to transform our profession, and to create the services needed to fill care gaps, and improve medication safety, as well as the health of our citizens.

“A Toolkit for Establishing Clinical Pharmacy Services: The Feasibility, Implementation, Performance and Sustainability Assessment” is a practical guide, and provides realistic and reasonable processes and materials to assist the user in establishing a clinical service. We embarked on the creation of this toolkit because we often encounter pharmacists who become overwhelmed, even paralyzed, by uncertainty in where to start and what to do, despite their strong desire and interest in establishing or expanding clinical services. Given the unique aspects of individual practices, and the wide array of potential services, our goal, for this toolkit, was to provide a solid foundational blueprint, which walks the user through the step-wise approach necessary for establishing any sustainable clinical service. The user will be guided through multi-pronged stages, designed to assist with determining service feasibility and sustainability, market analysis, planning and implementation, marketing and billing, as well as assessing service performance and impact.

In addition, *"A Case Demonstration Employing Chronic Pain Services"* is provided to directly illustrate the application of the stages and steps outlined within the toolkit. We chose chronic pain as our demonstration case because of the following reasons. Pharmacists are better known for their role in helping manage chronic diseases such as hypertension, hyperlipidemia and diabetes; however, they also have a significant role in reducing risk and optimizing the care of patients with chronic pain. While deaths from cardiovascular disease and cancer have fallen over the past decade, deaths from opioid misuse and overdose have dramatically increased; and in the fight against the opioid epidemic, much of the emphasis has been on prevention and prescribing limits. These types of strategies have worked well for reducing risk in opioid-naïve and acute pain patients, but little improvement has been realized among chronic pain patients, taking opioids long term. Pharmacist-provided opioid stewardship and optimal pain management clinical services are currently in both high demand and need.

Finally, it is important for the user to know this toolkit was created by an experienced and diverse team of pharmacists who represent a variety of practice settings; and the contents of the toolkit were reviewed and vetted by an advisory group of pharmacists and physicians. Therefore, I am confident that the guidance and resources provided in this toolkit are both relevant and pertinent. By obtaining this toolkit, you have taken the first of many important steps toward establishing new patient care services, and ensuring the sustainability of your pharmacy business or practice. Let me be the first to applaud and congratulate you, as you take the next steps in your "taking care of patients" journey.

Penny S. Shelton, PharmD
Executive Director
The North Carolina Association of Pharmacists

INTRODUCTION: USING THE TOOLKIT

Welcome to the North Carolina Association of Pharmacists Toolkit for Establishing Clinical Pharmacy Services. This toolkit has three primary purposes.

1. Provide pharmacists with key strategic steps to implement any new service
2. Demonstrate potential implementations of a chronic pain management service
3. Equip pharmacists with tools and resources that support chronic pain activities

The process of implementing pharmacy services into a practice setting is influenced by many factors including practice setting, current pharmacy practices, patient population, and resource availability. Underneath the variability, however, lies core activities that are frequently leaned on when exploring process change. Thus, creating a "backbone" that can be applied to any process change. Therefore, tools and resources supporting pharmacy service development need to focus on these core activities while also allowing flexibility in implementation if they are to support development of a vast variety of pharmacy services.

With this in mind, the toolkit is broken down into several sections. The first section of the toolkit focuses on the general phases to consider when implementing a new pharmacy service. Each phase is supported either by steps to help you walk through the process or things to think about when addressing that particular phase. The second section includes 3 chronic pain pharmacy use cases, applying particular processes from the toolkit to demonstrate how to use the toolkit concepts within the chronic pain space. Following that is a collection of educational items for pharmacists, prescribers and patients. The last section of the toolkit is a master list of the resources used throughout the toolkit each indicating where in the toolkit the resource was used.

One item to stress is that many of the pharmacy service activities that are exampled in this toolkit can be applied to a broad range of practice settings and may take on a multitude of configurations. We encourage that! The use cases are not designed to imply restrictions to possible service developments but to highlight a few examples to reinforce the learned activity as well as demonstrate the toolkit's flexibility.

You can follow this toolkit from start to finish, step by step or use the links to go to specific segments of the toolkit that are most helpful for you.

We thank you for your commitment to the practice of pharmacy and are grateful to support you through the use of our toolkit.

> *'Physicians diagnose then the pharmacist steps in to do the things they're good at such as chronic disease management like managing medications and tapers.'*
>
> **E. Blake Fagan, MD**

Pharmacy Service Development

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Pharmacy Service Development

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STAGE 1: PLAN
Planning for your New Pharmacy Service

Planning is a critical first step in launching a new pharmacy service. This toolkit is designed to identify steps and tools you may want to incorporate into your planning process.

> *"If you fail to plan, you are planning to fail"*
>
> **– Benjamin Franklin**

Many organizations have individuals or departments that can help you. It's recommended that once you have an idea of what you would like to do, reach out early to your leadership for support. Lean in on those who have walked through this process. Their insights and direction will be invaluable to you in reaching your goal.

Use the Pharmacy Service Start-Up Checklist below as a first step in tracking your progress as you build your new pharmacy service.

Tools/Resources:

- Pharmacy Service Start-Up Checklist:

Pharmacy Service Start-Up Checklist

Implementation Science

According to the National Institutes of Health (NIH), implementation science is "the study of methods to promote the adoption and integration of evidence-based practices, interventions, and policies into routine health care and public health settings."[1] Though the toolkit does not directly address implementation science principles, we thought it essential to include a couple of resources should you choose to explore the topic in more depth.

Tools/Resources:

- NIH resource collections highlighting both resources and education around implementation science practices: https://www.fic.nih.gov/About/center-global-health-studies/neuroscience-implementation-toolkit/Pages/resources.aspx

- An introduction to implementation science for the non-specialist: Bauer, Mark S et al. "An introduction to implementation science for the non-specialist." BMC psychology vol. 3,1 32. 16 Sep. 2015, doi:10.1186/s40359-015-0089-9

1 Implementation science news, resources and funding for global health researchers. National Institutes of Health. Fic.nih.gov accessed 11.27.2019

Step One: Conducting a Market Analysis

Identify the Need

When you have an idea for a new pharmacy service, conducting a needs assessment early in the planning phase can help identify the current landscape of care and the existing care gaps in your community. It can help you determine what your local market can support as well as identify potential community partners. Gaining insights from the community, prescriber, and business lens will better inform you on what pharmacy services would best benefit patients in your community.

Click on the tool below for sample questions to consider when conducting a needs assessment.

Tools/Resources:

- Pharmacy Service Needs Assessment Tool: Pharmacy Service Needs Assessment Tool

Toolkit Tip: Plan a mechanism to gather prescriber input. Consider creating a survey or conduct one-on-one interviews.

Toolkit Tip: Doing a needs assessment is an excellent way to identify potential community partners!

Individuals to consider as collaborators or champions

- Decision makers/leaders
- Prescribers
- Non-prescribing clinical service providers (pharmacists, nurses, case management, health department)
- Professional association leaders (The North Carolina Association of Pharmacists (NCAP), Area Health Education Center (AHEC), NC Opioid and Prescription Drug Abuse Advisory Committee (OPDAAC), American Chronic Pain Association (ACPA)
- Public service leaders

Establish the Current State of Affairs

Conducting an initial assessment of the current state of your pharmacy and activities will help maximize results with minimum resource utilization while ensuring patient safety.

SWOT and environmental analyses are exercises designed to identify internal and external factors that may affect achieving your goal.

SWOT Analysis

A Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis is a technique that will help you capitalize on your strengths, uncover weaknesses, identify opportunities, and minimize the threats that may impact the success of your pharmacy service. Strengths and weaknesses tend to be more internal influencers while opportunities and threats generally exist as external influencers. When conducting a SWOT analysis consider both internal and external questions to better understand your entire environment. This is known as an environmental analysis. Below are example questions to consider when conducting your SWOT analysis.

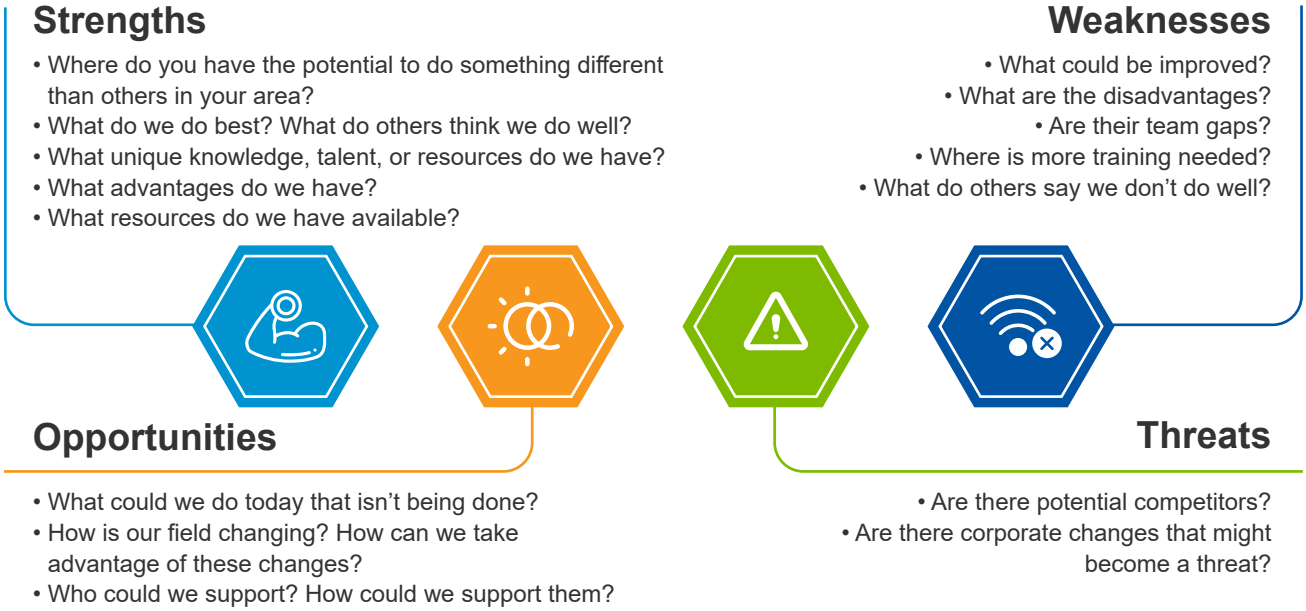
NOTE – When considering weaknesses, think of solutions to overcome them. Some may include adding partnerships, additional funding or permissions from higher levels of leadership.

Tools/Resources:

SWOT Template: SWOT Template

SWOT Analysis Worksheet: link

48 Questions to Ask in Your SWOT Analysis.
LINK https://www.score.org/resource/48-questions-ask-your-swot-analysis



Environmental Analysis

An environmental analysis is a strategic tool that helps the user understand the current environment and anything that contributes to it. Analyzing from both an internal and external viewpoint will provide a complete picture of your current state. Another benefit from this exercise is that it helps build out your SWOT analysis (mentioned earlier). See below for more information regarding internal and external analyses and a tool to assist you.

Internal Analysis

An internal analysis assesses resources, competencies, and competitive advantages within your place of work, helping you uncover strengths and weaknesses along the way. A thorough internal analysis covers the following five categories: general landscape, productivity, staff, technology, and existing clinical pharmacy services.

External Analysis

On the flip side, examining factors that affect your pharmacy from an external viewpoint helps you determine the opportunities and threats that may impact the success of your pharmacy service.

The following document below serves as a guide to help walk you through an environmental analysis. **Not all questions may need to be addressed.** Choose questions that are appropriate for your practice site.

Tools/Resources:

Environment Analysis Worksheet

Step Two: Defining the Service

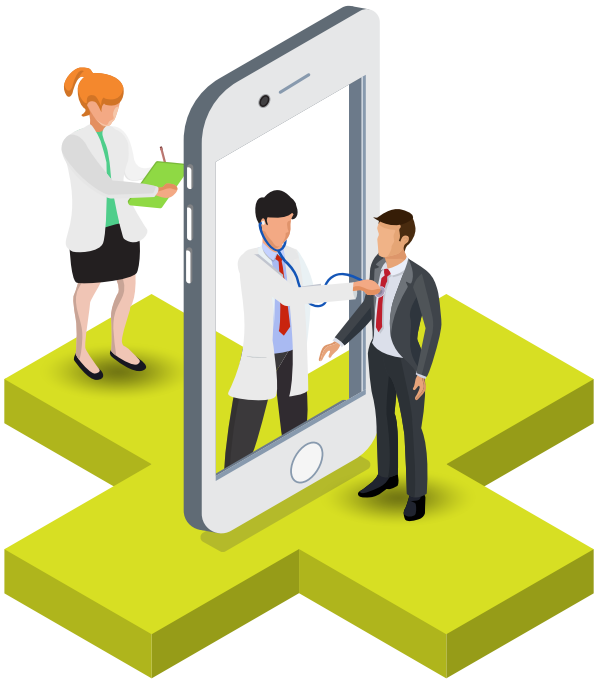
To best guide decision making, it's important to clearly define the service and its purpose. According to Moulin and colleagues, pharmacy service models leverage a pharmacist's specialized knowledge to optimize care, improve health outcomes, and add value to healthcare. This is accomplished by incorporating structure, process indicators, and outcome measures.[2]

Establish Service Mission and SMART Goals

Mission Statement

A mission statement describes the service or project, sets clear direction, and unifies staff members. A strong mission statement sets the stage for identifying the service's goals and who the service targets. It's essential to make sure the service's mission also aligns with the organization's overall mission. Consider the bullet points below in building a well thought out mission statement.

- **Who are the intended customers:** When thinking of customers, remember that this includes everyone who is affected by your activity including both the patients you are serving and the healthcare employees involved in their care.
- **What core values does the service support:** Highlight professional values that will guide activities to ensure safe, evidence-supported, and effective care.
- What is the service: Identify the service(s) that will be offered.
- **What are the goals and philosophy for the service:** Define specific objectives and benefits associated with the service.
- **Determine desired public image:** Think of how the service will be viewed by peers/community and determine key influencing factors.



2 Moulin, J. et.al 2013, 'Defining professional pharmacy services in community pharmacy', Research in Social and Administrative Pharmacy, vol. 9, no. 6, pp. 989-995. Accessed October 2019. https://doi.org/10.1016/j.sapharm.2013.02.005

Example Mission Statements

Our Safe Pain Management Service improves patient's lives by employing evidence-based practice and interventions known to reduce risks and enhance safety in those taking opioids for chronic pain.

For additional ideas, visit these links:

Writing a Business Plan for a New Pharmacy Service
https://www.pharmacist.com/sites/default/files/files/mtm_writing_business_plan.pdf

American Pharmacists Association (APhA) Pharmacy Mission Statement – To serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes.
https://www.pharmacist.com/apha-vision-mission-value-statements#:~:targetText=APhA%20achieves%20our%20Mission%20by,the%20art%20tools%20and%20resources.

NCAP Mission Statement – NCAP exists to unite, serve and advance the profession of pharmacy for the benefit of society. https://www.ncpharmacists.org/about-ncap

American Society of Health-System Pharmacists (ASHP) Mission Statement – The mission of pharmacists is to help people achieve optimal health outcomes. ASHP helps its members achieve this mission by advocating and supporting the professional practice of pharmacists in hospitals, health systems, ambulatory clinics, and other settings spanning the full spectrum of medication use.
https://www.ashp.org/About-ASHP/What-We-Do#:~:targetText=ASHP%20Mission,people%20achieve%20optimal%20health%20outcomes.&targetText=ASHP%20serves%20its%20members%20as,medication%20use%20and%20public%20health.

Community pharmacy in Washington – To provide the highest level of pharmacy service to the patients, providers and caregivers in our community, and to meet the unique needs of the individual through innovative practice, clinical excellence, professional leadership, quality commitment and superior service.
https://www.missionstatements.com/pharmacy_mission_statements.html

SMART Goals

After establishing the service's mission statement, the next step is to identify the service's goals that support the mission. Setting SMART goals help clarify ideas, streamline efforts, and encourage productive utilization of time and resources, increasing the likelihood of achieving your goals.

5 criteria build the foundation for every SMART goal. The criteria are described below.

S = Specific

- State exactly what you want to accomplish
- Address the 5 W's: WHO is involved, WHAT do I want to accomplish, WHEN/WHERE will it be done, WHY am I doing this -reasons, purpose, WHICH constraints and/or requirements do I have?

M = Measurable

- How will you evaluate if the goal is achieved?
- What data/metrics are available to support the goal?

A = Achievable

- Is the goal realistic?
- Consider resources available
- Goals should be ambitious and challenging however still possible and reasonable

R = Relevant

- Ensure that the goal is relevant to:
  - The service's purpose and mission
  - Patient population
  - Healthcare team members responsible for achieving the goal

T = Time-Bound

- Set time frames and due dates for goal completion
- Deadlines need to be reasonable yet create a sense of urgency

Toolkit Tip: Consider using Timelines, Gantt Charts, Excel spreadsheets, etc. to visually build out goals and supporting activities to stay on track!

Tools/Resources:

- The Essential Guide to Writing S.M.A.R.T. Goals: https://www.smartsheet.com/blog/essential-guide-writing-smart-goals

- University of California – Smart Goals: A How To Guide: https://www.ucop.edu/search/?q=smart+goals

Define Outcomes

Establishing accurate outcomes and supporting metrics is critical to demonstrate the value of your service and ensure sustainability. You may run across the term "objectives" used instead of "outcomes". In either case, both serve to provide a more specific and measurable target.

The ECHO model (Economic, Clinical, and Humanistic Outcome) is a way to communicate the value of a pharmacy service as a combination of clinical, economic and humanistic outcomes.[3] According to the model, outcomes are commonly grouped into three categories (located below).

Clinical outcomes – medical events that occur as a result of disease or treatment

Economic outcomes – direct, indirect, and intangible costs compared with the consequences of medical treatment alternatives

Humanistic outcomes – consequences of disease or treatment on patient functional status, or quality of life, measured along several dimensions

Outcomes may be captured in a variety of ways. The more common ones are listed below. Biomarker outcomes are considered indirect measurements, while the other four may be direct or indirect measurements of health.

Patient Reported Outcomes (PRO): the patient provides the assessment

Clinician Reported Outcomes (ClinRO): the healthcare professional provides the assessment

Observer Reported Outcomes (ObsRO): the parent, caregiver or another person other than the patient provides the information

Performance Outcome (PerfO): a quantified assessment that does not require interpretation or judgment to determine the outcome (ex. distance walked in 6 minutes)

Biomarker Outcome: an assessment requiring little to no patient motivation or judgmental influence from the rater. (ex. serum creatinine)

Toolkit Tip: Consider these options to help in selecting meaningful outcomes.

3 Kozma CM, Reeder CE, Schulz RM. Economic, clinical, and humanistic outcomes: a planning model for pharmacoeconomic research. *Clin Ther* 1993:15(6):1121-32.

- Find existing models to learn from (ASHP and other groups have excellent resources and are included at the end of this section).
- Determine what matters to your key stakeholders.
- What measures currently are there around the disease state?
- Do patient satisfaction or transitions of care metrics apply?

Using the Pharmacy Service Outcomes and Metrics Worksheet is a great tool to help you establish and organize your service's value.

Tools/Resources:

- Pharmacy Service Outcomes and Metrics Worksheet: Pharmacy Service Outcomes and Metrics Worksheet

The Economic, Clinical, and Humanistic Outcomes (ECHO) Model is helpful with outcomes research and clinical practice improvement. For additional learning on ECHO and outcomes research, see citations located in the Tools/Resources section below.

Tools/Resources:

- Kozma CM, Reeder CE, Schulz RM. Economic, clinical, and humanistic outcomes: a planning model for pharmacoeconomic research. *Clin Ther* 1993:15(6):1121-32.

- Gunter MJ. The role of the ECHO model in outcomes research and clinical practice improvement. *Am J Manag Care*. 1999;5(Suppl 4):S217-24.

The International Society for Pharmacoeconomics and Outcomes Research, Inc. developed a report to guide outcomes research:

Walton MK, et al. Clinical Outcome Assessments: Conceptual Foundation – Report of the ISPOR Clinical Outcomes Assessment – Emerging Good Practices for Outcomes Research Task Force. *Value Health*. 2015;18(6):741-52. https://doi.org/10.1016/j.jval.2015.08.006

> *'When you see a patient with a pharmacist and see the outcome in a month, really see the value in it. Value in where the load of medication management (dosing, frequency and selecting appropriate opioid tailored to patient's disease pathology) is shared by two providers vs single.'*
>
> **Utpal Patel, MD**

Metrics

Metrics, also known as key performance indicators, are used as surrogate markers to measure your service impact and patient outcomes.

Metrics can be categorized into different levels of complexities. Factor in the complexity of the metric and IT functionality/accuracy when determining what metrics will be tracked.

Metric Complexity	Examples
Basic Metrics	Completed patient visits Total number of patients enrolled in the program Total number of consultations Total number of documented activities in the Electronic Medical Record (EMR) Medication errors **Time Based:** Expected clinic sessions Risk Adjusted Panel Index[4] Expected clinic sessions per year Expected clinic sessions year to date (YTD) Clinic sessions completed YTD # of clinic sessions ahead or behind YTD # of clinic sessions remaining Total relative value units (RVUs) Total work RVUs at 1.0 clinical full-time employee Average # of patients seen per session
Medium-Level Metrics	Adherence measures Objective measures related to the intervention (pain scores, blood pressure, complexity of interventions)
High-Level Metrics	Short and long-term patient outcomes

Consider metrics and outcomes that reflect both the value of the service (more outcome focused) and the efficiency of the service (more internal optimization focused). That way, when assessing the service in the "DO" and "ACT" phases of process change, you can more easily identify opportunities for improvement.

Tools/Resources:

- FAQ: Basics of Ambulatory Care Pharmacy Practice Date of Publication: July 2019 – ASHP https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/ambulatory-care/basics-of-ambulatory-care-pharmacy-practice.ashx

4. Quan H, Li B, Couris CM, et al. Updating and validating the Charlson Comorbidity Index and score for risk adjustment in hospital discharge abstracts using data from 6 countries. *Am J Epidemiol*. 2011;173(6):676-682.

- Best Practices in Performance Measurement Part 1: Developing Performance Measures – A National State Auditors Association Best Practices Document: https://www.nasact.org/files/News_and_Publications/White_Papers_Reports/NSAA%20Best%20Practices%20Documents/2004_Developing_Performance_Measures.pdf

Specialty Pharmacy Specific Tools/Resources:

- Measuring Success in Specialty Pharmacy Practice: Pharmacy Times: https://www.pharmacytimes.com/publications/specialty-pharmacy-times/2017/november-2017/measuring-success-in-specialty-pharmacy-practice

- Proving Value in Specialty Pharmacy Practice: A New Yardstick: https://www.pharmacytimes.com/publications/ajpb/2017/ajpb_novemberdecember2017/proving-value-in-specialty-pharmacy-practice-a-new-yardstick

- ASHP Specialty Pharmacy resource guide: https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/specialty-pharmacy/specialty-pharmacy-resource-guide.ashx

- What Payers and Manufacturers Look for in Outcomes-and the Why Behind It – Therigy: https://www.therigy.com/blog/what-payers-manufacturers-look-for-in-outcomes-and-the-why-behind-it

Reporting and Tracking Functionality

Reports

Reports take on multiple functions when used in pharmacy care services. They can be used to identify patients, track progress, and preserve sustainability to name a few. Prior to creating reports, it is important to consider the purpose of the report, potential data sources, and existing reporting capabilities. Also consider reports that are already built that could support your efforts. Consider identifying someone who has experience or expertise in data reports. They might be able to assist you up front when outlining the quality improvement program that will accompany your new service.

It is important to identify applicable metrics that will demonstrate the success of your service. Tracking these metrics will allow you to efficiently follow that progress and facilitate informed decision making. Time and energy placed in outcome and metric development will pay off in dividends when initiating a tracking system.

Toolkit Tip: It's important to remember to be specific when defining parameters for the report. It may be helpful to trial the report to ensure it is telling you what you need to know.

Tracking

Tracking allows you to efficiently follow the progress of the metrics you determine most applicable to demonstrate the success of your service. A dashboard or scorecard helps provide a comprehensive view of key data elements in a visual manner. A well-developed dashboard will highlight key performance indicators, current trends, and allow for strategic decision making as you look to enhance the efficiency and quality of the service you are providing.

- Explore regional/state/national data for benchmarking possibilities.

- Obtain a baseline to use as your starting point in tracking your metric.
- Be sure to capture all activities related to your key metrics.
- The more hands-off, automated the tracking, the better.
- What is the best visual display of information (graph, chart, etc.)?
- You want data to be captured in real-time, if at all possible. Retroactive data capture can be more time-intensive and less accurate.
- Keep the documentation simple.
- Use trends to inform/make practice changes.
- How often will the information be updated (weekly, monthly, quarterly)?
- Identify targets for your progress.

Toolkit Tip: Baseline metrics can help communicate the value of your pharmacy service and identify prescribers/clinics/others who might benefit most from your service. Use this data in your outreach for partnering with prescribers.

Tools/Resources:

- Real-Time Dashboards: Quality Control for Pharmacy Practice – Pharmacy Today: https://www.pharmacytoday.org/article/S1042-0991(15)31387-6/pdf

Additional Items to Consider:

Guidelines/Recommendations/Governance

Based on the target of your service, what guidelines are available to guide, plan details, and justify your plan?

- What national guidelines are pertinent?
- What organizations support a service or patients like yours?
- What national initiatives serve similar patients?
- What local or state initiatives serve similar patients?
- What national and state legislation is there around the topic?
  - Look beyond the pharmacy profession to see examples of proactive initiatives
  - Consider other health disciplines like medical, nursing, or behavioral health

Quality Measures

"Quality measures are tools that help us measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. These goals include: effective, safe, efficient, patient-centered, equitable, and timely care."[5]

As a provider, you will want to stay up-to-date on the latest guidelines, initiatives, and quality measures.

Many organizations, including medical associations, provide guidance around what indicators improve the quality of patient care. Research existing measures that align with your service. Question leadership for input on quality measures important to the organization. Below is a list of organizations/measure sets to help you get started.

- NCQA: National committee for Quality Assurance – https://www.ncqa.org/
- NQF: National Quality Forum – https://www.qualityforum.org/
- TJC: The Joint Commission – https://www.jointcommission.org/
- CMS: Centers for Medicare and Medicaid Services – https://www.cms.gov/
- AMA: American Medical Association – https://www.ama-assn.org/
- AHRQ: Agency for Healthcare Research and Quality – https://www.ahrq.gov/
- URAC: Utilization Review Accreditation Commission – https://www.urac.org/
- HEDIS: Healthcare Effectiveness Data and Information Set – https://www.ncqa.org/hedis/measures/
- MACRA/MIPS: Merit-based Incentive Payment System – https://qpp.cms.gov/mips/quality-measures
- Medicare Stars Program: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData
- Physician Compare – https://www.medicare.gov/physiciancompare/

Tools/Resources:

- Mary Andrawis, Pharm.D., M.P.H, L T C Christopher Ellison, Pharm.D., M.M.A.S, BCPS, Steve Riddle, Pharm.D., FASHP, BCPS, Kurt (Charles) Mahan, Pharm.D., Ph.C., FCCP, Curtis D Collins, Pharm.D., M.S., BCIDP, FASHP, Philip Brummond, Pharm.D., M.S., FASHP, Jannet Carmichael, Pharm.D., FCCP, FAPhA, BCPS, Recommended quality measures for health-system pharmacy: 2019 update from the Pharmacy Accountability Measures Work Group, *American Journal of Health-System Pharmacy,* Volume 76, Issue 12, 15 June 2019, Pages 874–887 https://doi.org/10.1093/ajhp/zxz069

National Organizational Support

- Has a national organization supported, researched, or provided a statement surrounding your service type?
- What local branches are available in your state that have similar interests?

Identify Existing Services

- What types of pharmacy-led or pharmacy-collaborative services are currently in your community?
- Explore out-of-state models where a service is working well, especially in states where pharmacists have enhanced practice authority.
- What does care management look like in other cases where a service similar to yours is being provided?

If you haven't already, reach out to similar services around the country (or abroad) to learn best practices and avoid pitfalls others have experienced. Take the best and most pertinent ideas you find to help enhance the service you are providing. (Others are typically willing to share, and in reciprocity, please be willing to share with those who follow you.)

5 CMS.gov Quality Measures: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/index.html. Accessed 12/19/19

Step Three: Understanding Policy and Billing

Policy

A policy is a deliberate set of principles that guide decisions and help achieve rational outcomes.

As you build your service, establish policies that define, support, and protect your service. Below are a few examples of activities you may want to include when developing your own policies. Note, if your practice already has policy templates or guidelines, follow those.

- Patient eligibility and recruitment
- Patient expectations and liability agreements
- Record maintenance – which records will be maintained, how, and length of time
- Internal practice policies about the service and key performance elements
- Collaborative practice agreements, with scope of practice, formulary, practice role activities, etc.
- Where pertinent, credentialing and the frequency of renewal of house-staff privileges

Examples below cite different ways in which you may choose to construct policies and procedures. Some may choose to advocate a combination approach , incorporating both policy and procedure into the same written document. While others may chose to separate their written policy and procedure into separate documents as seen with the MAHEC example. It's a matter of preference as to which you choose however in cases where your operating procedures are lengthy and detailed you may see advantages to a stand alone procedure document in the event of future changes. In this scenario, future changes would not necessarily impact your policy.

- Clinic function policy examples from Salt Lake County Health Department in Utah, part of Comagine Health: https://healthinsight.org/component/jdownloads/send/460-clinic-policies/1858-fillable-policies-and-procedures-slcohd-document
- MAHEC – MAT Policies, Procedures, and Resources Manual: https://pub.mahec.net/sites/MatDownloads/add
- Collaborative consultation agreement from Cleveland Clinic: https://my.clevelandclinic.org/-/scassets/files/org/pharmacy/acc-physicianconsultagree.ashx?la=en

Value Based Contracts

As healthcare payment models continue to shift from a fee-for-service (FFS) design to a value-based reimbursement approach, more focus is being placed on the quality of healthcare and the costs associated with its delivery. Value-based contracts or risk-sharing agreements were first introduced in 2012 by The Centers for Medicare and Medicaid Services (CMS) with the creation of the Medicare Shared Savings Program (MSSP). This program provided a framework that incorporated clinical outcomes and the cost of care in reimbursement structures. It also opened the door for shifting some of the cost of delivering healthcare from the payor to the providers of care, in other words, taking on some of the 'risk' in caring for patients. For additional information on value-based contract models, see the resources below.

Incorporating more value-based contracts into their payment structures, healthcare systems are looking for new and innovative ways to provide high quality, low-cost care to their patients. Pharmacists can play a major role. Familiarize yourself with the risk-sharing contracts of greatest value to your organization and find ways to support those with your services. In some cases, you may be able to propose funding and demonstrate value for your service by evaluating cost savings or cost avoidance to the funding organization (health-system, insurer, parent company).

Tools/Resources

- National Pharmaceutical Council: https://www.npcnow.org/issues/access/provider-reimbursement/risk-sharing-agreements
- Exploring Value Based Contracting in Pharmacy Times: https://www.pharmacytimes.com/conferences/pqa-2019/exploring-value-based-contracting
- Strategies to Expand Value-Based Pharmacist-Provided Care – Pharmacy Quality Aliance: https://www.pqaalliance.org/pharmacist-provided-care-release
- Accountable Care Organizations 101 – APhA: https://www.pharmacist.com/article/accountable-care-organizations-101
- Value-Based Payment: Preparing for Changes in Payment for Services – APhA: https://www.pharmacytoday.org/article/S1042-0991(19)30939-9/pdf

Billing

Although a grant, a funded initiative, or a one-time benefactor might support a demonstration pilot, ongoing clinical services need a payment mechanism for sustainability. Payments can range from out of pocket to fee-for-service to corporate agreements to code-based billing. This is an area to spend significant research in the development of a new service. Resources to get you started are found in this section.

As of early 2020, the billing mechanism that has been most demonstrated for pharmacists is to bill incident-to a physician. In this scenario, the pharmacist sees the patient in the physician's practice while the physician is present in the practice (or health-system). Physician and pharmacist do not have to see the patient together, but both must be present in the practice during the pharmacist visit. This model allows some revenue generation for both the practice and the pharmacist. In many cases, if the physician and pharmacist see the same patient on the same day, the billing code can be increased (e.g. level 3 to level 4) allowing for the additional payment. This is all facilitated by a collaborative practice agreement. If there is more than one physician in the practice, create an agreement that includes all of the physicians to allow flexibility in collaboration and supervision.

Another billing mechanism that has been frequently used is to bill a facility fee (if your practice is within a health system). This results in a lower payment but is recognized and reinbursed by most payers.

- Other possible collaborative billing options include providing pharmacy services as part of transitions of care, chronic care management, annual wellness visit, or using pharmacy time-based codes.
- It is imperative to know and accurately follow the billing rules around whatever structure is used. Also, use the tools that are built into your technology to facilitate scheduling and billing.

NOTE, your state's professional pharmacy organization(s), state's Medicare intermediary, and national practice advancing organizations are key resources to know available billing strategies in your state.

Billing Strategy	Service Location	Notes
Incident-to physician	Physician's office	99211-99214 usually
Facility Fee	Health-system in facility	This is getting public and congressional attention and may change soon
Time-based	Not location specific	99605, 99606, 99607
Transitions of Care	Not location specific	99496 with 7 days of discharge 99495 within 8–14 days of discharge Requires evidence of general supervision by physician
Chronic Care Management	Not location specific	99490 Requires evidence of general supervision by physician such as the co-signing of all pharmacist progress notes
Annual Wellness	Not location specific	Full fee is shared among providers involved; usually within health system or primary care clinic
Built into overall cost of another service (integrated care model)	Depends on the service and overall fee structure	
Fee for service, out-of-pocket	Not location specific	
Medicare Part B billing	Specialty Pharmacy	Per Medicare guidelines
340B billing	340B qualified pharmacy	Greatest opportunity with specialty medications such as for hepatitis C, HIV, oral oncology

Tools/Resources

- FAQ: Pharmacist billing using "incident-to" rules non-facility (physician-based) ambulatory clinic – ASHP: https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/ambulatory-care/incident-to-billing-2019.ashx
- Billing Guidance for Pharmacists' Professional and Patient Care Services – National Council for Prescription Drug Programs white paper: https://www.ncpdp.org/White-Papers.aspx
- Understanding Health Care Billing Basics – APhA Pharmacy Today: https://www.pharmacytoday.org/article/S1042-0991(17)30973-8/fulltext
- Understanding Billing Opportunities for Pharmacists – presented at FSHP 2018 annual meeting: https://cdn.ymaws.com/www.fshp.org/resource/resmgr/2018_annual_meeting/speaker_handouts/dietrich-nickerson-troy.pdf

> ***'Providers often don't know about incident-to billing options, how it works, return on investment. As it not only provides additional revenue but an added value to overall patient care and safety.'***
>
> **Utpal Patel, MD**

Step Four: Establishing the Service Provision

> *'With patients, I am great at building relationships and diagnosis. I am not so great at prevention and chronic disease management. I would like to talk with the patient and say (pharmacist name) is going to be coming in to help you with your (fill in the chronic disease). What s/he wants is what I want for you.'*
>
> **E. Blake Fagan, MD**

Patient Identification

In drafting a clinical service, it's important to develop a systematic means to identify patients most appropriate for your service.

To do so, consider your response to the following questions:

- Which patient population(s) would benefit most if they were able to reach or achieve the goals associated with my service?
- What criteria or indicators can I utilize to systematically identify my target population?
- Is the complexity of the patients medical history a factor in determining service eligibility?
- Where would I consider the largest percentage of my target population to be located?
  - Are a large percentage of these patients already patrons of my pharmacy?
  - Can I build a clientele out of partnerships or relationships I currently have established with neighboring clinics or providers in my surrounding community?

Consider what options you may already have for identifying patients. While it is advisable to find ways to automate the process by utilizing reports, dashboards, scheduling/referral systems, or other electronic means, many pharmacies have found manual means for identifying patients equally effective. Regardless of your method, include the process for patient identification in your training and communication. Details related to your process should also be incorporated into your Policy and Procedures or outlined in a job aid.

Additional filters you may find helpful when defining your patient population include:

- Demographics: age, gender, geographic location
- Medications/Diagnosis/Healthcare Coverage
- SDoH – Social Determinants of Health
- Healthcare inequities and disparities
  - Social Determinants of Health and Language barriers

Consider possible screening methods:

- Electronic medical record (EMR) reports: design reports to capture targeted patient population
  - Consider diagnosis, medications (specific or drug class), labs, providers, specific clinic
  - Consider data platform (Epic®) – reporting workbench, crystal report, system lists

- Pharmacy management platform utilization data
- Surveys/questionnaires
- Referrals from clinics

Toolkit Tips: The more specific you are in identifying your patient population, the easier it will be to develop recruitment parameters and your business plan.

Customer/Stakeholder Identification

Depending on your practice setting, external resources may be needed to help identify patients. Consider clinical partners, key stakeholders, service organizations, and other community agencies as potential resources. Make a list of everyone who could help you build this service. What would be the role of each person on your list? Address where each key person will interact with your service. See example below:

Key person/service	Relation to my service	Most pertinent information
Physician champion	Development support and champion to other physicians and the community	How will my service help physicians save time and improve patient care?
Case manager/social worker	Identify community advocacy programs	What additional resources in the community are available for treatment/ support for both patient and caregivers?
Health Department	Facilitate access to treatment medications	Are there medication programs in the community to facilitate treatment/ prevention?
Clinic scheduling staff	Facilitate referrals	Provide information to patients about pharmacy services after the provider visit.
Office manager	Organize clinical activities	Organize schedule, supply paperwork, assist with data collection.
IT resources	Reporting/Data collection	Are reports pre-fabricated or will they require special coding? Can they be automated? Can they identify the initial target market/patient base?

Tools/Resources

Stakeholder Worksheet Tool: Stakeholder Worksheet Tool

Patient Care Interventions

Activities

In relation to the goal of your service, the service itself is viewed as the strategy to achieve the goal. The activities of a service are essentially the tactics that are undertaken to aid the strategy. These vary greatly depending on the actual service you would like to implement. General thoughts that can be applied to all activities include:

Tools/Resources:

- Pharmacy Service Activity Worksheet: Pharmacy Service Activity Worksheet

Documentation

Documenting your activities is important to demonstrate productivity, help with tracking activities and capture outcomes. Multiple touchpoints can be included in your documentation. For example, patient counseling sessions, telephone calls, screening, and test results are a few items to consider. It's recommended to start with a simple documentation process to encourage complete capture and consistency. This may be an electronic (EMR) or manual process. To ensure patient privacy, make sure to follow the Health Information Portability and Accountability Act (HIPAA) guidelines as you build out your documentation process.

Considerations:

- Consistency of documentation that includes capture of key metrics
- Efficiency of documentation plan

- Inclusion of parameters needed for billing
- Secure sharing of documentation with other members of the healthcare team, including the patient's physicians (secure e-mail, fax, secure video conferencing, face to face)

Tools/Resources:

- ASHP Guidelines on Documenting Pharmaceutical Care in Patient Medical Records https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/documenting-pharmaceutical-care-patient-medical-records.ashx

Health Information Technology Electronic Health Record Project Timeline Grid:

Health Information Technology – EHR Timeline Tracker

Phase	How long will it take?	Other considerations?
Scoping/Approvals		Who is needed for approval?
IT Request/Timing		What process would be needed?
Data Extraction or EHR Integration		Is sign off needed?
Data Analysis and Reporting		How will results or the report be disseminated?

Communication Strategy

Based on the specific service you are designing, who you communicate with, and with what mechanism and frequency you do it are important items to address.

Who	How	When
• Prescribers • Patients • Family members • Team members • Office managers	• Face to face • EMR messaging • Referrals • Clinic notes • Internal messaging • Telephonic	• Patient encounter • Identified through screening • Change in therapy

Additional ways to communicate include: best practice alerts, electronic messaging, secure instant messaging (IM), patient portals, talking points for the pharmacists and patient-facing apps.

Think about your practice's current state as well. How does your practice currently communicate with prescribers? With what frequency are prescribers accustomed to interacting with you and your team? Are there or will there be triggers to help initiate communication?

Toolkit Tip: Remember that communication strategies include two-way communication. Think how you will communicate out to others but also how others should communicate with you.

Tools

Anything that helps you provide the service can be considered a tool. For every step of the service workflow, evaluate what tools are needed to get the job done.

There is an endless variety of tools and resources. Some of them include the following:

Service Tools

- Screening Tools
- Assessment Tools
- Bag Tagging Tools
- Vouchers / Coupons
- Reporting and Tracking Tools

Education Tools

- Patient Facing Tools
- Prescriber Training Tools
- Medical Information Tools

Business Tools

- Medical Instruments
- Computers
- Video Imaging Tools
- Marketing Tools
- Communication Tools
- Billing Tools

Process Documentation

Putting it all together in a visual manner is what is referred to as process documentation. You may have also heard this called a workflow analysis. It provides guidance to everyone who is involved directly and indirectly with the process, can be used as a training device, and it puts everything in one place.

There are several steps in creating a process documentation. We have highlighted a few of these steps below:

Identify the Process Inputs

- List resources necessary to support each of the process steps

Brainstorm the Process Steps

- Gather information from start to finish
- Start with what triggers the process and move forward

Organize the Steps Sequentially

- Organize the process steps in order to create a process flow

Describe Who is Involved

- Indicate each individual who will be responsible for each task
- Define roles by job title
- Make sure anyone can follow the diagram

Visualize the Process

- This is to improve clarity and readability of your documentation
- Using a process flowchart neatly visualizes the process steps

Step Five: Building Your Business Plan

Depending on your practice setting, you might not need a full business plan. But there are components that will likely be useful to have completed as you prepare your overall plans to develop, implement, and measure the impact of your service.

Executive Summary

Mission

Market Analysis
- Environmental Analysis
- SWOT

Leadership Team

Service Description
- Operations
- Value Proposition

Communication Strategy

Financial Plan
- Costs
- Income
- Sustainability
- Billing

> *'I have seen a major improvement in a set of patients where I have been fortunate to avoid drug-drug interaction, averting potential drug toxicity and ultimately improved patient satisfaction and function with lower opioid MMEs.'*
>
> **Utpal Patel, MD**

Tools/Resources:

- Writing a Business Plan for a New Pharmacy Service – APhA:
  https://www.pharmacist.com/sites/default/files/files/mtm_writing_business_plan.pdf
- Developing a Business Case for Advancing Pharmacy Services – ASHP:
  http://www.ashpmedia.org/pai/csuitetoolkit/docs/Developing_a_Business_Case_for_Advancing_Pharmacy_Practice.pptx
- Write your Business Plan – US Small Business Administration:
  https://www.sba.gov/business-guide/plan-your-business/write-your-business-plan
- Business Plan Template for an Established Business – SCORE*:
  https://www.score.org/resource/business-plan-template-established-business
  (some sections not pertinent, but most will be a helpful guide)
- Financial projections template – SCORE:
  https://www.score.org/resource/financial-projections-template
  https://www.score.org/resource/break-even-analysis-template
- Family practice clinic business plan example:
  https://www.bplans.com/family_medicine_clinic_business_plan/executive_summary_fc.php
- Pharmacy Business Plan Example – the Discount Pharmacy:
  https://www.bplans.com/pharmacy_business_plan/executive_summary_fc.php

*SCORE is the Service Corps Of Retired Executives, an excellent resource for entrepreneurs and business owners.

Step Six: Getting Leadership Buy-In

By now, you should have a strong and detailed description and plan for your service. It is time to gain leadership buy-in. Having your leadership team endorse your efforts is crucial for support, resources, and longevity. They can also be a great source for insights and champions for the service. Depending on your location of business and type of service it is likely you will need the support of leaders both within and outside of pharmacy. Keep this in mind as you develop your proposal.

Stakeholders

Have an approach to demonstrate the effectiveness of your business that is pertinent to the focus of each decision maker. If your organization does not have a traditional 'C-Suite', consider members of your board of directors, advisory group, or even your Chamber of Commerce for your community that will need to embrace and support your service.

Stakeholders

Clinic Manager	Chamber of Commerce	Advisory Group	Physician Champions	Board of Directors	C-Suite

Stakeholders and high-level leaders will likely have different priorities; therefore, it is important to effectively summarize your service by focusing on what is important to them. For example, the Chief Financial Officer might want to know what startup costs are required, while the Chamber of Commerce may want information on how the service will be marketed to other community partners. It will be important to align your new pharmacy services with the goals and solutions that are the organization's current areas of focus. When delivering your message, it will be important to leverage pharmacists as medication experts, and illustrate how the outcomes of the service can benefit not only the patients, but the business overall.

Buy-In Proposal

To develop a proposal, you will need to efficiently and succinctly deliver a tailored message that highlights the value of your service. Leaders are interested in key topics touching on the "the what, the why, and the how". Share points around the purpose, goal(s), outcomes, activities, importance, resource needs, and sustainability specific to your service proposal. Use your business plan as a guide as you prepare.

- Avoid sharing every detail, however, provide enough detail to demonstrate thorough planning. Essentially this is your "sales piece"
- Be prepared to be asked how you will demonstrate and communicate outcomes back to the leadership team
- How does it align with priorities and what's in it for each person?
- How do the mission, goals, and outcomes align with their priorities?
- Be able to speak to the financial piece
- Don't get lost in the details
- Be prepared and practice

Toolkit Tip: Note, many pharmacists suffer from 'analysis paralysis'. Before you spend days preparing your details, take your concept to one of the major decision makers. Have enough detail to explain your concept, why it is important, what problem it is solving, and generally how you see it working. This decision maker can give you an initial impression of feasibility and timing. Often, this decision maker can also align you with other resources to help you further develop the details if you receive support for the concept.

Tools/Resources:

- ASHP – Practice Advancement Initiative: http://www.ashpmedia.org/pai/

Communicating Value

Elevator Speech

You'll need a brief, compelling description, often called an 'elevator speech'. This should have a 10 second version and a 30 second version. You can have a longer description with more detail when that is appropriate for your audience. Reference your mission statement to help guide your elevator speech.

Toolkit Tip: A simple way to test the clarity of the business concept is to try to state the idea clearly and succinctly in about 1 minute. If the pharmacist has trouble stating exactly what he or she proposes, it raises a red flag that elements of the basic idea may not have been sufficiently considered.

Value of a Pharmacist

Verbalizing and demonstrating the value of the pharmacy profession is important. You may need to be prepared to do so when looking for champions and prescribers to partner with and getting executive leadership buy-in. Look for tools, examples, or your elevator speech to help communicate your value. More examples can be found in the Value Based Contracting and Medication Reconciliation sections of this toolkit.

Resources/Tools:

- The Role of Pharmacy Through Collaborative Practice in an Ambulatory Care Clinic – Am J Lifestyle Med: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6506972/

- Improving Patient and Health System Outcomes through Advanced Pharmacy Practice – A Report to the US Surgeon General, 2011: https://dcp.psc.gov/osg/pharmacy/sc_comms_sg_report.aspx

- Ambulatory Care Pharmacy Practice Model Initiative – Recommendations of the Summit: https://academic.oup.com/ajhp/article-abstract/71/16/1390/5110988?redirectedFrom=fulltext

STAGE 2: DO
Implementing Your Pharmacy Service

Step One: Finalizing the Activities

Now that you have walked through the planning steps, it is time to select a pilot group of prospective patients to implement your plans. By starting with a small group that best matches your 'ideal patient' model, you can test your process to find any holes or issues you didn't expect. This approach of starting small to work out the problems ultimately saves time. When you launch the full-scale service, it will be more efficient and have fewer problems to overcome.

Note, as pharmacists, we tend to spend a lot of time in the planning phase trying to make the process perfect before trying it. Don't do this. You will learn more and learn it quickly with the initial implementation than you would learn in trying to envision holes in your process.

Talking Points

When you have identified your 'ideal patient' avatar, what is the primary need and reason to select this service for that patient? This is the central theme of your talking points when describing and recruiting patients to your service.

Your 'elevator speech' can be shared whenever talking with potential partners, referral sources, patients, and champions of your service.

Getting Patients to Receive Service

Patients need to know the service exists, how it could benefit them, and how it works. Your recruitment through referral sources, information available in your pharmacy or practice, and personal invitation via your reports will increase awareness.

- Make it easy for patients to get started
- Make it clear how to schedule the first appointment
- Have easy-to-read signage to report for the first appointment
- Have a defined registration process
  - Consider having staff to assist patients with any difficulty completing intake forms
  - If you plan to collect information prior to the first appointment, make it simple and give patients plenty of time to complete this before starting the appointment or bring with them.

Medication Reconciliation

Medication Reconciliation can be an effective way to initially engage patients and is a key step to analysis and decision making. It is the process of creating an accurate list of all possible medications the patient is taking, including prescription, over-the-counter, vitamins, herbals and nutraceuticals/

health supplements and then comparing it to the list that is in the patient's health record to ensure that the patient and care team have the most complete and accurate list. Pharmacists can play an important role in this process and be of great service to patients and physicians/prescribers.

Tools/Resources:

- ASHP published a medication reconciliation guidance document for pharmacists (July 2018) that is a quick reference and is supplemental to the AHRQ's Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation (https://www.ahrq.gov/patient-safety/resources/match/index.html.). The resource walks the reader through the process with suggestions and prompts to aid in completing a medication history interview and activity flowcharts. https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/ambulatory-care/medication-reconciliation-guidance-document-for-pharmacists.ashx
- Medication History Tool: Medication History Tool

Patient Education

Education topics include the underlying diagnosis or problem and the prescribed treatment plan. Other topics include the available treatment options – both pharmacologic and nonpharmacologic, the available resources in the community, and online for additional support.

As you consider available tools to educate your patients, consider the diversity of your patient population and have available tools in a variety of formats. This variety reinforces the learning and can help to meet needs such as hearing impairment, visual impairment, or language barriers. Incorporate formats such as written information, pictorial information, video clips, and tools in appropriate languages for your community.

Tools/Resources:

- ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/pharmacist-conducted-patient-education-counseling.ashx

Step Two: Establishing a Go-Live Plan

Internal Education Strategy

Have a thorough plan to orient all staff to the process and flow. Include the components that will set patients at ease and make their experience within your service a good one. Assure each staff member knows their own role and the roles of the rest of the team. Some important considerations:

- Who will greet the patient and how; consider how you want the patient to feel when entering your practice to receive service?
- Who will initiate the intake process and how?
- Who will initiate the clinical services?
- Who will provide each step of clinical services?
- Who will wrap up clinical services?
- Who will provide the last step of the visit and assure patient knows what happens next?
- Consider who can back up with the primary person assigned a role is not available

Partnering Strategy

Partnering with Physicians

At this point you have collected information from potential provider partners and referral sources. They are aware that you are planning this service. Now you want them to know the service is ready and to actively refer patients. Also, remind them of the process, how to refer, what patients can expect upon referral, and how you will communicate with them as the patient's provider. Don't forget to express the overall safety aspect of your project and the assurance of proper monitoring and assessing patient needs. To engage partners, you may need to utilize the top-down directive from senior leadership, and they will reach out to physicians. Other options include a letter to physicians or schedule an in-person meeting.

For the initial pilot of a few patients, consider focusing on one to two providers' patients to hone the referral and communication portions of your service. Select providers who can be champions of your service and provide constructive criticism as you work through the pilot process.

In some instances, changes in guidelines, health-system priorities, community priorities, or financial pressures could direct providers to fully participate as partners. Look for such opportunities to partner in ways that benefit multiple parties and initiatives.

Partnering with Patients

Selecting and recruiting patients that most closely match your 'ideal client' avatar will give you the best ability to assess the service that has been created. Invite these patients to share their constructive criticism. Ask questions to assess the feelings upon entering the service, the flow of the service, the clarity of information, the satisfaction with the service, and any feedback for improvement that can be captured and used for improvement.

Ask initial patients for testimonials to add to your marketing. These patients can also talk with others in the community to help champion your service.

One example can be found here: https://blog.hubspot.com/service/testimonial-request-template.

Communication Tools

Your communication tools can take several forms.

Key Points for Specific Target Audiences:

Ideal Patients

- Announce new service
- Why and how patient would benefit from service
- How to get more information
- How to enroll

Providers

- Announce new service
- Why and how patient(s) would benefit
- Which patients would be best candidates
- How to refer

Other Clinicians

- Announce new service
- Why and how patient(s) would benefit
- Which of their clients would be best candidates
- How to refer

Community

- Announce new service
- Why and how their client(s) would benefit
- Which patients would be best candidates
- How local community organiztions could help with advertising and recruiting
- How to refer

Health-System

- Announce new service to health-system leadership, pharmacy department leadership and service/people who could be referral sources
- Why and how patient(s) would benefit
- Which patients would be best candidates
- Which portions of the health-system might be best referral sources
- How to refer

Sample Communications

As stated above, consider the way you want a patient to feel when entering your practice. Hone your communication materials and messaging to reflect that culture. Some elements to include are:

- How to prepare for a visit
- What to expect
- An overview of the process
- What the patient can anticipate as an outcome and next steps

For staff who will be greeting your patients, what greeting should be delivered? How much attention should be given to the arriving patient?

For staff who will be finishing the patient's visit, what farewell information should be shared? What information or materials should the patient take away from the visit?

Key Talking Points for Patient Telephonic Conversations

Communicating with patients by telephone introduces unique challenges. More emphasis is placed on word choice, tone, and timing due to the absence of non-verbal elements providing context. However, non-verbal activities are still important because they are reflected in your voice when you speak. So even though no one can see you, remember to smile when speaking to patients on the phone. Though they can't see you, they will be able to notice a difference.

When communicating by telephone consistent messaging is important, especially if more than one person is conducting the phone calls. Prior to initiating this element of your service, develop key talking points.

Toolkit Tip: Getting someone to answer your call is sometimes difficult. If there is a way to notify the patient ahead of time that you will be reaching out to them the patient may be more likely to answer and participate in the call.

Steps for a successful telephonic conversation:

- Introduction
  - Identify yourself and purpose of call early in the conversation
  - Be personable and use a conversational approach to begin the conversation
  - Be very conscientious of the tone of your voice
- Sharing of information
  - Be specific
  - Select words carefully
  - Stay on task
- Collecting information
  - Be clear
  - Only ask one question at a time
  - Prepare an organized way to record information collected
  - Listen
  - Use language the patient uses to ensure complete understanding
- Summarize and provide final message about next steps
- Final greeting
  - Thank the individual on the phone

STAGE 3: STUDY
Studying Your Pharmacy Service

Data Reporting and Analyzing

After your pharmacy service is initiated, take the time to analyze what you have learned. Collect your outcomes data and compare to what was predicted and to any benchmarks identified in the planning phase for baseline assessments. Go through each step of the process that was planned and assess if it is the right step performed in the best way. Look at the internal flow and the flow for the patient. Review information gained from patient surveys and provider feedback. Request staff feedback and ideas for improvement.

Then, make any changes to the process, update the staff, update referral source partners if impacted, and revise communication tools if changes need to be made.

Consider conducting a new SWOT analysis. From your experience in the pilot, confirm your strengths. Identify weaknesses that are discovered and brainstorm how you can turn those weaknesses into opportunities. Identify and consider steps to navigate any additional external threats that are found.

Make any design, implementation or other strategic changes to the original service plan.

Once all changes are in place, initiate full recruitment for your service. Don't forget to communicate changes to all those involved in the service.

Reevaluate outcomes data and process on a regular basis. Make a plan for frequency of evaluation and include data points from many sources.

Regular Feedback

Feedback from multiple sources supports a process of constant improvement. Collect feedback and ideas for changes that can be implemented on a scheduled basis. Do be flexible to make urgent changes quickly when patient safety or other major issues are identified. Other changes can be more carefully considered and planned strategically.

Change is inspired when feedback is obtained from those who are directly involved with or recipients of the pharmacy service activities. Gathering data from staff, patients, providers, and other clinical partners will provide feedback from a variety of viewpoints. Remember to include data from the metrics you highlighted in "Step 2 – Defining the Service" section of this toolkit. Your supporting dashboards or reports will help analyze quantity, quality, financial impact, and clinical outcomes of services provided. Remember to share status updates with your customers and team members!

Patient Satisfaction/Experience

One way to gather insight is the use of patient satisfaction surveys. The key is to develop a short, simple-to-answer patient satisfaction survey that can be understood by your patients. There are many ways this can be done.

Examples include:

- In office, post-appointment paper or electronic surveys
- Web-based surveys through URLs, online survey tools, or patient portals
- Mail surveys
- Phone surveys
- In office conversation

When designing the survey, here are some tips to consider:

- Include patient reported outcomes relevant to your service
- HCAPS (Hospital Consumer Assessment of Healthcare Providers and Systems) survey questions
- Domains that resonate with the leadership team
- Potential problem areas
- Other areas identified in pilot feedback

TOOLKIT TIP: Patient satisfaction collection can be a help when prioritizing changes in your plan, your process, and your flow. Ensure questions are actionable, open-ended (not binary yes/no), and directly related to what you want to know.

Physician / Customer Satisfaction

Your prescribers are key to referrals and the success of your clinical interventions. They may also be your biggest advocate. Forging that relationship through outcomes is a great way to open the door for future opportunities.

As with patients, you can collect their feedback with a written survey, an electronic survey, or a personal conversation. Their staff can also be a conduit for feedback.

Important questions to address in your communications include:

- How and why the prescriber is referring patient?
- Is the prescriber clear about the appropriate use of your services and which patients are best to refer?
- Is the referral mechanism experiencing any issues?
- Is communication of your recommendations being received in a timely manner?
- Are there any alternative communication methods that would be preferred or more effective?
- Does the prescriber know how to reach you with any questions?
- Is there any feedback to help make your service even more helpful to the prescriber and the patients?

Toolkit Tip: Physicians involved in the completion of this toolkit expressed a desire for a direct line to the pharmacist, ideally the pharmacist who is collaborating on the specific patient. Some successful models of exchanging cell phone numbers were identified.

STAGE 4: ACT
Acting on What You've Learned

Sustainability Plan

In a paper by Gloria Sachdev called Sustainable business models: Systematic approach towards successful ambulatory care pharmacy practice (ASHP 2014) she states that "The four pillars of business sustainability are leadership, staffing, information technology, and compensation".[6] She goes on to mention that the lack of demonstrating the service's value to administrators and payers was the key reason for failure. What steps can be taken to prevent your service from a similar fate? Focusing on the four pillars and communicating a concise message will increase your chance of longevity. Review the references below for additional guidance and tools to assist you in this process.

Tools/Resources:

- Sustainable business models: Systematic approach toward successful ambulatory care pharmacy practice – Ambulatory Care Summit briefing papers: http://europharm.pbworks.com/w/file/fetch/107642664/sachdev2014_sustainable%20business%20models%20in%20pharmacy.pdf
- The Dynamics of Sustainability: A Primer for Rural Health Organizations by the U.S. Department of Health and Human Services Health Resources and Services Administration: https://www.ruralhealthinfo.org/assets/1211-4984/dynamics-of-sustainability.pdf
- Sustainability Tools – Rural Health Information Hub: https://www.ruralhealthinfo.org/toolkits/rural-toolkit/5/planning-resources
- Sustainability Planning Template of the Department of Health and Human Services (HHS) – HHS.gov: https://www.acf.hhs.gov/ana/resource/ana-sustainability-toolkit

Assessments

Supporting the Provision of Your Service

You planned your workflow and process, but now you are assessing if it is working as planned. As an exercise to evaluate your entire process, with your team, write out these steps:

- What is your internal workflow from patient recruitment to patient follow up?
- What is the patient workflow and what are all of the steps of the patient journey from initially learning about your service to ongoing follow up (if pertinent)?
- Is this patient workflow what you anticipated or do changes need to be made?
- What elements are not going as planned?
- Is the patient experience as you planned (the answer can be from observation and from patient satisfaction survey results)?

[6] Sachdev G. Sustainable business models: Systematic approach toward successful ambulatory care pharmacy practice. *Am J Health-Syst Pharm*. 2014; 71: 1366-74

Financial Viability

If possible, it's a good idea to assess the return on investment for your service. Here are key data points you will need for this analysis:

- Number of patients served
- Time spent by each team member per patient visit
- Overhead costs per unit of time (e.g. lighting, heat, costs to be open per hour)
- Initial capital costs such as clinical equipment, computers, space modification costs
- Ongoing costs such as technology support, licensure, computer application costs
- Reimbursement per patient
- Use of comparatively clinically effective therapies per Institute for Clinical and Economic Review (ICER) standards
- Wellness and longevity outcomes such as quality adjusted life years (QALY)

Once you have this information, calculate the number of patients required to break even. Then calculate any loss or profit over this break-even point.

Based on all of the data you have collected, analyze how the process can be altered to maintain great patient care while optimizing revenue. Identify the changes needed to keep your service cost-effective.

Tools/Resources:

Pharmacy Clinical Service Finances		
Start-Up Costs		
Space modification	**17,000**	
Equipment	**2,300**	
Other capital expenses	**250**	
TOTAL START UP	**19,550**	
Fixed Expenses		
Pharmacist salary+ benefits (0.2FTE)	**33,000**	
Other involved staff salary	**11,616**	
Technology expenses	**236**	
Overhead*	**1,200**	
TOTAL FIXED	**46,052**	

Revenue				
	Visits/month	Reimbursement rate	Monthly	Annual
Reimbursement per visit				
Medicare	18	49.84	897.12	10765.44
Medicaid	30	45.92	1377.6	16531.2
Other' insurance	8	56.48	451.84	5422.08
Other insurance	5	54.92	274.6	3295.2
Unpaid	5	0	0	0
Education Class fees	30	30	900	10800
Other revenue			0	0
			TOTAL Annual Revenue	**46813.92**

*Overhead is portion of electric, water, lease, other standing expenses for the space
Sample salary plus benefits calculcation for time involed in clinical service =(125000*0.2)*1.32

Service Expansion

This is the point at which you use the service you have created, the outcomes gathered, and the experience you've gained to engage in community outreach activities with the goal of targeting new patients. The skill of storytelling in crucial here. You have all the pieces to tell a great story, it's knowing how to put it all together to make the story truly reflect your work and influence those around you. There are many ways this may be done and we have included an example below to help you think through this process.

Begin by gathering your results and think about the story you want to tell.

Why did you start this service originally?

What goals did you set out to accomplish and what were your results?

How has this impacted your patients and customers and what has resonated most with them?

Next, put some thought into which additional providers you want to identify as collaborators. Would it be offices or physicians with a high number of patients with a certain disease? Perhaps physicians with a large number of prescriptions for a medication that helps identify your target patient? Or maybe offices with less resources available to them in the community? Whatever it may be, find a metric that helps you strategically narrow the field of potential contacts to streamline your efforts.

Finally, put your story into writing or some form of visual to enhance the telling. Storyboards or infographics are a great tool to do this. Think simple, concise, and one to two pages.

Case Demonstration Employing Chronic Pain Services in **Ambulatory Settings**

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Case Demonstration Employing Chronic Pain Services in Ambulatory Settings.

DISCLAIMER

This implementation toolkit was developed based on a collaboration between NCAP and Pfizer (with financial support provided by Pfizer Inc). Please see full disclaimer for this toolkit on Page 2.

Pain Service: Manage guideline-supported treatment regimens as appropriate for patients with chronic pain. This document has helpful resources for any outpatient clinic chronic pain service. Included are links to key quality measures.

Purpose

The following is a guide as to how one may use the toolkit to include chronic pain services within your ambulatory care pharmacy role. The example is not all inclusive and it is recommended to consider specifics within your practice setting when developing your service.

STAGE 1: PLAN

Planning Your New Chronic Pain Pharmacy Service

Step One: Conducting a Market Analysis

When building your case for a chronic pain pharmacy service, it's important to keep in mind what the needs are from the community, prescriber and your pharmacy business while at the same time considering how your environment will both support and resist your efforts.

Conducting a Chronic Pain Needs Assessment

Below is an example of a chronic pain focused needs assessment. Embedded within the document are links to chronic pain resources to help evaluate needs from a community, prescriber and business viewpoint.

Chronic Pain
Pharmacy Service Ne

One way to gather information from prescribers is to provide them a survey with questions focused around their needs and value assessment of pharmacy services. Below is a sample survey including questions modified from a publication by Giannitrapani, et.al. featured in BMC Family Practice, 2018 publication.[1]

Prescriber Survey for
Pharmacy Chronic Pa

Working Through a SWOT Analysis

A Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis focuses on the internal strengths and weaknesses and the external opportunities and threats your new service may need to consider. Using questions that focus on both internal and external environmental factors will guide you through your SWOT Analysis. Below is an example of environmental questions you may want to consider addressing in your SWOT analysis. The SWOT Analysis Template was added for convenience.

Environmental
Analysis Worksheet C

SWOT Template
Final.docx

1 Giannitrapani KF, Glassman PA, Vang D, et al. Expanding the role of clinical pharmacists on interdisciplinary primary care teams for chronic pain and opioid management. *BMC Fam Pract.* 2018;19:107-116. doi:10.1186/s12875-018-0783-9

Step Two: Defining your Chronic Pain Pharmacy Service

Following guidance from the toolkit, below are sample mission and purpose statements that can be used for this service.

Creating your Mission and Purpose Statements

Mission Statement: We aim to improve safety, provide effective, guideline supported pain management and improve quality of life for patients with chronic pain.

Purpose Statement: Suboptimal chronic pain management over many years has put individuals and the overall community at risk. We will improve chronic pain management by optimizing medication regimens and aligning with guideline recommendations.

Creating a SMART Goal

Building a strong **SMART goal** addresses five major areas. Below is an example of a SMART goal that would work for a chronic pain pharmacy service.

SMART Goal –

Specific: We will initiate non-opioid (and non-drug) treatment regimens and reduce opioid utilization where appropriate for patients experiencing chronic pain, to improve functionality, patient safety and optimize quality of care and outcomes, while setting realistic patient expectations for their pain management and disease course, in my practice setting.

Measurable: We will measure the number of chronic pain patients and associated outcomes impacted by our chronic pain service. Metrics include: increase the number of patients enrolled in my pain program, decrease the (number, morphine milligram equivalent (MME), or daily doses) of opioid utilization, and improve the PEG scores (measuring pain level, functionality, QoL) of my chronic pain patients. [Note, PEG is average pain intensity (P), interference with enjoyment of life (E), and interference with general activity (G).]

Toolkit Tip: Information gathered during your baseline market analysis and patient identification activities can be used to create meaningful metrics – i.e. impact X% of eligible patients, decrease total MME by X%, decrease # of opioid prescribed by X%, increase X% of patients with non-opioid therapy, improve overall PEG score by X%

Achievable: A case for change is made by assessing the baseline data for my pain population and the chosen outcomes are achievable through care team collaboration (i.e., other pharmacy personnel, provider team). Pain programs using a similar model have been successful across the country.

Relevant: Improving safety, quality of life and health outcomes in the chronic pain population is a key focus of national health care efforts in our country and my practice.

Time-Bound: Enroll X number of patients into my chronic pain service using a good communication strategy with my chronic pain patients and the provider network giving care to **these patients by X date and meet outcomes metric goals by X date.**

Final Pharmacy Service Overall SMART Goal: Over the next XXX months, we will initiate guideline and state supported chronic pain treatment regimens including non-opioid options, reduce opioid utilization where appropriate for patients experiencing chronic pain, improve functionality, patient safety and optimize quality of care, capturing impact by following measurable outcomes including patient enrollment numbers, opioid utilization, number of patient education encounters, adherence to Centers for Disease Control (CDC) guidelines and functionality scores , while setting realistic patient expectations for their pain management and disease course.

SMART goal Worksheet for Chronic Pain Service attached:

SMART goal for Chronic Pain Pharma

Consider building more targeted Specific, Measurable, Attainable, Relevant, and Timely (SMART) goals for your major activities. Examples are featured below.

Take a comprehensive medical and pain history including all current and past medications for pain, medication adherence and reason for medication discontinuation
• **Smart Goal:** To have 100% compliance on documenting a comprehensive medication and pain history on every patient seen within the service over the next 6 months.
Access efficacy of current regimen and cross reference with available guidelines to determine need for change
• **Smart Goal:** Assess all patients pain and function using standardized tools and analyze current regimens to verify alignment with literature recommendations and patient medical history within the first 1–2 patient visits.
Provide medical management or send recommendations to partnering prescriber based on practice setting
• **SMART Goal:** Identify and communicate with prescribers therapy modications including dose adjustments, adjuvant therapies and tapers when indicated within one day of evaluation.
Support risk mitigation and assessment strategies such as urine drug screening, naloxone, informed consent and treatment agreements where applicable
• **SMART Goal:** To have 100% of patients on opioid therapy with up-to-date risk mitigation strategies including urine drug screen, informed consent/treatment agreement, and naloxone if applicable within first 1–2 patient visits.
Provide patient education
• **SMART Goal:** Educate 100% of patients on opioid therapy enrolled in program on risk of misuse, overdose and diversion prevention, and safe storage and disposal
Patient Outreach/follow-up Activities
• **SMART Goal:** follow up for all identified patients at least monthly.

Defining Outcomes and Metrics

There are many factors to consider when deciding what outcomes and metrics will best represent the goals of your chronic pain pharmacy service. Below is an example of outcomes and metrics that are relevant to the management of chronic pain.

Outcome and Metrics Chart Ambula

Step Three: Awareness of Governing Policy and Billing Opportunities

Policies and Regulations Associated with the Management of Pain

Understanding policy and regulatory requirements associated with your pharmacy service is a crucial step in providing safe and effective care to your patients. Policy and regulations will directly affect the what and how of your operation. Below is one example as to how to approach your exploration into policy and regulation accompanied by specific examples. Refer to the needs assessment worksheet in Step 1 for additional resources.

When writing your policies, be sure to incorporate the latest national and state rules and guidelines. North Carolina State Medical Board summary of The Strengthen Opioid Misuse Prevention (STOP) Act of 2017: https://www.ncmedboard.org/images/uploads/article_images/The_STOP_Act_summary-OnLetterhead.pdf

North Carolina Board of Pharmacy Controlled Substance Rules and Regulations Pocket card:

CSpocketcardRev1117.pdf

Other sources of guidance can be the Centers for Disease Control, the US Food and Drug Administration, the Federal Controlled Substances Act, the Federation of State Medical Boards, and national pharmacy organizations. The American Society of Health-System Pharmacists (ASHP) Opioid Task Force guidelines are an example of national organization guidance.

Keep in mind guidelines and standards do change over time, so be sure to always use the most current version.

Billing Considerations for a Chronic Pain Pharmacy Service

Refer to the billing section of the toolkit here. Some strategies specific to chronic pain management include co-visits, Medicaid credentialing, chronic care management, and transitional care management services.

- Clinical Pharmacist Practitioners (CPPs) get credentialed from NC Medicaid at 100% of provider rate – identify Medicaid population.
- MTM/Medicare Medication Reconciliation as part of annual exam
  - Woodall T, Landis SE, Galvin SL, Plaut T, Roth McClurg MT. Provision of annual wellness visits with comprehensive medication management by a clinical pharmacist practitioner. *Am J Health Syst Pharm.* 2017 Feb 15;74(4):218-223. doi: 10.2146/ajhp150938.
- Cost Savings/Improved Outcomes – monetize loss of productivity – admission for overdose, etc.
- Participate in documentation of the individual patient care plan to support appropriate billing and reimbursement of services.

Quality Measures

When thinking of quality measures your chronic pain service could impact, remember to include measures that both directly pertain to pain management activities as well as general patient management activities. For example, think of how your service may impact Merit-based Incentive Payment System (MIPS) measures from each of the 4 categories (quality, cost, improvement activities and promoting interoperability). Tie in patient satisfaction through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and 30-day readmissions. For a list of agencies and measure sets, look under the quality measures section in the service development section of the toolkit. Also, refer to the needs assessment worksheet in Step 1 for additional chronic pain specific measures.

Collecting Guidance from Other Organizations that Support the Management of Chronic Pain

Multiple organizations have published guidance around chronic pain management. The list below identifies many of these organizations though it is not a comprehensive list.

- CDC Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html
- Department of Health and Human Services: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
- American Academy of Family Physicians: https://www.aafp.org/patient-care/public-health/pain-opioids/cpm-toolkit.html
- Management of Chronic Pain and Opioid Misuse: A Position Paper from the AAFP: https://www.aafp.org/afp/2017/0401/p458.html
- American Academy of Pain Medicine: https://painmed.org/clinician-resources/clinical-guidelines
- American Society of Anesthesiologists Task Force: https://anesthesiology.pubs.asahq.org/article.aspx?articleid=1932775&_ga=2.182459942.1634522965.1577592618-1784423046.1577592618
- Refer to the needs assessment in Step 1 for additional guidance

Examples of Already Existing Chronic Pain Pharmacy Services

- Virginia Mason in Washington State has a pharmacist embedded in a physical medicine and rehabilitation clinic.
  - *Boren, L.L., Locke, A.M., Friedman, A.S., Blackmore, C.C. and Woolf, R. (2019), Team-Based Medicine: Incorporating a Clinical Pharmacist into Pain and Opioid Practice Management. Journal of Injury, Function and Rehabilitation, 11: 1170-1177. doi:10.1002/pmrj.12127* https://dx.doi.org/10.1002/pmrj.12127
- The Toronto General Hospital Transitional Pain Service: development and implementation of a multidisciplinary program to prevent chronic postsurgical pain: *https://doi.org/10.2147/JPR.S91924*
- Sample of items to cover with patients at an office visit for the treatment of chronic pain:
  - Veterans Affairs/Department of Defense Clinical Practice Guideline for Opioid Therapy in Chronic Pain: Clinical Pharmacy Services in a Multidisciplinary Specialty Pain Clinicm DOI. 10.1111/papr.12745

Items to Cover with Patients at Office Visits for Treatment of Chronic Pain
Initial Visit(s) for Patient with Newly Diagnosed Chronic Pain
(not previously on opioids for > 3 months)

- ☑ Initial Pain Questionnaire (optional)
  a. Covers the following **<u>required</u>** items: current pain level; current physical, functional, and social domains to improve upon; and specific treatment goals to encompass all domains
- ☑ Documentation of informed consent (required)
- ☑ Pain contract (required)
- ☑ Opioid Risk Tool (required, unless another screening tool is used)
  a. Score of ≥ 8 necessitates pain specialty referral
  b. Score of 4-7 necessitates a discussion/referral with patient about behavioral therapy
  c. Score of <4 indicates low risk of aberrant behavior predicted
- ☑ DIRE or SOAPP screening questionnaires (optional)
- ☑ PHQ-9 and GAD-7 (required for screening if applicable)
- ☑ Assessment of need for naloxone prescription (required)
- ☑ Documentation of appropriate prescription filling per the NC Controlled Substance Registry or local PDMP.
- ☑ Urine Drug Screen (required)

Step Four: Designing the Chronic Pain Pharmacy Service

Identifying your Target Patient Population

When determining what patients to target for your chronic pain pharmacy service you should consider your goals and metrics, quality measures, billing opportunities and patients at greatest risk/need. In this section of the toolkit we will provide more guidance around considerations of potential at-risk patients and how to screen for your ideal patient population.

Consider the following at-risk patients for your pharmacy service:

- ☑ Patients with uncontrolled pain reflected by standardized assessments, higher than average contact with health system, patient report, etc.
- ☑ Patients with chronic pain and multiple co-morbidities
- ☑ Patients receiving chronic opioid therapy (greater than consecutive 3 months duration, intermittent or regularly scheduled) AND any of the following:
  - ☑ Chronic opioid therapy greater than 90 MME per day
  - ☑ Concomitant chronic benzodiazepine use
  - ☑ Receiving opioids from multiple providers
  - ☑ Routine urine drug screening results inconsistent with current opioid use
  - ☑ Routine urine drug screening results indicate undisclosed use of illicit substances
  - ☑ Opioid Risk Tool (ORT) screening indicates moderate to high risk of opioid misuse
  - ☑ More than one occurrence of request for early refill of opioid
  - ☑ Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD) score indicates moderate to high risk of respiratory depression
  - ☑ Suicide risk screen indicates a risk exists

Identifying the appropriate patients for your service and developing a way to screen for them is an important step in developing your service. Available patient identification techniques will differ based on practice setting.

Examples include:

- Survey patient population to identify specific criteria of need for inclusion
- Pull data from your pharmacy or medical system via ICD-10 chronic pain conditions
- Chronic Opioid Registry (i.e. Epic® electronic health record (EHR), etc.)
- Patients in targeted Accountable Care Organizations (ACOs)
- Medication reports by clinic level or retail setting (i.e. Opioid use or other pain medication)
- Report of a specific demographic (i.e. Medicaid, zip codes, etc.)
- Reach out to your provider network to determine patients with pain or lists they have received from insurance companies requesting action such as utilization review or follow-up care.
- Request referrals to your service (TIP: See Communication Section)

Gathering Your Stakeholders to Support Your Service

Customer Identification: Ideas include: Your pain patients, providers and staff giving care to your patients as part of the patient care team in your clinic setting, those prescribing medications to your patient population. Other ideas include providers identified by leadership as needing additional intervention, provider who have patients with high utilization of healthcare services, providers that prescribe the most opioids/pain medications, providers that use opioids as first line for chronic pain management, colleagues working with pain patients via population health initiatives or opioid stewardships, health information technology colleagues who can help gather data/reports, etc.

Patient Care Interventions

As you build out your activities, keep in mind where in the patient flow the activity will take place, who will be doing the activity, what resources and tools will be needed to complete the activities and how does the activity support your goals and metrics.

The attached document is an activity grid example for a chronic pain pharmacy service within the ambulatory setting.

Chronic Pain Service In Ambulatory Space Service Activities

ADDITIONAL ACTIVITIES BASED ON PRACTICE SETTING

- Address concomitant disease states such as insomnia, depression, anxiety, etc.
- Facilitating prior authorization requests related to pain management medications and services
- Participate in provision of office-based medication-assisted treatment (MAT) (buprenorphine or naltrexone) for opioid use disorder (OUD)
- Order laboratory tests other than urine drug screening (UDS), interpret test results, document assessment of test results and document recommendations related to testing as appropriate for the care of the patient with chronic non-cancer pain

Documenting and Communicating Your Ambulatory Chronic Pain Activities

Key items to keep in mind when deciding on your documentation strategy:

- Start with something simple and what works for your practice, EHR or Note templates.
- Due to the legal ramifications of working with patients using opioids, complete and accurate documentation is critical.
- Create a documentation process that will be used as part of your communication strategy to other care team members and the patient.
- If you are using an EHR, ideally some variables should be captured in a discrete field for tracking, extracting and data analysis/reporting and quality/performance goal achievements.
- Participate in documentation of the individual patient care plan to support appropriate billing and reimbursement of services.

Refer to the Documentation section of Pharmacist Chronic Pain Tools and Resources for additional resources around documentation and communication tools.

Documenting Your Ambulatory Chronic Pain Activities Process

Building out a process workflow is helpful in understanding how the overall service will look. Process workflows highlight what each person is doing and when and in what order. Below are two examples of workflows. The first one is a general workflow highlighted key activities for a chronic pain pharmacy service. The second is an example of how this particular use case may look.

Chronic Pain Workflow in Ambulatory Care Setting

Chronic Pain Workflow in Ambulatory Care Setting

Case Demonstration Employing Chronic Pain Services in **Community Settings**

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Case Demonstration Employing Chronic Pain Services in Community Settings

STAGE 1: PLAN

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Case Demonstration Employing Chronic Pain Services in Community Settings

Pain Service: Evidence-based chronic pain collaborative practice. Although written with the busy community pharmacist in mind, this case demonstration has practical resources especially relevant to any smaller practice that is not directly within a health system.

Purpose

Community pharmacists are acutely aware of the opioid crisis, and how it affects their community. According to the NC Department of Health and Human Services in 2018 about 5 North Carolinians died each day from an unintentional overdose (OD).[1] While efforts have been made to improve prescribing by putting legislative limits on opioids in the setting of acute pain, very little has been realized among chronic pain patients taking opioids long-term. In addition, while tackling the opioid burden, North Carolina has seen an increase in benzodiazepine prescribing increasing death rates from concomitant use by as much as 10-fold.

Pharmacists recognize opioid dispensing at an all-time high and worry to what extent their patients may be predisposed to the risks associated with continued use.

Often pharmacists have noticed an increase in the number of patients concerned with their opioid use but aren't sure how to manage their pain in other ways. Some have expressed a desire to stop opioids but fear the idea of returning to a life of uncontrollable pain.

This use case addresses the challenges faced by local providers in monitoring the safety of patients on opioid therapy and realizes the impact a pharmacy-based pain service could have in helping to mitigate risks, monitor effectiveness, and reinforce care planning that leads to improved outcomes.

For these reasons, this sample pharmacy has chosen to implement a ***Safe Pain Management Service*** that addresses care gaps in patients with chronic pain. Fostering implementation of strategies and interventions aimed at breaking cycles of inappropriate pain management and non-assessment that contribute to the development of opioid misuse and opioid use disorder.

1. North Carolina Opioid Action Plan Data Dashboard accessed at https://injuryfreenc.shinyapps.io/OpioidActionPlan/

STAGE 1: PLAN
Planning Your New Chronic Pain Pharmacy Service

Step One: Assessing the Market for a Chronic Pain Service

When building your case for a pharmacist chronic pain service it's important to keep in mind what the needs are from the community, prescriber and your pharmacy business while at the same time considering how your environment will both support and resist your efforts.

Conducting a Chronic Pain Needs Assessment

Below is an example of a chronic pain focused needs assessment. Embedded within the document are links to chronic pain resources to help evaluate needs from a community, prescriber and business viewpoint.

Chronic Pain
Pharmacy Service Needs

Example Community Pharmacy Market Analysis: To better understand your customer base at highest risk, you can run population reports from your store's database to identify unique patients with an opioid claim in the last 90 days. From this report you can filter unique patients based on the below high-risk characteristics.

Total number of unique patients (non-cancer and > 18 yo) with an opioid claim(s) [Denominator]
Total number of unique patients (non-cancer and > 18 yo) on high dose opioids ≥ 90MME/day for > 90 days*
Total number of unique patients (non-cancer and > 18 yo) with concurrent use of opioids and benzodiazepines (BZD) for ≥ 30 consecutive days
Total number of unique patients (non-cancer and > 18 yo) with concurrent use of > 2 short-acting opioids for ≥ 30 consecutive days
Total number of unique patients (non-cancer and > 18 yo) with 1 or more opioid fills in a consecutive 4-month period (Chronic Pain)
Total # naloxone dispensed over last 6 months

** These examples are based on current Centers for Disease Control (CDC) guidelines. Please use the most current guidelines when designing and providing your service.*

NOTE: *Do attempt to rule-out patients prescribed opioids in settings where opioids might be appropriate, such as cancer pain or palliative care. This can be difficult to determine from the reports in some systems. Recognizing cancer patients and even adolescents for that matter may use opioids for*

conditions outside of palliation, where safety monitoring is clearly warranted, we didn't want to exclude these populations without just cause. If you are unable to determine the rationale for use of opioids from reviewing your internal reports, attempt to gather this information during patient evaluations in the pharmacy or through discussion with the prescriber.

One way to gather information from prescribers is to provide them a survey with questions focused around their needs and value assessment of pharmacy services. Below is a sample survey including questions modified from a publication by Giannitrapani, et.al. featured in BMC Family Practice, 2018 publication.[2]

Prescriber Survey for Pharmacy Chronic Pain

Defining Metrics

Evaluating baseline data not only provides information pertaining to the volume of patients at risk within your practice, but also provides valuable insight into what you may want to look at in measuring the success of the service.

For chronic pain therapy risk reduction, two key subgroups of interest could be those taking high dose opioids or on concomitant use of benzodiazepines and opioids. For this emphasis, following are metrics that could be core measures.

- Reduce the # of identified patients taking opioids ≥ 90MME/day by ≥ 30% over 2 next years*
- Reduce the # of identified patients concomitantly using opioids & BZDs by ≥ 30% over next 2 years
- Increase naloxone dispensing by 30% from baseline reporting over the next 2 years

As stewards for opioid safety and the healthcare providers best positioned to foster harm reduction through distribution of naloxone, it can also be imperative to measure our impact supporting co-prescribing of naloxone in our high-risk patients. We know that co-prescribing naloxone has been associated with,

- 63% fewer emergency department visits
- 27% – 46% fewer opioid overdose deaths

** These examples are based on current CDC guidelines. Please use the most current guidelines when designing and providing your service. MME is Morphine Milligram Equivalents.*

Document for each patient the identified risks and screening tools use in determining those risks. Actions and recommendations based on findings from the assessments and patient interview along with physician correspondence and related outcomes are noted and will be used to monitor your progress in meeting core measures. (See Defining Outcomes and Metrics table on page 61).

Collaboration is key, so the next step is to reach out to local providers, especially those who had the higher percentages of patients who met your target criteria. You can survey, and meet in person when

2. Giannitrapani KF, Glassman PA, Vang D, et al. Expanding the role of clinical pharmacists on interdisciplinary primary care teams for chronic pain and opioid management. BMC Fam Pract. 2018:19;107 doi:10.1186/s12875-018-0783-9

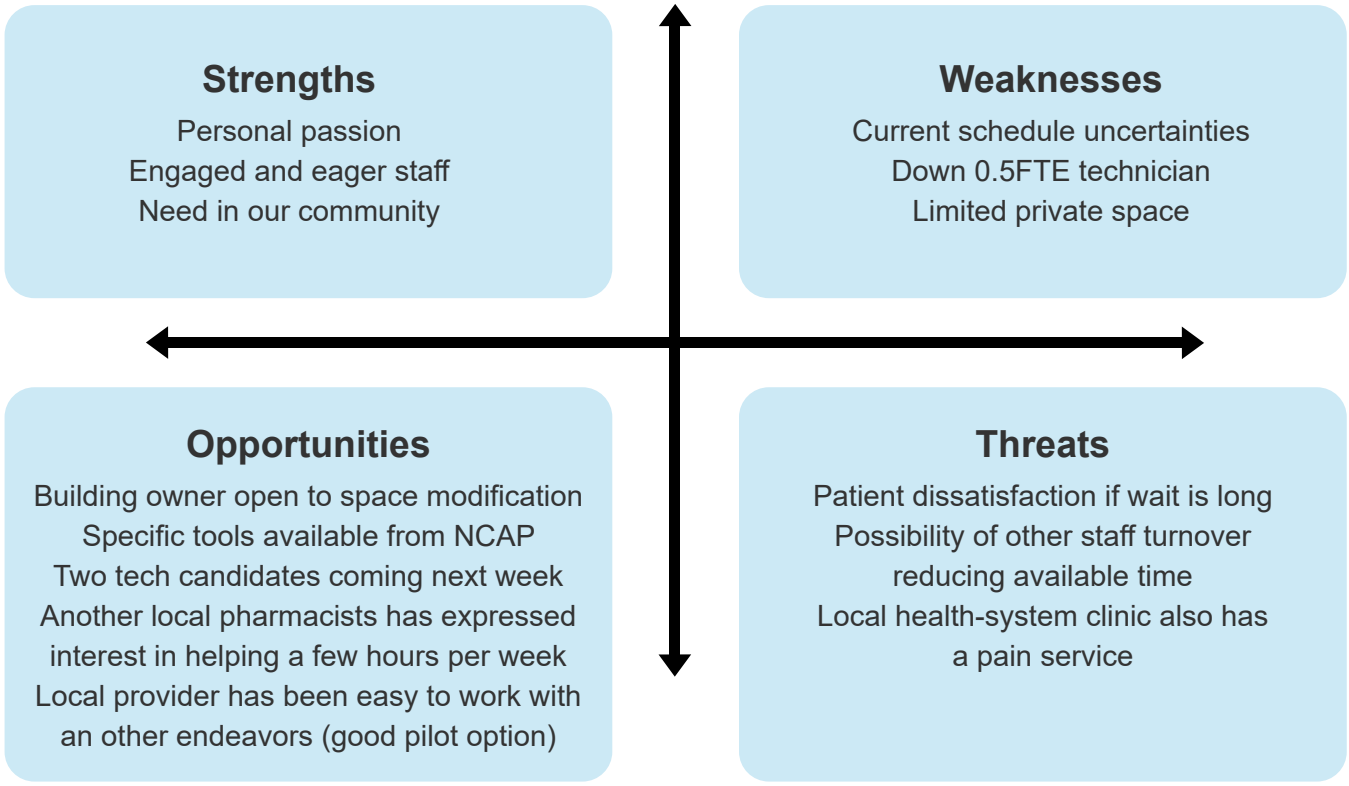
possible, with those providers to better understand their current initiatives to address changing pain management patterns and where they could use the most help. Your database and the data in your reports can help the providers better understanding how their prescribing compares to local peers and identify places where changes could be most effective.

Initial collaboration specifically with one or a small number of local providers as an initial step (pilot) can help to implement a plan to identify, educate, and facilitate prescribing changes for identified high risk patients.

Working Through a SWOT Analysis

A SWOT analysis focuses on the internal strengths and weaknesses and the external opportunities and threats your new service may need to consider. Using questions that focus on both internal and external environmental factors will guide you through your Strengths, Weaknesses, Opportunities, and Threats (SWOT) Analysis. Below is an example of environmental questions you may want to consider addressing your SWOT analysis. The SWOT Analysis Template has been added for convenience as well.

Community Pharmacy SWOT template:



Tools/Resources:

Environmental Analysis Worksheet with a chronic pain focus:

Environmental Analysis Worksheet C

Step Two: Defining Your Chronic Pain Pharmacy Service

Following guidance from the toolkit, below are sample mission and purpose statements that could be used for this service.

Creating Your Mission and Purpose Statements

Mission Statement: Development of a mission statement is important to help align the work of your staff towards a common end. The mission statement not only serves as a compass during improvement efforts but also draws others to the effort. It helps to mark the development of a high value service. Mission statement development should be a collaborative effort of the entire staff.

An example mission statement:

Our Safe Pain Management Service improves patient's lives by employing evidence-based practice and interventions known to reduce risks and enhance safety in those taking opioids for chronic pain.

Staff buy-in: Word to the wise, adopt this as your new MANTRA

> **"You can do it all, … if you don't try to do it all yourself."**

"Recognizing this service's implementation will require full staff participation and a shift in the current workflow, it is important to get buy-in from the entire pharmacy team."

Make sure to;

	**Lay out the vision:** stating why the new service is needed, and why it matters to your organization. Make it a point to convey how the staff's work could positively impact their job satisfaction and ways in which you plan to measure success.
	**Personalize the tasks:** helping each staff member better understand their role in making the service a success and how vital their work would be to improving patient outcomes.
	Let your staff know that they will be asked to take part in defining the work they would be undertaking.
	**Follow-up:** staying in touch with each of your staff during the development and implementation process to reinforce your mission and ensure they feel supported through any challenges that arise.
	**Instill the need to be prepared to "change the change":** recognizing that when things aren't going quite the way you want them to, you need to be prepared to adjust your game plan. Everyone's feedback will be crucial in making the necessary corrections to ensure success and longevity of the service.

To prepare staff for "adjusting the game plan," it is important to cover how to operationalize making changes. Use a simple yet powerful tool for accelerating quality improvement such as Plan, Do, Study, Act (PDSA) model.

Essentially the steps in a PDSA cycle are to,

- **Step 1: Plan**—Create a plan (i.e. workflow) for testing your service.
- **Step 2: Do**—Work your plan but do it on a small scale. (i.e. try it only in a few patients)
- **Step 3: Study**—Set aside time to debrief with your staff to learn what worked, what didn't work, where the unintended consequences (surprises) were, what were the successes, the challenges, the failures.
- **Step 4: Act**—Based on your learnings, what modifications do you want to make to improve.

Understanding this concept will allow you to rapidly cycle through the necessary changes you'll need to improve workflow efficiency and standardize the delivery of your Chronic Pain Service.

Creating SMART Goals

Building a strong **SMART goal** addresses 5 major areas. Below is an example of a SMART goal established for a chronic pain pharmacy service.

By developing and administering our new Safe Pain Management Service we plan to reduce the number of patients on high dose opioids (> 90 MME) by >30%, the number of patients using concomitant benzodiazepines and opioids by > 30%, and increase the number of patients from baseline receiving Naloxone by 30% over the next 2 years.

SMART Goal

See the (link to SMART goal section of the agnostic toolkit) SMART goal information in the Toolkit for Establishing Clinical Pharmacy Services.

Here are example SMART goals you can set with your patients and collaboratively share with providers:

1. Patient will call and make appointment with massage therapist at 919-555-1212 by November 20 as an added elements of overall pain control. (**S**pecific to massage, **M**easurable with the date, **A**chievable with the phone numbers, **R**elevant to overall pain goals, and **T**imeline with due date.)
2. Mrs. Gordan will use her transcutaneous electrical nerve stimulation (TENS) unit for 10 minutes before bed each night and record her sleep on the sleep scale each morning over the next two weeks. She will bring these recordings to her follow up on (specific date).
3. Mr. Lewis will decrease his oxycodone use per the provided taper guide and write his actual use and pain level daily on the calendar provided and bring to follow up appointment (specific date).
4. Ms. Chui will today transition from oxycodone to buprenorphine 2.4mg/naloxone 0.7mg one daily and track pain scores as instructed for one week and return (specific date) with that information.

Defining Outcomes and Metrics

There are many factors to consider when deciding what outcomes and metrics will best represent the goals of your chronic pain pharmacy service. Below is an example of outcomes and metrics that are relevant to the management of chronic pain in a community pharmacy.

Identifiable Risks
Patient taking high dose opioids (> 90 MME/day)*
Patient taking > 2 short-acting opioids simultaneously
Patient taking opioids and benzodiazepines simultaneously
Patient presented to pharmacy with a prescription for an extended-release opioid with no recent history of opioid use following CSRS review
Patient identified with Chronic Pain (defined by 1 or more opioid fills in a consecutive 4-mo period)
Screening and Assessment
Patient Screened for OD risks utilizing CSRS review (WORKFLOW)
Patient Screened for OD risks using utilizing Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression Tool (RIOSORD) or NC Standing order for naloxone
Patient Screened for risk of developing Opioid Use Disorder using the Opioid Risk Tool (ORT)
Pain Assessment completed (4 A's: Analgesia, Adverse Events, Activities of Daily Living (Pain Interference Scale), Aberrant Behaviors)
Actions (Care Plan)
Recommendation made to provider to switch opioid to alternative agent
Recommendation made to provider to Taper Opioid with intent to discontinue
Recommendation made to provider to Taper Benzodiazepine with intent to discontinue
Recommendation made to provider to reduce dose of opioid to improve safety
Recommendation made to provider to reduce dose of Benzodiazepine to improve safety
Recommendation made to patient to consider Pain Agreement (+ Aberrant Behavior Assessment)
Recommendation made to patient to consider naloxone for rescue emergency
Notification sent to provider of positive ORT Screen
Outcomes
Opioid switched to non-opioid alternative agent
Opioid Discontinued
Benzodiazepine Discontinued
Opioid Dose Reduced
Benzodiazepine Dose Reduced
Pain agreement implemented (+ aberrant behavior assessment)
Patient provided Naloxone and Opioid Emergency Action Plan
Pain Assessment follow-up scheduled at regular intervals

CSRS is Controlled Substance Reporting System; another term is PDMP, or Prescription Drug Monitoring Program

**** These examples are based on current CDC guidelines. Please use the most current guidelines when designing and providing your service.***

Step Three: Awareness of Governing Policy and Billing Opportunities

Policies and Regulations Associated with the Management of Pain

Understanding policy and regulatory requirements associated with your pharmacy service is a crucial step in providing safe and effective care to your patients. Policy and regulations will directly affect the what and how of your operation. Below is one example as to how to approach your exploration into policy and regulation accompanied by specific examples. Refer to the need's assessment worksheet in Step 1 for additional resources.

When writing your policies, be sure to incorporate the latest national and state rules and guidelines. North Carolina State Medical Board summary of The Strengthen Opioid Misuse Prevention (STOP) Act of 2017:

- North Carolina Board of Pharmacy Controlled Substance Rules and Regulations Pocket card: https://www.ncmedboard.org/images/uploads/article_images/The_STOP_Act_summary-OnLetterhead.pdf
- North Carolina Board of Pharmacy Controlled Substance Rules and Regulations Pocket card:  CSpocketcardRev1117.pdf

Other sources of guidance can be the Centers for Disease Control, the US Food and Drug Administration, the Federal Controlled Substances Act, the Federation of State Medical Boards, and national pharmacy organizations. The American Society of Health-System Pharmacists (ASHP) Opioid Task Force guidelines are an example of national organization guidance. Keep in mind guidelines and standards do change over time, so be sure to always use the most current version.

Billing Considerations for a Chronic Pain Pharmacy Service

See the Billing section of the Toolkit for Establishing Clinical Pharmacy Services (link to section).

- Consider obtaining your Clinical Pharmacist Practitioner (CPP) credential if you have a significant Medicaid population. CPP's may be eligible for reimbursement through North Carolina (NC) Medicaid.
- Some community pharmacists see the best billing opportunities right now from within the prescriber's office. This allows incident-to billing. You could identify a time that an exam room is available (perhaps a particular half-day) and see patients those days while the prescriber is in the building. For especially complex patients this would give the opportunity to see those patients together at a higher rate (then share those funds).
- Time-based pharmacy billing codes are gaining recognition by payers (99605, 99606, 99607). Stay in communication with your state association and colleagues in community pharmacy to share successes and techniques with reimbursement.
- Consider a risk-sharing, value-based contract if your service could save money for the local health-system, community agency, payer, or other party. This would allow your service to save cost then divide the savings. This can include cost savings associated with fewer overdose admissions, lost productivity of employees receiving excessive doses of pain medications, and other types of positive outcomes.

Toolkit Tip: Fully participate in documentation of individual patient care plan to support appropriate billing and reimbursement of services. Correct billing is critical to sustaining your service and sustaining reimbursement

Quality Measures

One of the ways your community pharmacy pain service can benefit prescribers and even possibly the local health system is the impact on quality measures.

Learn More

When thinking of quality measures your chronic pain service could impact, remember to include measures that both directly pertain to pain management activities as well as general patient management activities. For example, think of how your service may impact Merit-based Incentive Payment System (MIPS) measures from each of the four categories (quality, cost, improvement activities and promoting interoperability). Tying in patient satisfaction through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey and 30-day readmissions. For a list of agencies and measure sets, look under the quality measures section in the service development section of the toolkit. Also, refer to the needs assessment worksheet in Step 1 for additional chronic pain specific measures.

Collecting Guidance from Other Organizations to Support the Management of Chronic Pain

Multiple organizations have published guidance around chronic pain management. The list below identifies many of these organizations though it is not a comprehensive list.

CDC Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/drugoverdose/prescribing/guideline.html, https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html

Department of Health and Human Services: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

American Academy of Family Physicians: https://www.aafp.org/patient-care/public-health/pain-opioids/cpm-toolkit.html

Management of Chronic Pain and Opioid Misuse: A Position Paper from the American Academy of Family Physicians (AAFP): https://www.aafp.org/afp/2017/0401/p458.html

American Academy of Pain Medicine: https://painmed.org/clinician-resources/clinical-guidelines

Refer to the needs assessment in Step 1 for additional guidance

3. McPherson L. Pharmacist-driven, patient-centered interventions in pain management. Pharmacy Today. 2016;22(9):43.

Examples of Already Existing Chronic Pain Pharmacy Services

Some ideas from Lynn McPherson:

"Community pharmacists can help by asking patients with chronic pain to describe their pain. If the patient describes the pain using terms that are consistent with neuropathic pain, such as burning, stabbing, shooting, and/or pins-and-needles, the patient may be a good candidate for an adjuvant analgesic. Community pharmacists can keep an eye out for patients with chronic pain who are only receiving opioid therapy; often opioids offer little or no relief for neuropathic pain, and nonopioids, such as acetaminophen or a nonsteroidal agent, are ineffective. "Feeling the burn: Updated recommendations for treating neuropathic pain" is a synopsis of the International Association for the Study of Pain (IASP) Neuropathic Pain Special Interest Group review of pharmacologic treatments for neuropathic pain. This synopsis should be required reading for all community pharmacists."[3]

https://www.pharmacytoday.org/action/showPdf?pii=S1042-0991%2816%2930808-8

Tools/Resources:

- This article provides some guidance specifically oriented to community pharmacy practice.
  Firm A, Bertrand C. The Community Pharmacist's Guide to Pain Management. Pharmacy Today. 2015;21(11):41-52.
- An Australian study demonstrating, 'interventions involving pharmacists in medication management were generally effective in improving medicine use, adherence, adverse event detection and harm minimization producing positive health outcomes.'
  Mishriky J, Stupans L, Chan V. Expanding the role of Australian pharmacists in community pharmacies in chronic pain management – a narrative review. Pharmacy Practice. 2019;17(1):1410-1416.
- Community pharmacists see patients at a critical time during transitions of care to home. Here are some ways to focus on those patients.
  Sourial M, Lese MD. The Pharmacist's Role in Pain Management During Transitions of Care. US Pharm. 2017;42(8):HS-17–HS-28.

Step Four: Designing the Chronic Pain Pharmacy Service

Identifying Your Target Patient Population

Your target patient population was identified through your market analysis in Step 1.

Creating a written workflow is a necessary next step to automate tasks and improve the efficiency of your service. Mapping out processes provides:

1. Greater insight into the "Big-Picture" of your service model.
2. Opportunity to identify and eliminate unnecessary or redundant tasks.
3. Improvement in staff accountability and a reduction in the need for micromanagement. Everyone knows their assigned tasks and what needs to be done.
4. Improvement in communication.

5. Improvement in customer experience.
6. Improvement in service quality by allowing task assignment to be driven by an individual skill set rather than availability.

Patient Care Interventions

Establishing Service Provisions: As you realize your mission, your goal to improve the lives of your patients with Chronic Pain and the measures you've established to gauge your success, it is important to understand the activities, tools and resources you will need to support your service.

Include appropriate

- **Screening tools** such as,
  - The NC Controlled Substance Reporting System https://www.ncdhhs.gov/divisions/mhddsas/ncdcu/csrs to quick reference MME high doses, identification of high-risk concomitant therapies (i.e. Benzodiazepines), multiple prescribers, and pharmacies that may represent aberrant behaviors consistent with developing opioid use disorder.
  - Opioid Risk Tool (ORT) to determine a patient's predisposition to developing opioid use disorder.
  - Risk index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD) to determine a patient's risk for overdose (OD) and respiratory depression. RIOSORD

- **Talking Points** for staff to help facilitate and normalize introduction of your service and screening processes, like:

Would you mind answering a few questions we ask all our patients…?	"These questions help us provide you with the best possible care…"	Always remember to ask permission: **"WOULD THAT BE OKAY?**
Would you mind answering a few health-related questions we ask all our patients…?	"These questions help us ensure that we are keeping you safe…"	
Would you mind answering a few life-style related questions we ask all our patients…?	"These questions help us ensure your medications are safe, effective, and free from potential drug interactions…"	

- **Pain Assessment tool(s)** help to monitor longitudinal response and effectiveness to of opioid therapy and when risks outweigh the benefit of continued opioid use. At a minimum, pain assessment tools should address,
  - The type, description and perception of the patient's pain.
  - How their pain interferes with their level of functioning (i.e activities of daily living (AOLs).

- Adverse events associated with opioid use to determine when and if additional med management is needed or more importantly when the side effects pose added risks to the patient with continued opioid use.
- A list of aberrant behaviors clinicians may observe in patients that are often associated with opioid use disorder.

The PADT – *Pain Assessment Documentation Tool is* an excellent resource to capture this information. See also the sample PADT adapted for community pharmacy use.


PADT Progress Note


Opioid Use Progress Note


Progress Note plate Pain Interfere


Progress Note plate Aberra nt

- **Naloxone resources** such as,
  - The North Carolina State Health Director's Standing Order for Naloxone http://www.naloxonesaves.org/files/2019/01/2018-Standing-Order.pdf – to better under stand provisions related to pharmacists dispensing naloxone in our state.
  - Talking points for staff to initiate and have meaningful conversations with patients regarding their need for naloxone. https://www.pharmacist.com/sites/default/files/audience/LetsTalkAboutNaloxone.pdf
  - Opioid Emergency Action Plan – to educate and prepare patients, family and or friends in the event of an opioid emergency (accidental overdose). Including information that speaks to:


Opioid Emergency Action Plan Patient Han

    - Signs of an opioid emergency
    - Instructions for preparing and using naloxone
    - Provisions for where naloxone is kept

- Adjuvant Pain Management Resources in your community made available to patients in list format, such as,
  - Massage therapy
  - Acupuncture
  - Exercise classes like Tai Chi, yoga, water therapy
  - Psychologists who specialize in pain management

Refer to the Tools and Resources section of the toolkit for examples of each of these strategies

- Pharmacy Care plans shared with partner prescribers that promote risk reduction strategies and improve safety such as
  - Alternatives to opioids
  - Tapering or discontinuing opioids and or benzodiazepines
  - Dispensing Naloxone
  - Utilization of Pain agreements

Refer to the Tools and Resources section of the toolkit for examples of care plans.

- **Pain Management Agreements** to promote safety of patients who specifically through observation, screening or assessment show signs of aberrant behavior.

Refer to the Tools and Resources section of the toolkit for examples of pain management agreements.

- **Provider Correspondences** to effectively communicate patient findings, recommendations, services provided and care plan coordination. Resources supporting these activities can be found in the Tools and Resources section of the toolkit.
- **Patient Education Materials** to guide your education and provide information to reinforce what you share with your patient.

At the link you will find many patient education resources. Note, several are in English and Spanish. The Providence Health and Services Patient and Families Toolkit also has a wealth of patient education resources materials geared to alternative methods for improving pain such as, https://oregon.providence.org/our-services/p/providence-persistent-pain/persistent-pain-toolkit/patient-and-families-toolkit/

- Understanding Pain
- Sleep
- Mood
- Nutrition
- Physical Activity
- Tapering Medications

Documenting and Communicating Your Ambulatory Chronic Pain Activities

Here are several documentation and communication tools to consider. All can be found in the Tools and Resources section of the Toolkit.

- Physician Service Communication Form
- Progress Note Template Care Plan
- RESPOND Checklist
- Pain Assessment and Documentation Tool Progress Tool (PADT)
- Progress Note Template Aberrant Behavior
- Progress Note Template Pain Interference Scale
- Opioid Use Progress Note

Documenting your Community Chronic Pain Activities Process

Building out a process workflow is helpful in understanding how the overall service will look. Process workflows highlight what each person is doing and when and in what order. Below are example workflows that incorporates staff and/or trainees.

Community Chronic Pain Pharmacy Case Workflow:

Chronic Pain
Patient Flow Example

Case Demonstration Employing Chronic Pain Services in **Specialty Settings**

TABLE OF CONTENTS

DISCLAIMER

This implementation toolkit was developed based on a collaboration between NCAP and Pfizer (with financial support provided by Pfizer Inc). Please see full disclaimer for this toolkit on Page 2.

Case Demonstration Employing Chronic Pain Services in Specialty Settings

The following is a guide as to how one may use the toolkit to include chronic pain services within your specialty care pharmacy role. These activities are not limited to the specialty pharmacy space and may be employed in a wide variety of pharmacy practices. The example is not all inclusive and it is recommended to consider specifics within your practice setting when developing your service.

Purpose:

Facilitate patient access, adherence and understanding of the prescribed chronic pain treatment regimens and services. These resources for prior authorization, high-risk patient medication access, and adherence can be applicable in any setting.

STAGE 1: PLAN

Planning Your New Medication Access and Adherence Focused Chronic Pain Pharmacy Service

Step One: Assessing the Market for a Medication Access and Adherence Focused Chronic Pain Pharmacy Service

Unlike other pharmacy services that might need additional assessment to determine if a service is warranted based on need and patient volume, a service centered around medication access and adherence is inherent to pharmacy practice. Many patients frequent the pharmacy to pick up medications, some that require a prior authorization (PA) and Risk Evaluation and Mitigation Strategy (REMs) process and have need for patient assistance programs, assessment for risk of non-adherence and education. Assessment tools to determine which patients may benefit from which specific service.

It is good to be mindful of any quality performance measures (i.e., Medicare Access and CHIP Reauthorization Act / Merit-Based Incentive Payment System (MACRA/MIPS), Centers for Medicare and Medicaid Services (CMS) Star Ratings, Healthcare Effectiveness Data and Information Set (HEDIS), etc.) that payors, health systems, medical groups and other practice settings are working to enhance as pharmacists can play a significant role in achieving those measures.

Examples of a few pharmacy-based measures in place or being proposed are:

1) Primary Medication Nonadherence (PMN): The percentage of prescriptions for chronic medications e-prescribed by a prescriber and not obtained by the patient in the following 30 days. A lower rate is better.
2) Opioid Measures (e.g., medication-assisted therapy (MAT), substance use disorder (SUD), naloxone.
3) Concurrent Use of Opioids and Benzodiazepines.
4) Specialty Pharmacy Turnaround Time: The average number of days between a specialty pharmacy receiving a new prescription for a specialty medication and the prescription being ready for pick-up or scheduled for delivery. A lower average turnaround time indicates better performance.

See the Toolkit for Establishing Clinical Pharmacy Services: *The Feasibility, Implementation, Performance and Sustainability Assessments* and the **Case Demonstration Employing Chronic Pain Services in Ambulatory Settings** to obtain general information on additional strategies for assessing the market for a chronic pain service and working through a strengths, weaknesses, opportunities, and threats (SWOT) analysis.

Step Two: Defining your Medication Access and Adherence Focused Chronic Pain Pharmacy Service

Following guidance from the toolkit, below are sample mission and purpose statements that could be used for this service.

Mission Statement: We aim to improve patient access to prescribed chronic pain treatment regimen, education, safety, and monitoring for patients with chronic pain.

Purpose Statement: New regimens with high cost and dispensing requirements may make access for patients challenging and place chronic pain patients at risk for suboptimal care. We will improve chronic pain management by optimizing access, adherence and education to the prescribed chronic pain treatment regimen.

Building a strong **SMART goal** addresses five major areas. Below is an example of a SMART goal that would work for a chronic pain pharmacy service.

SMART Goal

Specific: We will initiate and facilitate the prior authorization (PA) and dispensing requirements [i.e. Risk Evaluation and Mitigation Strategies (REMS)] for the chronic pain medications, assess patient affordability and attempt to provide patient assistance and enhance the patients understanding of and adherence to the chronic pain treatment regimen.

Measurable: We will measure the PA's processed, patients receiving patient financial assistance (i.e. co-pay cards, vouchers, free or discounted medications via manufacturer or grant assistance), adherence (i.e. fill/refill history or direct pharmacist interaction) and patient education. Metrics include: number of PA processed/approved, number of patients receiving patient assistance through any method, number of refills and number of pharmacist education interactions documented with chronic pain patients.

A **Achievable**: Achievable through the development of a specific process to ensure the patient can access and maintain the prescribed chronic pain treatment for the appropriate duration for the pain condition. A case for change is made by assessing the baseline PA and dispensing rates, conducting assessments of adherence and patient assistance needs for my pain population and achieving the chosen outcomes through care team collaboration (i.e. other pharmacy personnel, provider team, payer community, manufacturers and private foundations).

R **Relevant**: Improving access and adherence to appropriate treatment regimens in the chronic pain population is a key focus of national health care efforts in our country and my practice.

T **Time-Bound:** Enrolling all chronic pain patients with Rx requiring assistance described above into my chronic pain service during a given time period, using good communication strategies with my chronic pain patients and the provider, payer, manufacturer, private foundation network giving care to these patients by X date and meet outcomes metric goals by X date.

Final SMART Goal:

Over the next XXX months, we will enhance patient access, maintenance and understanding of prescribed treatment regimens by facilitating prior authorizations and REMS education dispensing requirements, by identifying, requesting and processing patient co-pay cards, vouchers, free or discounted medications via manufacturer or grant assistance and by providing education on the benefits of the treatment and the importance of sustaining therapy, while measuring the impact of these services with defined metrics to be achieved by XXX date.

Toolkit Tip: This SMART Goal gives the flexibility for the pharmacy to use this as a pilot over 3 – 6 months and then use that data to strengthen the larger request of target commitment for 6 – 12 months or longer.

Defined Metrics:

% of patients requiring PA assistance (approval/ denial/appeal)

% of patients requiring financial assistance (co-pay cards, vouchers, free or discounted medications via manufacturer or grant assistance)

% of pharmacy team patient education interactions documented

% of X refills based on chronic pain patient need (sustained refill history)

SMART Goal Worksheet Attached (for Medication Access and Adherence Focused Chronic Pain Pharmacy Service):

SMART Goal Worksheet_Medicatio

Step Three: Policy and Billing for your Medication Access and Adherence Focused Chronic Pain Pharmacy Service

Although pharmacists are yet to universally establish themselves as health care providers able to bill payers, they have an opportunity to work as auxiliary personnel under an eligible provider who may bill for a pharmacist's services. Reimbursement for pharmacist services can be problematic. In most cases it is based on the scope of practice associated with a provider who is eligible to submit claims.

Visits with pharmacists allow more time and focused attention in longitudinal management of the patient's needs with the added benefit of freeing up physicians to spend more time diagnosing new problems and achieving better control rates, which results in overall higher reimbursement.
Some of the most significant strains on health care providers - managing multiple high-risk patients, physician burnout, and insufficient capacity have been significantly improved by physician pharmacist collaborations.

- Pharmacist services can currently be billed in facility fees with different requirements that would need to be met (depending on the facility and codes provided). These levels of service will have specific specifications.
- Some pharmacists see the best billing opportunities right now from within the prescriber's office. This allows incident-to billing. To bill a service incident to the physician, the pharmacist must be under direct supervision of the supervising physician. The physician must also be physically available (i.e. in the practice or office suite) to treat the patient at the time of the service. Carrying out incident to billing might include identifying a time that an exam room is available (perhaps a particular half-day) and see patients those days while the prescriber is in the building. For especially complex patients this would give the opportunity to see those patients together at a higher reimbursement rate (then share those funds).
- Time-based pharmacy billing codes are gaining recognition by payers (99605, 99606, 99607). Stay in communication with your state association and colleagues in community pharmacy to share successes and techniques with reimbursement.
- Consider a risk-sharing, value-based contract if your service could save money for the local health-system, community agency, payer, or other parties. This would allow your service to save costs then divide the savings. This can include cost savings associated with fewer overdose admissions, lost productivity of employees receiving excessive doses of pain medications and other types of positive outcomes.

Some general service examples that pharmacists can provide regarding the chronic pain visit with a pharmacist are included below. Refer to the services described in this Medication Access and Adherence Focused Chronic Pain Pharmacy Service Document when considering areas to explore for billing.

- Pain agreements reviewed and signed annually with the patient
- Using diagnosis code for High Risk Medication Use
- Using proper Pain Assessment tools for recommendations
- Maximum duration of medications prescribed during visit is not more than 90 days
- Urine Drug Screens (UDS) performed (at a minimum) bi-annually

Step Four: Establish the Service Provision / Activities for your Medication Access and Adherence Focused Chronic Pain Pharmacy Service

Patient Identification / Screening:

Patient identification occurs as part of the medication process reporting through medication denial and prior authorization (PA) criteria appearing in pharmacy patient profile and conducting baseline assessments of non-adherence risk, knowledge of treatment and financial means.

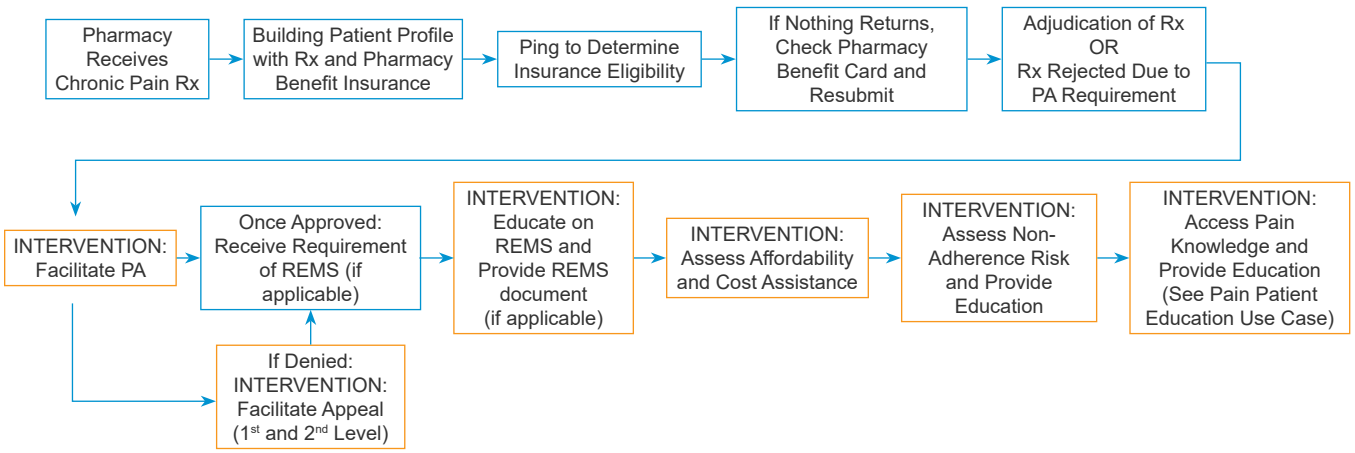
Customer Identification:

Ideas include: Identify high risk medications that require PA and REMS and the prescribers that most frequently prescribe these targeted medications.

Identify At-Risk Patients:

- Patients receiving high risk medications requiring a PA
- Patients with affordability concerns that fail to pick up medications regularly
- Patients with previous utilization of manufacturer or grant programs
- Patients with decreased health literacy

Patient Care Interventions / Activities:



Intervention 1: Identify PA need and work with practice to complete PA criteria using resources (i.e.CoverMyMed, CareEverywhere (Epic®), Fax, or other available software).

- **Resources:** Identify criteria through insurance website and complete PA documentation. Below are a few sites to aid in this process.
  - CoverMyMeds Login: https://account.covermymeds.com/
  - NC Medicaid (NC Tracks): https://www.nctracks.nc.gov/
  - Prior Authorization Process Documentation Tool:

Prior Authorization Process Documentation Tool

- **Owner:** Pharmacist or clinical support staff (technician or medical assistant)

Intervention 2: Facilitate appeal on denied PAs through various levels until final (Approval or Denial) processes have been satisfied.

- **Level 1 (initial denial):** Address denial/disqualifying reasons (i.e. unmet disease criteria, non-trial of preferred agents) by gathering literature regarding need related to the disease state, provide supplemental data (patient need, prescriber desire) and re-submit documentation.
- **Level 2 (specialist review or peer-to-peer):** Conduct additional literature search (manuscript, presentations, etc.) to provide to insurer OR have pharmacist or prescriber call the insurer directly to discuss literature review and patient need.
- **Level 3:** Response received (approval or denial). If denied, reapply in 3-6 months later once patient meets criteria (continue monitoring patient).
- **Resources**: Use appropriate source and reliable search criteria for specific disease state. (i.e. PubMed, Google Scholar). Review guidelines, national meeting presentations, review patient history, etc.
  - Guideline Central: https://www.guidelinecentral.com/alternatives-to-ahrqs-national-guidelines-clearinghouse/
  - Google Scholar: https://scholar.google.com/
  - PubMed: https://www.ncbi.nlm.nih.gov/pubmed/
  - Documentation Search Example:
    - **Scenario**: Medication X is not covered by plan and the pharmacy receives the denial from the insurance.
      - Initial denial is reviewed for information that needs to be clarified or added for resubmission after original denial.
        - Diagnosis code
        - Proper medication dosage clarification
      - Response to insurance re-sent and documented
- **Level 1 denial** – Address denial and disqualifying reasons.
  - Clarify contraindications to the use of **insured agents** as it relates to the patient's condition.

- Clarify need clarifying why patient requires this specific medication.
- Add any additional circumstances (patient story, clinical descriptions, etc.) to appeal letter.
- Include evidential support and references to appeal letter to strengthen argument for use.

- **Level 2 denial** – Addressing further issues / scheduling a peer-to-peer review
  - Scheduling telephone consultation with prescriber and insurance medical officer for final insurance review

- **Final determination:**
  - Desired medication is approved and allowed to be dispensed by the pharmacy to patient
  - Desired medication is denied by insurance
    - Prescriber will need to use formulary agent for 3-6 months for patient to try and fail therapy.
    - After a trial period, if the formulary medication is not achieving the desired results, the presciber may choose to re-prescribe medication and start the prior-authorization process again.

- **Owner:** Pharmacist and clinical support staff (technician or medical assistant) with prescriber

Intervention 3: Identify REMS requirements (if applicable) and ownership (Pharmacy or Prescriber) and provide education (verbal and written) to patient

- Identify ownership through electronically adjudicated claim. If prescriber or pharmacy is not active for that particular REMS program, the registration requirements need to be met through REMS program (based on FDA / manufacturer requirements) before proceeding.

- **Resources:**
  - FDA Website for specific medication guide REMS documents to provide and review with patients: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm
  - Roles for REMS of Pharmacist/Prescribers/Caregivers: https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems
  - To stay informed and receive REMS email alerts: https://updates.fda.gov/subscriptionmanagement
  - Frequently Asked Questions (FAQ) about REMS: https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems
  - DailyMed – another site with approved prescribing information: https://dailymed.nlm.nih.gov/dailymed/
  - If additional questions arise, you can contact FDA at (855) 543-3784 or (301) 796-3400, or by email at druginfo@fda.hhs.gov

- **Owner:** Pharmacist

Intervention 4: Assess patient affordability risk and need for patient assistance. Identify financial assistance program in support of chronic patient and aid with enrollment

- Search by medication brand name or manufacturer name and locate link to co-pay cards or company assistance programs online or call medical information for the manufacturer to identify a representative to help locate and provide sample via the patient's clinic.
- **Resources**:
  - Medicine Assistance Tool (MAT): is a search engine linking to many of the patient assistance resources that the biopharmaceutical industry offers. Allows for entering all medications needed in one list and an online questionnaire directing to available personalized assistance resources https://medicineassistancetool.org/
  - RxAssist: offers a comprehensive database of patient assistance programs to search medication name or manufacturer name and link directly to the medication assistance program website, as well as practical tools, news, and articles https://www.rxassist.org/
  - NeedyMeds: List of about 600 applications with dates next to each listing that reflect last update for prescription assistance, additional links for support via coupons, copays, by disease, government programs, transportation and multiple support resources https://www.needymeds.org/program-apps
    - BeMedWise: a program of NeedyMeds with multiple support materials to improve health outcomes through the adoption of responsible medication practices and promote the safe use, storage and disposal of medicines with a network of national and international partners https://bemedwise.org/
  - Patient Advocate Foundation: A Co-Pay Relief Program providing direct financial assistance to insured patients who meet certain qualifications https://www.patientadvocate.org/connect-with-services/copay-relief/
- **Owner:** Patient, pharmacist and/or clinical support staff (technician or medical assistant)

Intervention 5: Assess risk of non-adherence, refill/fill history and provide education

- Definition of Medication Adherence: The extent to which patients follow agreed-upon provider recommendations about day-to-day treatment with respect to the timing, dosage, and frequency of their prescribed medications.[1,2]
  - World Health Organization. Adherence to Long-Term Therapies: Evidence For Action. Geneva, Switzerland: World Health Organization, 2003.
  - Bosworth HB. Enhancing Medication Adherence: The Public Health Dilemma. Philadelphia, PA: Spring Healthcare, 2012.

- **Resources:** Many resources exist and here are a few to get started
  - Assessment: Medication Adherence Questionnaire – Drug Adherence Work-up (DRAW©):

    DRAW.pdf

    - Supporting Article: Development of the Drug Adherence Work-up (DRAW) tool. Doucette WR, et al. *J Am Pharm Assoc* (2003). 2012;52(6):e199-204. doi: 0.1331/JAPhA.2012.12001 https://www-sciencedirect-com.eu1.proxy.openathens.net/science/article/abs/pii/S1544319115305859?via%3Dihub
  - Assessment: Adherence to Refills and Medications Scale (ARMS©):

    Adherence Assessment_ARMS12

    - Supporting Articles:
      - For the ARMS-12: Kripalani S, Risser J, Gatti ME, Jacobson TA. Development and evaluation of the Adherence to Refills and Medications Scale (ARMS) among low-literacy patients with chronic disease. *Value in Health* 2009;12(1):118-123. PMCID: PMC 3171175. https://www-sciencedirect-com.eu1.proxy.openathens.net/science/article/pii/S1098301510606821?via%3Dihub
      - For the ARMS-7: Kripalani S, Goggins K, Nwosu S, Schildcrout J, Mixon AS McNaughton CD, McDougald Scott AM, Wallston KA, for the Vanderbilt Inpatient Cohort Study. Medication nonadherence before hospitalization for acute cardiac events. *J Health Commun* 2015;20(sup 2):34-42. PMCID: PMC4705844. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4705844/pdf/nihms747008.pdf
  - Assessment: Medication Non-Adherence Risk Assessment – Adult Medication: http://adultmeducation.com/downloads/Nonadherence_Risk_TOOL.pdf
  - Patient Resources – Practical tips for improving adherence: https://www.patientresource.com/medication_adherence_practical_tips.aspx
  - Education (Pharmacist) – CDC grand rounds on Adherence: https://www.cdc.gov/grand-rounds/pp/2017/20170221-presentation-medication-adherence-H.pdf
- Create an adherence contract with your patient
- Evaluate dispensing histories from Electronic Health Records (EHR), manual review of patient dispensing records or a controlled substance monitoring system such as the (CSRS), the Prescription Drug Monitoring Program (PDMP) or PMPAware.
- Consider telephone outreach calls
- **Owner:** Pharmacist or clinical support staff (technician or medical assistant)

Intervention 6: Provide Patient Chronic Pain Education – See the Case Demonstration Employing Chronic Pain Education to Healthcare Team Members and Patients:

- Patient Care Intervention – Documentation and Communication Strategies:
  - Patient Care Intervention – Activities Documentation Template:

Patient Care
Intervention Checkli

  - Medication Access – Prior Authorization and Appeal Documentation and Communication Template:

PA Documentation
& Communication Fo

  - Others:
    - For each patient and medication appeal, create a place (paper or electronic) to store the appeal process documents. These can include support articles, literature, insurance denial/approval letters, and other documents. Having this repository will allow easier tracking when it comes to 1st and 2nd level denials.
    - Using CoverMyMeds will store the other requests electronically for the pharmacy.

See the **Toolkit for Establishing Clinical Pharmacy Services: The Feasibility, Implementation, Performance and Sustainability Assessments** and the **Case Demonstration Employing Chronic Pain Services in Ambulatory Settings:** to obtain general information on additional strategies for **"Building the Business Plan"**, **"Getting Leadership Buy-In",** and the final stages of **"Do, Study, Act".**

Chronic Pain

Education for Healthcare Team Members and Patients

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Chronic Pain Education for Healthcare Team Members and Patients

DISCLAIMER

This implementation toolkit was developed based on a collaboration between NCAP and Pfizer (with financial support provided by Pfizer Inc). Please see full disclaimer for this toolkit on Page 2.

You have decided to provide services specifically to your patients in pain. As you know, pain is a complex and highly subjective. As you work through this section, you will find an overview of pain, pain assessments, communication guides, and several tools to aid you in your service.

Purpose:

Educating yourself and others on Chronic Pain. In this section are a wide variety of tools, guidelines, communication documents and much more. There are tools for personal education, patient education, and provider education.

Chronic Pain Education for Healthcare Team Members and Patients

Undergoing A Comprehensive Pain Assessment

Understanding Pain

The first step in pain management is understanding the pain your patient is experiencing. Use the four questions below to guide you when assessing pain.

1. What is/are the type(s) of pain your patient is experiencing?

- There are many types of pain. The general categories are –
  - Acute Pain
    - Acute mild pain (e.g. sprained ankle, scraped knee)
    - Acute severe pain (e.g. post-surgical or major motor vehicle accident)
  - Chronic Pain
    - Visceral pain that is internal and associated with the thoracic, pelvic, or abdominal organs
    - Neuropathic pain from real or aberrant nerve signals
    - Inflammatory pain (e.g. rheumatoid arthritis, bursitis)
    - Functional pain that has no obvious origin

2. What is the pathophysiology of the pain?

- We know that pain is an unpleasant sensation driven by neurons
  - Neuron signaling occurs when there is an unpleasant signal at a nociceptor in the bone, tissue, organs, vessels, viscera, or muscles
  - The message is transmitted when substances are released upon nociceptor stimulation that produce action potentials sending signals through the spinal cord to the brain
  - Pain control involves inhibition of these nociceptive signals

3. What is the severity of the pain?

- Your patient is your best source to describe severity; there are several tools (link to pain assessment tools below) available to help measure severity.
- Assess pain severity at rest and with activity
- Assess TOLERABLE pain for the patient so you know what your therapeutic goal is
  - Tolerable pain allows daily function despite the pain
  - Your patient's level of tolerable pain is your therapeutic goal

4. What details are associated with the pain? One way to assess this is by using the pain assessment pneumonic OPQRST:

- Onset – when and how did it start
- Provocation or Palliation – what makes it better or worse
- Quality of the pain – get a detailed description of the pain
- Region and radiation – where is it and where does it travel
- Severity – use the 0-10 or faces type of scale
- Time – from the time it started how has it changed

Resources for additional learning:

National Pain Strategy – National Institutes of Health and Department of Health and Human Services (HHS)

The Interagency Pain Research Coordinating Committee's (IPRCC) response to the 2011 IOM pain report (see below): https://www.hsdl.org/?view&did=792119

Relieving Pain in America – A Blueprint for Transforming Prevention, Care, Education, and Research

In 2010, the National Institutes of Health (NIH) contracted with the Institute of Medicine (IOM) to conduct a study and report out recommendations "to increase the recognition of pain as a significant public health problem in the United States." This report now known as the IOM report: *Relieving Pain in America – A Blueprint for Transforming Prevention, Care, Education, and Research The Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education: Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington (DC): National Academies Press (US); 2011.* Available from: https://www.ncbi.nlm.nih.gov/books/NBK91497/

Assessment of Chronic Pain: Domains, Methods, and Mechanisms

This article covers pain assessments and methods used to identify pathophysiological mechanisms contributing to pain: *Fillingim RB, Loeser JD, Baron R, Edwards RR. Assessment of Chronic Pain: Domains, Methods, and Mechanisms. J Pain. 2016;17(9 Suppl):T10–T20. doi:10.1016/j.jpain.2015.08.010*

American Society of Regional Anesthesia and Pain Medicine

This link will take you to the ASRA website on chronic pain education resources, divided into different types of pain, for the healthcare provider:

https://www.asra.com/pain-resource/article/144/chronic-pain-resources

American Academy of Family Physicians Chronic Pain Management Toolkit

Contains information on pain and risk assessments, tools that help identify gaps in practice flow, evaluation and treatment of chronic pain patients, and the necessary conversations surrounding pain, treatment goals, and risk identification and mitigation along with many other important aspects on the care of the chronic pain patient: https://www.aafp.org/patient-care/public-health/pain-opioids/cpm-toolkit.html. Located on the AAFP website in the Pain Management and Opioid Misuse section: https://www.aafp.org/patient-care/public-health/pain-opioids.html

New England Journal of Medicine (NEJM)

List of pain publications in chronological order that are featured in the NEJM: https://www.nejm.org/medical-research/pain

2017 VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain

Department of Veterans Affairs & Department of Defense clinical practice guidelines for chronic pain based on evidence through December 2016: https://www.healthquality.va.gov/guidelines/Pain/cot/

SAMHSA-HRSA Center for Integrated Health Solutions

This website provides information around pain management for the healthcare provider. Topics include: screening tools, shared decision making, motivational interviewing, SBIRT, Pain Management and several other related topics: https://www.samhsa.gov/integrated-health-solutions

North Carolina Medical Board

This website provides links to both the summary and the full text of the NC STOP Act 2017: https://www.ncmedboard.org/resources-information/professional-resources/publications/forum-newsletter/notice/new-summary-of-ncs-new-opioids-law-the-stop-act

Tools/Resources:

(Items below are located in the Tools and Resources section of the Toolkit)

- **Pain Assessment Tools**
  - o Brief Pain Inventory–Pain Interference Scale
  - o Graded Pain and Function Scale
  - o OPQRST
  - o Pain Assessment Questions and Scales
  - o Patient Assessment and Documentation Tool
  - o Pain Assessment Documentation Tool
  - o Pain Chart
  - o PEG-3 – Pain Screening Tool
  - o Ongoing Pain Assessment Form

- **Adjuvant Assessment Tools**
  - o PHQ-2: https://cde.drugabuse.gov/instrument/fc216f70-be8e-ac44-e040-bb89ad433387
  - o PHQ-9: https://www.mdcalc.com/phq-9-patient-health-questionnaire-9
  - o GAD-7: https://adaa.org/sites/default/files/GAD-7_Anxiety-updated_0.pdf

- The American Chronic Pain Association website contains many helpful tools that can be used with patients to help assess their chronic pain: https://www.theacpa.org/pain-management-tools/communication-tools/

Understanding your Patient

This section highlights the next part of pain assessment and that is keying into your patient's beliefs and goals surrounding their chronic pain treatment. Here are some factors to collect to ascertain the patient's health perspective:

Health Behavior Change

- Patient Health Belief Model (HBM) – A change model that has been used to explain and predict health-related behaviors. According to the Boston University School of Public Health, a patient's actions are influenced by 6 perceived ideas related to the health behavior in question. These include the perceived susceptibility, severity, benefits, barriers, stimulus for change, and ability to follow through with that change.
  - For more information on the HBM, visit the Boston University School of Public Health's webpage: http://sphweb.bumc.bu.edu/otlt/MPH-Modules/SB/BehavioralChangeTheories/BehavioralChangeTheories2.html

- Social Determinants of Health (SDoH) are the conditions in which people are born, grow, live, work and age[1]. These determinants can greatly influence a person's ability to change behaviors and should be considered to better understand your patient's access to basic resources.

Motivation – Use motivational interviewing skills to identify your patient's motivation in addressing pain

- Berger B. A sense-making approach to motivational interviewing. Pharmacy Today. 2016;23(4):46-47.

- SAMHSA – Motivational interviewing: https://store.samhsa.gov/sites/default/files/d7/priv/tip35_final_508_compliant_-_02252020_0.pdf

Levels of pain tolerance – as mentioned above, to completely alleviate pain might not be possible, therefore setting reasonable goals along with managing expectations is an important conversation to have with the patients.

Level set expectations – how much pain relief is your patient expecting

Psychological impact of the pain – how is the patient's pain leading to or worsening depression, anxiety or insomnia.

Functional impact of the pain – how much is this pain impacting your patient's clarity of thought, decision making, and executive functioning

Tools/Resources:

(Items below are located in the Tools and Resources section of the Toolkit)

Social Determinants of Health

- SDOH Screening-Tool-English-Providers
- SDOH Screening-Tool-Spanish-Providers
- NC DHHS Social Determinant of Health Screening Questions: https://files.nc.gov/ncdhhs/documents/SDOH-Screening-Tool_Paper_FINAL_20180405.pdf
- Social Determinants of Health Screening Questions (Brief) – NC DHHS: https://www.ncdhhs.gov/about/department-initiatives/healthy-opportunities/screening-questions

1. World Health Organization. Social determinants of health. Who.int/social determinants/sdhdefinition/en/. Accessed 12/20/2019

- Six Ways to Talk About Social Determinants of Health – (link SDOH_6 Ways to Talk about Social Determinants of Health)
- Social Determinants of Health 101 for Health Care: https://nam.edu/wp-content/uploads/2017/10/Social-Determinants-of-Health-101.pdf
- Healthy People 2020: https://www.healthypeople.gov/2020/about/foundation-health-measures/Determinants-of-Health
- Healthy People 2030 https://health.gov/healthypeople
- AAFP – The EveryONE Project(TM) Advancing health equity in every community: https://www.aafp.org/dam/AAFP/documents/patient_care/everyone_project/sdoh-guide.pdf

Co-existing Conditions to Consider

Pain, especially chronic pain, rarely occurs without impacting emotional and mental health. Now add sleep disruption, and this can become a vicious cycle that is difficult to break.

Sample Pain Evaluation Process

When assessing chronic pain, consider using the 5 A's to address the five different levels of analgesia. In addition to the pain rating, determine how the pain interferes with daily activities, experience with adverse events, and your own clinician observation of aberrant behaviors. Affect (mood/quality of life) can be assessed with PHQ-2, and if positive, complete the PHQ-9. The GAD-7 can help assess current issues with anxiety since this often coexists with chronic pain. This group of assessments allows you to establish a baseline and justification for treatment, as well as monitor the effectiveness of any treatment regimen. These tools also help the clinician decide whether to pursue risk reducing strategies, tapering, or other adjustments therapy.

Evaluating your Treatment Options

Once you better understand and have evaluated the patient and the impact pain is having on your patient, appropriate pain treatment options can be considered. There are many variables to be factored into a patient-specific treatment regimen.

- Type of pain (acute or chronic, visceral or neuropathic)
- Severity of pain
- Location of pain (topical vs systemic options)
- Pain medication history (previous successful treatments)
- Careful patient selection – see risk evaluation tools
- Nonpharmacologic options
- Tolerance, dependence, withdrawal
- Concomitant disease states
- Age
- Cost
- Treatment guidelines for the particular type of pain
- Risk-benefit ratio of all potential interventions
- Impact of potential adverse consequences
- Risk of nonmedical use
- Use of combination products

Non-Pharmacologic Treatment Options

Pain management goes way beyond the prescribed medications. There are many other strategies that can work in conjunction with the pharmacotherapy or even in place of the pharmacotherapy to manage the pain. Nonpharmacologic treatment options or adjuvants include:

- Heat/ice
- TENS unit
- Massage
- Acupuncture
- Biofeedback
- Cognitive therapy
- Psychotherapy
- Hydrotherapy
- Spiritual counseling
- Hypnosis
- Stretching/movement

Tools/Resources:
(Item below is located in the Tools and Resources section of the Toolkit)

- CDC Nonopioid Treatments for Chronic Pain

Pharmacologic Treatment Options

The type of pain will help determine what evidence-based treatment options may be best for your patient*.

Acute mild	Acute severe	Visceral	Neuropathic	Inflammatory	Functional
APAP	Opioids	Opioids (if severe)	AED or TCA	APAP or NSAID	TCA or tramadol
NSAIDs	NSAIDs/APAP	Adjuvants: AED, TCA	Lidocaine	Long-acting opioids	SSRI/SNRI, pregabalin
Opioids		AED	SSRI or SNRI	Clonidine or baclofen	
		TCA	Long-acting opioid		

Adapted from O'Neil C. Pain Management. In: Pharmacotherapy Principles and Practice; 2019: 527. AED = Anti-epileptic drugs such as gabapentin, pregabalin, carbamazepine

SNRI = serotonin norepinephrine reuptake inhibitor; TCA = tricyclic antidepressant

APAP = acetaminophen; NSAID = nonsteroidal anti-inflammatory drugs

*Adapted from O'Neil C. Pain Management. In: Pharmacotherapy Principles and Practice; 2019: 527.

Nonopioid Pharmacologic Treatment Options

Consider these nonopioid analgesic options:

- Acetaminophen
- Salicylates
- NSAIDs/COX-2 inhibitors
- Tricyclic antidepressants
- Antiepileptic drugs
- Serotonin norepinephrine reuptake inhibitors
- Topical analgesics

Opioid Pharmacologic Treatment Options

When using opioids, there are many considerations. The tools that follow help you explain opioid use, assess when it is appropriate, screen for risks, and develop a plan for lowest possible dose with lowest possible risk.

It is important to understand these important terms related to opioid use and be able to educate patients and their loved ones.

Tolerance – nerve transmitters in the body adapt during chronic use; doses last a short time and are less effective over time.

Physical dependence – natural physiologic process; the body lets the medication treat the pain and decreases its own actions to manage the pain (downregulation of neurotransmitter production and receptor activity).

Withdrawal – when the medication is removed, or decreased too quickly, and the brain and body resumes it's natural neurotransmitter production and receptor activity, the patient experiences body aches, insomnia, irritability, tachycardia, weakness, yawning, shivering, gastrointestinal symptoms (nausea, vomiting, diarrhea).

Addiction – a compulsive, chronic physiological or psychological need for a habit-forming substance, which results in dysfunctional, often non-medical, use of the substance or rather chronic use if to feel euphoria or to manage lows vs. for pain management.

Pseudoaddiction – in patients with severe, unrelieved pain, when access to the medication is jeopardized, the patient behaves as if addicted or desperate because so afraid to experience withdrawal or breakthrough pain.

Tools/Resources:

(Items below are located in the Tools and Resources section of the Toolkit)

- CDC App for Opioid Prescribing Guideline
- CDC Calculating Total Daily Dose of Opioids
- Assessing Benefits and Harms of Opioid Therapy
- Medical Risks of Long-Term Opioid Use
- Community Pharmacist's Guide to Pain Management
- Turn the Tide – Prescribing Opioids for Chronic Pain

Guidelines

Keep in mind, guidelines change over time. These are the current guidelines at the time of the initial printing of this toolkit.

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI:
http://dx.doi.org/10.15585/mmwr.rr6501e1
https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm

Perspective publication on the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain

Dowell D, Haegerich TM, Chou R. No Shortcuts to Safer Opioid Prescribing. N Engl J Med 2019; 380:2285-2287DOI: 10.1056/NEJMp1904190
https://www.nejm.org/doi/full/10.1056/NEJMp1904190

Department of Health and Human Services

May 2019 Pain Management Best Practices Inter-Agency Task Force Report – Updates, Gaps, Inconsistencies, and Recommendations – Pain Management Final Report: U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html
https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

American Medical Association Task Force Recommendations

https://www.aafp.org/dam/AAFP/documents/patient_care/pain_management/hops19-ama-opioid-recs.pdf

North Carolina and National Initiatives

- The Pain Society of the Carolinas: https://www.carolinapain.org
- OPDAAC Coordinating Workgroup: https://www.ncdhhs.gov/about/department-initiatives/opioid-epidemic/nc-opioid-and-prescription-drug-abuse-advisory-1
- Understanding the STOP Act: https://www.ncmedboard.org/landing-page/stop-act
- North Carolina Department of Health and Human Services has several initiatives around opioid use: https://www.ncdhhs.gov
- Office of the Assistant Secretary for Health Pain Management Best Practices Inter-Agency Task Force: https://www.hhs.gov/ash/advisory-committees/pain/index.html
- Along with guidelines there are several tools and apps available to further aid in good pain management and safe opioid use.

Assess Risk

Prior to using opioids, potential risk factors should be carefully screened. This screening should continue throughout the duration of opioid use

Tools/Resources:
(Items below are located in the Tools and Resources section of the Toolkit)

- Aberrant Drug Taking Behaviors Information
- Progress Note Template Care Plan
- Opioid Risk Tool (ORT)
- Recognizing Opioid Abuse
- Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)
- DIRE Score: Patient Selection Tool for Chronic Opioid Analgesia
- CAGE Substance Abuse Screening Tool: https://www.hopkinsmedicine.org/johns_hopkins_healthcare/downloads/all_plans/CAGE%20Substance%20Screening%20Tool.pdf

Toolkit Tip: One of the places where pharmacists can play an important role in opioid management is assistance in reading and translating urine drug test results. This is also another opportunity to educate patients. Consider assessing your patient's understanding and comfort with urine drug screening.

Tools/Resources
(Items below are located in the Tools and Resources section of the Toolkit)

- Urine Drug Testing in Clinical Practice Education
- A Practical Guide to Urine Drug Monitoring: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6368048/
- CDC DUIP Urine Drug Testing Fact Sheet

Opioid Use Disorder

There are defined criteria for opioid use disorder. Be familiar with these and help prescribers identify these factors

Tools/Resources:
(Items below are located in the Tools and Resources section of the Toolkit)

- DSM-5 Criteria for Opioid Use Disorder
- Pharmacists: On the Frontline

Opioid Deprescribing and Dose Management

Another important role is to identify when opioid use can be tapered off and stopped. Pharmacists are in a unique role to talk with patients more frequently and guide opioid tapers, due to their accessibility and more frequent interactions with patients.

Tools/Resources
(Items below are located in the Tools and Resources section of the Toolkit)

- CDC Pocket Guide for Tapering Opioids
- HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics – HHS Opioid Deprescribing
- Oregon Opioid and Benzodiazepine Tapering Flowsheet
- Clinical Opioid Withdrawal Scale (COWS): https://www.aoaam.org/resources/Documents/Clinical%20Tools/Clinical_opiate_withdrawal_s.pdf
- US Department of Veterans Affairs Opioid Taper Decision Tool
- Tapering Long-term Opioid Therapy in Chronic Noncancer Pain: Evidence and Recommendations for Everyday Practice – Mayo Clinic June2015

Benzodiazepine Deprescribing

Benzodiazepine use in conjunction with opioids has been shown to greatly increase risk of overdose and death. Therefore, current guidelines strongly discourage concomitant use. Pharmacists can play an important role in guiding benzodiazepine tapers. (Note, there are exceptions. Work with the prescriber and patient to determine the safest regimen for a particular patient and guide any tapers carefully to avoid increased physical and psychological pain.)

Tools/Resources
(Items below are located in the Tools and Resources section of the Toolkit)

- Benzodiazepine Toolkit
- Is a Benzodiazepine or Z-Drug Still Needed for Sleep
- Benzodiazepine and Z-Drug Deprescribing Algorithm
- National Center for PTSD – Helping Patients Taper from Benzodiazepines

Naloxone

Naloxone can reverse opioid overdose. Consider the additional dispensing and education for use with all opioid prescriptions. North Carolina has a standing order for naloxone, so no additional prescription is required. It is important that both patients and their caregivers/loved ones/friends know how to appropriately administer naloxone so they are not trying to figure it out right when it is needed. (Note, encourage the person administering to be beside or behind the patient. Most overdose patients are aggressive or vomit upon receiving a dose of naloxone.)

Tools/Resources
(Items below are located in the Tools and Resources section of the Toolkit)

- Pharmacist Education – Guide for Pharmacists Dispensing Naloxone to Patients – Preventprotect.org
- 2018 NC Standing Naloxone Standing Order
- Impact of a pharmacist-driven intervention on the outpatient dispensing of naloxone – Griffin 2019: Griffin S, Wishart B, Bricker K, Luebchow A. Impact of a pharmacist-driven intervention on the outpatient dispensing of naloxone. *J Am Pharm Assoc*. 2019; 59:S161-S166.

- Pharmacist Education Let's Talk About Naloxone
- Acquiring Naloxone in NC
- Naloxone Conversation Tips
- Opioid Emergency Action Plan
- Naloxone Pharmacy Card
- Naloxone Toolkit
- Naloxone Access Options
- Naloxone Patient Flyer – Patient Education Opioid Safety and How to Use Naloxone

Pain Agreements

One way to help assure all involved in opioid use are clear about the terms for continued use is to have a pain agreement signed by the patient. Here are examples and templates for agreements. The pharmacist can help assure all parameters are met with ongoing therapy.

Tools/Resources:
(Items below are located in the Tools and Resources section of the Toolkit)

- Department of Veterans Affairs Consent for Long-Term Opioid Therapy for Pain
- NIDA Sample Pain Agreements
- Pain Management Agreement
- American Academy of Family Physician Sample Agreement Form
- Womack Army Medical Center Sole Provider Agreement

Communicating with Members of the Healthcare Team

Pain should be managed in collaboration with the rest of the healthcare team. The roles, overlap for reinforcement, and communication between team members should be made clear prior. There are several templates available to help guide clear communication.

Tools/Resources:
(Items below are located in the Tools and Resources section of the Toolkit)

- Physician Service Communication Form
- Progress Note Template Care Plan
- Respond Prescriber Communication Strategy
- Pain Assessment and Documentation Tool (PADT)
- Progress Note Template Aberrant Behavior
- Progress Note Template Pain Interference Scale
- Opioid Use Progress Note

Prescriber Communication

Prescriber education spans from knowledge of the service you provide to patient-specific information for collaboratively shared patients. See the “Communicating with Members of the Healthcare Team” section above for specific communication tools.

Patient-specific Communication

One the communication tools the:

- Physician Service Communication Form

This form is customizable and allows the pharmacist to communicate assessment findings and request action on the part of the provider.

Service Detailing

A template brochure is available for your modification and use. This brochure is designed to help you share information, with prescribers and other healthcare partners, about the service you provide.


CDC Pharmacists Brochure


NCAP Toolkit_One Page Infographics

When talking with prescribers and other potential partners about your service, take an academic detailing approach. This is an effective way to communicate your service, educate peers, and build trust.

When promoting your service to prescribers, consider these steps:

- briefly describe who you are, where you are from, the details of your service, and why their practice and patients might benefit
- make sure to include messaging that shares how your service promotes best practices and improved patient outcomes
- ask open-ended questions to understand more about the physician’s practice, as well as their preception and attitude toward your service
- reflect and strategize with the prescriber on how your service can assist them with their specific patient or practice needs.
- be prepared to identify potential barriers and solutions based on the components of your service
- be prepared to provide leave-behind materials for the practice
- be prepared to show and leave behind patient education and referral information for your service.

Additional tips to enhance the efficacy of your communication are to be as brief and to the point as possible. As soon as you leave, provide a link to the materials you mentioned. Point to specific practice recommendations, evidence-based guidelines, and best practices. Make your information truly practical and easy to understand.

Patient Education

The more your patient understands his/her pain and what you and the rest of the healthcare team are doing to address the pain, the better the patient can fully participate and adhere to the agreed upon plan.

Keep in mind with various pain types and the fact that each patient experiences and describes pain differently, taking the time to help your patient understand and fully describe their pain will better inform the treatment team. Allowing the team to create a more accurate treatment plan.

Tools/Resources:
(Items Below are located in the Tools and Resources section of the Toolkit)

- Understanding Pain Patient Education Handout
- Understanding Pain Patient Education Handout (in Spanish)
- Mood, Mindset and Pain Patient Education Handout
- Mood, Mindset and Pain Patient Education Handout (in Spanish)

General health maintenance education complements patient's chronic pain goals. Below are tools to help your patient with general health maintenance.

Tools/Resources:
(Items Below are located in the Tools and Resources section of the Toolkit)

- Nutrition and Pain Patient Education Handout
- Nutrition and Pain Patient Education Handout (in Spanish)
- Physical Activity Patient Education Handout
- Physical Activity Patient Education Handout (in Spanish)

Sleep and pain are so co-dependent. Following resource is specific to helping your patient get adequate sleep.

Tools/Resources:
(Items Below are located in the Tools and Resources section of the Toolkit)

- Sleep Management Patient Handout
- Sleep Management Patient Handout (in Spanish)

Patient understanding is critical when developing and implementing a plan to decrease pain medications. There can be fear, mistrust, and significant adherence issues if not approached collaboratively.

Tools/Resources:
(Items Below are located in the Tools and Resources section of the Toolkit)

- Patient Education on Tapering and Decreasing Pain Medication
- Patient Education on Tapering and Decreasing Pain Medication (in Spanish)

When opioids are in use, a thorough understanding of naloxone use is very important. You are highly encouraged to have patients demonstrate the skills of appropriate administration prior to leaving your practice with the medication.

Tools/Resources:
(Item below is located in the Tools and Resources section of the Toolkit)

- Naloxone Patient Flyer

Additional Chronic Pain-related Resources for Patients

The American Chronic Pain Association

This online resource contains many helpful tools designed for patients. It provides resources touching on several important topics associated with chronic pain including how to communicate with providers, self-management skills and educational videos.
https://www.theacpa.org/pain-management-tools/
https://www.theacpa.org/pain-management-tools/communication-tools/

Education Resources for Patients with Chronic Pain

This resource highlights existing patient education materials relevant to patients with chronic pain:
https://depts.washington.edu/fammed/improvingopioidcare/wp-content/uploads/sites/12/2019/05/Education-Resources-for-Patients-with-Chronic-Pain_2019-05-02.pdf

Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders

This publication provides guidance on how to effectively educate patients on chronic pain: Center for Substance Abuse Treatment. Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2012. (Treatment Improvement Protocol (TIP) Series, No. 54.) 5, Patient Education and Treatment Agreements. Available from: https://www.ncbi.nlm.nih.gov/books/NBK92049/

Intermountain Health Opioid Literature

Provides several patient education materials including handouts and videos covering key topics around pain: https://intermountainhealthcare.org/services/pain-management/patient-education/

TOOLS AND RESOURCES

TABLE OF CONTENTS

IMPORTANT NOTE:

This implementation toolkit was developed based on a collaboration between NCAP and Pfizer (with financial support provided by Pfizer Inc). Please see full disclaimer for this toolkit on Page 2.

Tools and Resources
Service Development

SD = Pharmacy Service Delivery
AM = Ambulatory Care Demonstration Case
CP = Community Pharmacy Demonstration Case
AA = Adherence and Access Demonstration Case
ED = Chronic Pain Education

Service Delivery Tools and Resources

Pharmacy Service Start-Up Checklist (SD)

Pharmacy Service Start-up Checklist.doc

Pharmacy Service Needs Assessment Tool (SD AM CP)

Pharmacy Service Need Assesment.doc

Chronic Pain Pharmacy Service.doc

SWOT Analysis Template and SCORE SWOT Analysis Worksheet (SD CP)

SWOT Template Final

Environmental Analysis Worksheet Tool (SD AM)

Environmental Analysis Worksheet.d

Chronic Pain Environmental Analysis Work

SMART Goal Tools (SD AM CP AA)

The Essential Guide to Writing S.M.A.R.T. Goals by SmartSheet
https://www.smartsheet.com/blog/essential-guide-writing-smart-goals

SMART Goal Worksheet for Medication Access and Adherence (AA)

SMART Goal Worksheet Medicatic

Smart Goal Worksheet for a Chronic Pain Service (AM)

SMART Goal for Chronic Pain Pharma

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SMART Goals for Chronic Pain Service Activities (AM CP)

SMART Goals Worksheet.docx

Pharmacy Service Outcomes and Metrics Worksheet (SD AM)

Pharmacy Service Outcomes and Met.d

Outcomes and Metrics Chart Ambula

Health Information Technology Project Timeline Grid (SD CP)

HIT Project Timeline Grid.docx

Stakeholder Worksheet Tool (SD)

Stakeholder Worksheet Tool .doc

Activities Worksheet (SD AM AA)

Activities Worksheet.docx

Chronic Pain Activity Worksheet.docx

Patient Care Intervention Checklist (AA)

Patient Care Intervention Checklis

SD = Pharmacy Service Delivery
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Medication History Tool (SD AM)

Medication History Tool.docx

PDSA Cycle Template:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/PDSACycledebedits.pdf (SD CP)

ASHP Pharmacist Billing/Coding Quick Reference Guide June 2019 (SD)

ASHP Pharmacist Billing_Coding Quick.

Chronic Pain

Care Delivery Tools and Resources

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Chronic Pain Patient Flow Example (AM CP)

Chronic Pain Patient Flow Example .PDF

Chronic Pain Service in the Ambulatory Space Pharmacy Workflow Example (AM)

Chronic Pain Workflow in ambula

Progress Note Template Care Plan (AM CP ED)

Progress Note Template Care Plan .

Progress Note: Pain Assessment and Documentation Tool (PADT) (AM CP ED) Adapted from https://healthinsight.org/Internal/assets/SMART/PADT.pdf

PADT Progress Note.doc

Opioid Use Progress Note (AM CP ED)

Opioid Use Progress Note.doc

Progress Note Template Aberrant Behavior (AM CP ED)

Progress Note Template Aberrant .c

Progress Note Template Pain Interference Scale (AM CP ED)

Progress Note Template Pain.doc

Ongoing Pain Assessment Form (AM CP ED)

Ongoing Pain Assessment Form.dc

Office Visit Checklist (AM)

Office Visit for Treatment of Chroni

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Communication Tools

Physician Survey for Chronic Pain Needs Assessment (SD AM CP) Adapted from Giannitrapani, K.F., Glassman, P.A., Vang, D. et al. Expanding the role of clinical pharmacists on interdisciplinary primary care teams for chronic pain and opioid management. BMC Fam Pract 19, 107 (2018) doi:10.1186/s12875-018-0783-9

Prescribe Survey for Pharmacy Chronic.dc

Respond Prescriber Communication Strategy (AM CP ED)

https://pharmacistrespond.org/theme/tikli/css/images/pdfs/RESPOND-Checklist.pdf

Physician Service Communication Form (AM CP ED)

Physician Service Communication Forr

CDC Pharmacists Brochure

CDC Pharmacists Brochure.PDF

Screening Tools

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Pain Assessment Tools and Resources

Brief Pain Inventory (AM CP ED)
https://www.mdanderson.org/documents/Departments-and-Divisions/Symptom-Research/BPI_UserGuide.pdf

Graded Pain and Function Scale (AM CP ED):
http://www.oregonpainguidance.org/app/content/uploads/2016/05/Graded-Pain-and-Function-Scale.pdf

Pain Assessment Questions and Scales (AM CP ED)

Pain Assessment Questions and Scale

Pain Chart (AM CP ED)

Pain Chart.docx

PEG-3 (AM CP ED): http://www.oregonpainguidance.org/tools/

Pain Assessment Documentation Tool (AM CP ED)
https://www.drugabuse.gov/sites/default/files/files/PainAssessmentDocumentationTool.pdf

5 A's of Analgesia (AM CP ED)
https://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0019/212761/5_As_of_Analgesia.pdf

Adjuvant Assessment Tools

Patient Health Questionnaire – 2 questions
https://cde.drugabuse.gov/instrument/fc216f70-be8e-ac44-e040-bb89ad433387

Patient Health Questionnaire – 9 questions
https://www.mdcalc.com/phq-9-patient-health-questionnaire-9

Generalized Anxiety Disorder 7-item Scale
https://www.integration.samhsa.gov/clinical-practice/gad708.19.08cartwright.pdf

Opioid Risk Tools and Resources

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Opioid Risk Tool (AM CP ED):
https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

Opioid Risk Tool Revised (AM CP ED):
http://core-rems.org/wp-content/uploads/2019/05/ORT-OUD-tool.pdf

DIRE Score (AM CP ED)

DIRE Score.doc

RIOSORD Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (AM CP ED)

RIOSORD.docx

Recognizing Opioid Abuse (CP ED):
https://www.drugabuse.gov/nidamed-medical-health-professionals/opioid-crisis-pain-management

Recognizing Opioid Abuse.pdf

Aberrant Drug Taking Behaviors (AM CP ED):
https://www.drugabuse.gov/nidamed-medical-health-professionals/opioid-crisis-pain-management

Aberrant Drug Taking Behaviors.PDF

DMS-5 Criteria for Opioid Use Disorder (CP ED):
https://www.oregonpainguidance.org/wp-content/uploads/2019/07/DSM-5-Criteria-OPG-form.pdf?x91687

Social Determinants of Health Tools (ED)

Social Determinants of Health Screening Tool:
https://www.ncdhhs.gov/about/department-initiatives/healthy-opportunities/screening-questions

A New Way to Talk about Social Determinants of Health:
https://www.rwjf.org/en/library/research/2010/01/a-new-way-to-talk-about-the-social-determinants-of-health.html

Pain Agreements (AM CP ED)

SD = Pharmacy Service Delivery
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Drugabuse.com sample Patient Agreement Forms:
https://www.drugabuse.gov/nidamed-medical-health-professionals/opioid-crisis-pain-management

Sample Patient Agreement Forms(2).

National Institute on Drug Abuse; National Institutes of Health; US Department of Health & Human Services – Opioids Patient Agreement

Opioids Patient Agreement.PDF

Pain Management Agreement Example

Pain Management Agreement(1) .docx

Long-Term Opioid Therapy Informed Consent Form (AM ED):
https://www.ethics.va.gov/docs/policy/copy_of_vha_10_0431C.pdf

American Academy of Family Physician Sample Agreement Form (AM ED):
https://www.aafp.org/dam/AAFP/documents/patient_care/pain_management/agreement.pdf

Womack Sample Agreement Form (AM ED)

Sole Prescriber Program Agreement

Urine Drug Testing

Urine Drug Testing (AM ED):
https://www.remitigate.com/wp-content/uploads/2015/11/Urine-Drug-Testing-in-Clinical-Practice-Ed6_2015-08.pdf

CDC DUIP Urine Drug Testing Fact Sheet (AM ED)

CDC DUIP Urine Drug Testing Fact Sheet

Non-Opioid Management Tools and Resources

SD = Pharmacy Service Delivery
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CDC Nonopioid Treatment Education (AM CP ED)

CDC NonOpioid Treatments For Chron

Mood, Mindset and Pain Patient Education Handout (CP ED):
http://www.oregonpainguidance.org/patient-resources/patient-education-toolkit/

Nutrition and Pain Patient Education Handout (CP ED):
http://www.oregonpainguidance.org/patient-resources/patient-education-toolkit/

Physical Activity Patient Education Handout (CP ED):
http://www.oregonpainguidance.org/patient-resources/patient-education-toolkit/

Sleep Management (CP ED):
http://www.oregonpainguidance.org/patient-resources/patient-education-toolkit/

Opioid Management Tools and Resources

Understanding Pain Patient Education Handout (CP ED):
http://www.oregonpainguidance.org/patient-resources/patient-education-toolkit/

CDC App for Opioid Prescribing Guideline (CP ED)

CDC App Opioid Prescribing Guideline.

North Carolina Stop Act Resources (CP):
https://www.ncmedboard.org/images/uploads/article_images/The_STOP_Act_summary-OnLetterhead.pdf

Veterans Affairs Department of Defense Clinical Practice Guidelines (CP):
https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf

Community Pharmacist's Guide to Pain Management (CP ED):
http://www.ncpa.co/issues/APNOV15-CE.pdf

CDC Assessing Benefits and Harms of Opioid Therapy (AM CP ED)

CDC Assessing Benefits Harms of Op

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CDC Calculating Total Daily Dose of Opioids (CP ED)

CDC Calculating Total Daily Dose of O

Medical Risks of Long-Term Opioid Use (CP ED)

Medical Risks of Long-term Opioid Us

NC Board of Pharmacy Pocket Card (AM CP):

http://www.ncbop.org/about/Student%20Projects/CSpocketcardRevNov2013.pdf

Turn the Tide Pocket Guide (AM CP ED):

https://www.cdc.gov/drugoverdose/pdf/TurnTheTide_PocketGuide-a.pdf

Opioid and Benzodiazepine Tapers

HHS Opioid Deprescribing (AM CP ED)

HHS Dosage Reduction Discontinu

Opioid Tapering Resource (AM CP ED): Berna C, Kulich RJ, Rathmell JP. Tapering Long-term Opioid Therapy in Chronic Noncancer Pain: Evidence and Recommendations for Everyday Practice. Mayo Clin Proc. 2015;90(6):828-842.

CDC Pocket Guide for Tapering Opioids (AM CP ED)

CDC Pocket Guide Tapering Opioids For

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US Veterans Affairs Opioid Taper Tool (AM ED):
https://www.pbm.va.gov/AcademicDetailingService/Documents/Pain_Opioid_Taper_Tool_IB_10_939_P96820.pdf

Oregon Pain Guidance Opioid and Benzodiazepine Tapering Flowsheet (CP ED):
http://www.oregonpainguidance.org/tools/

Benzodiazepine Toolkit (AM CP ED):
http://www.cpsa.ca/wp-content/uploads/2016/08/Clinical-Toolkit_BDZ_Nov_2016.pdf?x91570

Bruyere Benzodiazepine Deprescribing Resources (AM CP ED)

Benzodiazepine & Z-Drug (BZRA) Deprescribing Algorithm:
https://deprescribing.org/wp-content/uploads/2019/03/deprescribing_algorithms2019_BZRA_vf-locked.pdf

Is a Benzodiazepine or Z-Drug still needed for sleep?:
https://deprescribing.org/wp-content/uploads/2018/08/benzodiazepine-deprescribing-information-pamphlet.pdf

Effective Treatment for PTSD Helping Patients Taper from Benzodiazepines (AM ED):
https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/59_PTSD_NCPTSD_Provider_Helping_Patients_Taper_BZD.pdf

Patient Education on Tapering and Decreasing Pain Medication (CP ED):
http://www.oregonpainguidance.org/patient-resources/patient-education-toolkit/

Naloxone Tools and Resources

NC Standing Naloxone Standing Order (AM CP ED):
http://www.naloxonesaves.org/files/2019/01/2018-Standing-Order.pdf

Naloxone Access (AM CP ED): https://www.naloxonesaves.org/where-can-i-get-naloxone/

Naloxone Toolkit (AM CP ED): https://www.injuryfreenc.ncdhhs.gov/DataSurveillance/NaloxoneDistributionToolkitFinalApproved-042219.pdf

Naloxone Pharmacist Education and Talking Points (AM CP ED)

Pharmacist Education – Guide for Pharmacists Dispensing Naloxone to Patients:
https://prescribetoprevent.org/wp2015/wp-content/uploads/training_tool_translations_english.pdf

Pharmacist Education – Let's Talk About Naloxone:
https://www.pharmacist.com/sites/default/files/audience/LetsTalkAboutNaloxone.pdf

Pharmacist Education – Impact of a pharmacist-driven intervention on the outpatient dispensing of naloxone: Griffin S, Wishart B, Bricker K, Luebchow A. Impact of a pharmacist-driven intervention on the outpatient dispensing of naloxone.
J Am Pharm Assoc. 2019; 59:S161-S166.

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Pharmacist Talking Points

Naloxone Conversation Tips.doc

Patient Education (AM CP ED)

Naloxone Patient Flyer: https://www.pharmacy.ca.gov/publications/naloxone_fact_sheet.pdf

Opioid Emergency Action Plan Patient Handouts

Opioid Emergency Action Plan Patient H

Naloxone Pharmacy Card - Patient Educat

Medication Adherence and Access

Medication Adherence and Access Tools and Resources

Medication Adherence Questionnaire – Drug Adherence Work-up (DRAW©) (AA)

DRAW.pdf

ARMS Medication Adherence Form 12 and 7 (AA)

Adherence Assessment_ARMS12

Patient Care Intervention Checklist (AA)

Patient Care Intervention Checklist

Prior Authorization Documentation and Communication Form (AA)

PA Documentation & Communication Fo

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Closing

Let these steps and resources guide you to your next new service. Remember to reach out to others who are doing what you plan to do or are doing something that required similar steps.

Break down this process into steps or stages. You don't have to do it all at once. In using this toolkit, be sure you use the links to guide you to specific areas.

Remember The North Carolina Association of Pharmacists has many tools and knowledgeable members to further assist you in your service development.

Those who designed this toolkit wish you great success and welcome your feedback!

Acknowledgments:

We are grateful to the following members of The North Carolina Association of Pharmacists workgroups for their extensive input on this toolkit.

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