Government of the
District of Columbia

A COLLABORATIVE APPROACH FOR SAFE USE OF OPIOIDS

DEVELOPED BY DHCF & THE DISTRICT'S DUR BOARD IN COLLABORATION WITH STAKEHOLDERS

November 5, 2021

WHAT IS IN THIS ISSUE

DUR BOARD'S MESSAGE

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The government of the District of Columbia through the Department of Health Care Finance (DHCF) and the Drug Utilization Review (DUR) Board in consultation and collaboration with the District's clinical community is pleased to release this important resource material, "A Collaborative Approach for Safe Use of Opioids."

The DUR Board, your appointed health care provider representatives to DC Medicaid and experts on medication utilization within the DC Medicaid population has worked alongside our colleagues within DC Medicaid for more than a year to research, develop, and authorize this resource material.

The DUR board recognizes the value of opioid therapies to the care of our patients as well as the importance of promoting, monitoring, and advancing better and best practices in opioid stewardship. To have an appropriate opioid use, at least the following dimensions should be considered:

Creation of interdisciplinary partnership, the target population (the patient), the community served, health care delivery system, laws, regulations and policies, clinical and scientific evidence as well as expert and key stakeholder input and the DUR Board, to the best of its ability considers these dimensions in the process of prospective and retrospective drug utilization review.

We invite and encourage our physicians, dentists, podiatrists, advanced practitioners, pharmacists, nurses, substance abuse specialists, behavioral health professionals, health care professional educators and learners, and all other health care professionals to review and apply this resource material.

Practical approaches for applying available Opioid Guidelines in our day-to-day practices include integration into education and training resources, referencing or appending to clinical and administrative policy and procedures/standard operating procedures, and introducing into clinical pathways, treatment algorithms, protocols, order sets, as well as adopting as part of the ongoing quality assurance and performance improvement activities and programs that include Quality of Life (QoL) measures.

All key aspects of the medication use process are reflected including prescribing, preparation, dispensing, administration, and monitoring/patient education. Consequently, there is something important for all of us to consider in this document. As always, we invite you to continue to share your feedbacks with DC Medicaid and/or the DUR Board as we work to provide high quality health care and prevent avoidable opioid-related harm to our patients.

DHCF'S MESSAGE

DHCF
Department of Health Care Finance

DHCF recognizes the value that prescription opioids have in mitigating and managing both acute and chronic pains. The fact that the use of opioids has been implicated in deaths related to overdose has prompted DHCF to develop this resource material in collaboration with the District's DUR Board.

This resource material, "A Collaborative Approach for Safe USE Of Opioids," was developed to create common understanding and appreciation of the danger posed when opioids are not appropriately used.

It is DHCF's interest to establish a teamwork spirit through active engagement of all potential stakeholders identified to have, one way or the other, a role in the management and control of opioids prescribing, dispensing, and use. The tenets of this partnership include:

1) recognizing the roles of prescribers, pharmacists, professional associations, and other concerned stakeholders;

2) understanding and appreciating problems related to opioid from everyone's perspective;

3) identifying possible approaches to remediate problems; and

4) facilitating a successful adoption and implementation guidelines, policies and procedures that result in optimizing care and improving patient safety.

DHCF'S MESSAGE
(continued)

There exist CDC and the District's guidelines dealing with Opioids prescribing and dispensing. It is DHCF's belief that developing a guideline and making them available for providers to adopt is not, by itself, a sufficient remedy to alleviate problems observed consequent to inappropriate use of opioids. Creating a common understanding and appreciation of the problem by all stakeholders is rather a critical step. This resource material serves as a tool to

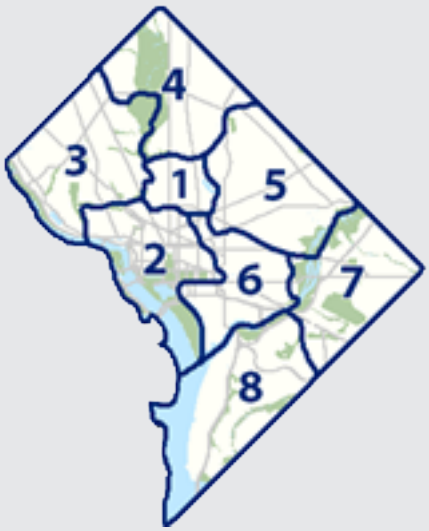
1) improve safe and appropriate prescribing by balancing with patients' need for opioids;

2) improve clinical decision-making when prescribing;

3) enhance prescription monitoring; and

4) support appropriate pain management and dissemination of information.

DHCF expresses its deep appreciation to the many providers in the District who are consistently discharging their professional obligations in assessing and establishing medical necessity prior to prescribing and dispensing opioids to their patients. Healthcare providers consistently follow existing clinical and step therapy requirements by adhering to federal and state regulations and maintain their professional competence to assess and determine patient-specific treatment options and needs



ACKNOWLEDGEMENTS

Draft of this document was distributed to 20 potential stakeholders to get their inputs. The distribution list includes Black Nurses Association of Greater Washington, DC Area (BNA of GWDCA), District of Columbia Board of Medicine, District of Columbia Board of Pharmacy, District of Columbia Board of Nursing, District of Columbia Board of Dentistry, District of Columbia Academy of Physician Assistants (DCAPA), District of Columbia Dental Society (DCDS), District of Columbia Hospital Association (DCHA), District of Columbia Primary Care Association (DCPCA), District of Columbia Department of Behavioral Health Addiction Prevention and Recovery Administration, Georgetown University School-Medicine, GW School of Medicine and Health Sciences, Howard University College of Medicine, Howard university College of Pharmacy, Johns Hopkins School of Medicine, Medical Society of the District of Columbia (MSDC), Nurse Practitioner Association of the District of Columbia, Washington D.C. Pharmacy Association (WDCPhA), and Washington Metropolitan Society of Health-System Pharmacists (WMSHP).

Those who responded and provided their input include the District of Columbia Board of Medicine, Howard university College of Pharmacy, Johns Hopkins School of Medicine, Medical Society of the District of Columbia (MSDC), Nurse Practitioner Association of the District of Columbia, and Washington Metropolitan Society of Health-System Pharmacists (WMSHP).

The Department of Health Care Finance (DHCF) and the District's Drug Utilization Review (DUR) Board would like to take this chance to acknowledge, extend, and express their sincere appreciation and gratitude to those who offered practical suggestions and feedback. The ideas and recommendations obtained from stakeholders-teaching institutions, professional associations and boards of health care professionals-were valuable and helpful to shape the resource material to its final form.

BACKGROUND

Opioids are powerful analgesics for pain. However, their use is not without risks. Opioids can be dangerous to health and may serve as causes of preventable deaths. Abuse/misuse of opioids is also associated with heavy economic burden and contributes to social and political crisis.

According to the Center for Disease Control and Prevention (CDC),[1] 70, 237 drug overdose deaths occurred in the United States in 2017 and of this, 67.8% involved opioid overdose deaths. Interventional efforts and regulatory mechanisms, invested to manage and treat substance use disorders (SUDs), are also associated with heavy cost burdens. Overall costs of prescription opioid overdose that are spent on healthcare, criminal justice, workplace etc. were estimated to be $78.5 billion in a study that looked at 2013 data and published in 2016.[2] Moreover, individuals with SUDs are reported to more likely use medical services including outpatient visits, emergency services, and inpatient hospital stays.[3]

The District of Columbia Drug Utilization Review (DUR) Board and the Department of Health Finance (DHCF) in collaboration with the FFS Pharmacy Benefit Manager (PBM) regularly review the appropriateness of prescription drugs including opioids.

The common observation is that patients continuously receive prescriptions for opioids concomitantly with other CNS depressant drugs that may have potential interactions and/or result in adverse outcomes. Also, there exists insufficient or lack of effective care coordination and streamlined communication systems.

For example, a retrospective review of various sources indicate that polysubstance use, such as concomitant use of opioids and benzodiazepines, is one of the most consistent predictors of problematic opioid use and associated harms, including overdose and death.[4]

Concomitant use of opioids and CNS depressants is generally considered "low value care" and potentially dangerous.[5]

Hospitalizations and emergency department visits in Canada involved adverse events due to concurrent use of opioids and benzodiazepines (presenting in one out of five);6 and in the U.S., more than 30% of overdoses involving opioids also involve concurrent use of benzodiazepines.[7]

Of note, efforts dealing with the management and treatment of opioids use commonly focus on changing individual behaviors[8] that are believed to produce only limited impacts. Social determinants of drug use which include social, cultural, economic, and physical environments are practically overlooked while strongly associated with substantial impacts that negatively affect intended treatment outcomes.

For example, situations in which people live, including factors such as income, food, housing, and access to services, strongly contribute to drug use behaviors. Research reports that compared to their stably housed peers, unstably housed youth present with higher rates of substance use problems and concurrent mental health disorders.[9]

Thus, it becomes essential to collaborate efforts and coordinate resources by working holistically and systematically and by implementing interventions that take into consideration both the individual's behavior and social determinants of drug use. Otherwise, the likelihood of failing to treat drug use successfully and effectively is inevitable.

The DUR board, DHCF, and the PBM recognize the fact that many DC Medicaid providers are consistently: (i) discharging their professional obligations by following all the necessary steps to assess and establish medical necessities prior to prescribing opioids; (ii) showing their concerted efforts to meet existing policies such as clinical and step therapy requirements; (iii) adhering to federal and state regulations when dealing with opioid prescribing and dispensing; and (iv) maintaining their professional competence to prescribe and dispense opioids by following appropriate policies, procedures, and diagnosis methods in an effort to identify a patient-specific treatment options and needs.

Development of this resource material was only initiated to bolster existing initiatives and to elevate all efforts to the next level of best practice by implementing a coordinated and holistic approach; and by engaging all potential stakeholders, identified to have a role to play and are directly or indirectly involved in the management and control of opioid prescribing, dispensing, and use.

Both the DUR Board and DHCF strongly believe that making guidelines available for providers to adopt is not by itself a complete remedy to problems seen consequent to abuse/misuse of opioids. Creating a common understanding and appreciation of the problem

by all stakeholders are believed to be critical. In this regard, the DUR Board and DHCF promote and appreciate a coordinated and holistic approach with active engagements of all potential stakeholders would result in effective management of opioids and their related adverse outcomes; and address some of the shortfalls that the DUR board, DHCF, and the PBM are continuously observing:

- Opioids being over-prescribed and overused, beyond a clinically justifiable treatment duration; and usually in combination with other drugs including benzodiazepines, muscle relaxants antipsychotics, clonidine, promethazine, and antipsychotics.

- Drugs intended to treat SUDs are being concurrently prescribed with opioids.

- A gap in patient care coordination exists amongst medical and pharmacy providers, payers, and support services. The District's DUR Board and DHCF considers the engagement of all potential stakeholders in the process to be of paramount importance. Establishing a teamwork spirit; recognizing the roles of the subject matter experts, prescribers, pharmacists, professional associations, and other concerned stakeholders such as social work, housing authority, court system/drug court, prison health care, substance use disorder treatment facilities, and employment services; and learning about the extent of the problem from everyone's perspective are synergic and important approaches to remediate the problem and facilitate a successful adoption and implementation of policies and procedures.

INITIATIVES IN EFFECT

DHCF adopts the DC Health,[10] Pocket Guideline for Prescribing Opioid for Chronic pain, and the CDC guideline developed in 2016,[11] which provide information about available nonpharmacologic and pharmacologic treatment options to treat pain; give recommendations about when to start prescription opioids, and assess the benefits and risks; detail the importance of selecting appropriate opioid formulations, dose, and treatment duration; underline the importance of planning regarding when and how to reassess treatment progress and determine the need to continue or discontinue prescribed opioid(s) etc.

In addition, on March 9, 2017, DHCF, along with the DUR Board, implemented a pharmacy lock-in program and a morphine milligram equivalent (MME) initiative with the intention to limit the use of prescription opioids to clinically appropriate indications, treatment durations; and prevent beneficiaries from using drugs in excess of the customary dosage; or multiple drugs which may be medically harmful.

Since the effectuation of the pharmacy lock-in program and MME, positive and encouraging outcomes have been achieved. Such interventions have helped, facilitated, and enabled:

- The identification of patients who are on multiple medications (polypharmacy), fill prescriptions at multiple pharmacies, and/or get prescriptions from multiple doctors.

- The provision of patient specific telephonic Medication Therapy Management (MTM) when appropriate; and the prescriber and pharmacist outreach and education on areas including usage of DC Prescription Drug Monitoring Program (PDMP) before prescribing and dispensing.

- Find ways to closely work and establish relationships with providers, which was found to be helpful in coordinating patient care by sharing and communicating encountered anomalies.

- Learn, collect, review, and appreciate some practical clinical challenges that providers (prescribers and pharmacies) are facing while doing their best to realistically treat patients.

- Receive constructive feedback from providers related to initiatives and recommendations that the DUR Board is regularly undertaking, distributing, and communicating with providers.

DEVELOPMENT PROCESS

To facilitate the process of developing this resource material "A Collaborative Approach for Safe Opioid Use," a draft was prepared by the District's DUR Board and DHCF. The draft was distributed to identified potential stakeholders to collect their input. Although the draft was distributed to a larger group of potential stakeholders, only some have responded and provided valuable input.

After receiving the comments from stakeholders, an internal task force from DHCF and the DUR Board reviewed the comments and incorporated ideas that were found to be relevant and important.

In the end, the resource material was finalized in consultation and discussion with stakeholders who have provided their input.

The process was helpful not only in collecting input, but also in appreciation and creation of a common understanding when it comes to the inappropriate or illicit uses of opioids and their multifaceted impacts.

Participation of stakeholders in the process was also expected to support and implement a collaborative approach for safe Opioid use.

PURPOSE

- Implement a collaborative and coordinated approach in dealing with the multifaceted problems and impacts of the opioid crisis.
- Highlight that opioid management is a shared responsibility. There is a greater need for communicating, consulting, presenting, and discussing a patient case with a colleague; a peer group; or multidisciplinary pain consultation team or referring the patient to a pain specialist.
- Describe the roles and responsibilities of all potential stakeholders that include but not limited to the subject matter experts, prescribers, pharmacists, professional associations, and other concerned stakeholders such as social work, housing authority, court system/drug court, prison health care, substance use disorder treatment facilities, and employment services.
- Support undergoing national initiatives aiming at preventing unnecessary deaths and health crises occurring due to inappropriate opioid prescribing and use.
- Comply with the federal and state legislative requirements established to manage and control opioid use, abuse, and fraud; and Contribute to efforts helpful in efficiently managing resources and improving outcomes while reducing costs associated with inappropriate use of opioids

RESPONSIBILITY

Prescribing Provider

- Should have the common understanding that opioids are effective analgesics for pain management. However, the tendency to promote the use of prescription opioids more routinely is not evidence based.[12] Evidence is insufficient to determine the effectiveness of long-term opioid therapy and that evidence supports a dose-dependent risk for serious harms.[13,14]
- Should take into consideration that treatment of an individual's physical symptoms is not enough to manage and prevent opioid use behavior unless combined with the individual's environment-social determinants of drug use-which include the social, cultural, economic, and physical environments.
- Should be aware that most chronic pain usually begins with acute pain. The benefits of opioids for acute pain may diminish quickly; and the use of prescription opioids for a prolonged period is associated with risks of addiction.
- Prescribing providers are expected to establish treatment goals before starting opioid therapy and review at periodic intervals.[15] Diligence should be applied to diagnose, evaluate, identify patients' risk benefits prior to initiating long-term opioid therapy, and maximally apply their professional judgment to weigh in whether the patient is the right candidate for opioid therapy or if the patient's condition can be treated with alternative options.
- Prescribing providers should inform patients on available alternative non-opioid or non-pharmacologic options to treat pain and educate them about the potential adverse effects associated with chronic opioid use.
- In the absence of precaution or contraindication and depending on type and severity, it is always best to initiate pain treatment with:
  - Non-pharmacologic options including but not limited to, exercising, physical therapy; yoga; chiropractic therapy; interventional procedures, such as epidurals and spinal cord stimulators; cognitive behavioral therapy; and relaxation therapy. Even with the use of non-pharmacologic options, therapies that have been shown to be helpful should be continued.

  - Nonsteroidal anti-inflammatory drugs (NSAIDs) or acetaminophen for mild to moderate pain.

  - Gabapentin (Neurontin), pregabalin (Lyrica), anticonvulsants (carbamazepine, oxcarbazepine), select tricyclic antidepressants, and serotonin-norepinephrine reuptake inhibitor antidepressants (duloxetine, venlafaxine) may be better treatment options for pain caused by nerve damage.

  - Opioid sparing analgesia approaches e.g., perioperative use of NSAIDs and local anesthetics are adopted based on. professional and evidence-based standards of care.

- As part of diligent patient care, diagnosis, evaluation, identification, and adherence of patients, it would be important for prescribing providers to perform urine drug tests and employ applicable risk stratification tools.

- Whenever a decision is reached to start an opioid therapy for pain, prescribers should adopt the 2021 DC Health[16] and 2016 CDC[17] guidelines.

- Prescribing providers should review the patient's history of controlled substance prescription using the District's prescription Drug Monitoring Program (PDMP) to help inform the provider's clinical decision making. They should continue to review PDMP data when starting Opioid therapy for pain and periodically during opioid therapy at clinically appropriate intervals. However, PDMP reports should be carefully examined and should not be used, by themselves, as a reason to discontinue or deny care to the patient.

- Observe, monitor, and take enhanced precautionary measures when an individual patient presents with aberrant behaviors such as:

  – Request early and /or repeated refills.

Pharmacy Provider

- Should inform patients of available alternative non-opioid or non-pharmacologic treatment options to treat pain and educate them about the potential adverse effects associated with chronic opioids use.

- Educating patients about available treatment options; treatment benefits and risks including addiction, physical dependence, and tolerance, overdosage; potential drug-drug-disease interactions taking into consideration patient's learning style, literacy, culture, language, and psychological and physiological barriers etc.

- Should check and review the Prescription Drug Monitoring Program (PDMP), available at https://districtofcolumbia.pmpaware.net/login, to find out whether or not a patient is receiving opioids or a combination of drugs from other sources that may put their health at risk due to overdose or a potential drug-drug interaction.

- Observe, monitor, and take enhanced precautionary measures when an individual patient presents with aberrant behaviors such as:

  – Request early and /or repeated refills.

  – Denied by other pharmacy providers.

  – Presents with what is suspected to be forged, altered, or counterfeit prescriptions.

  – Frequently ask for replacement of lost drugs.

  – Obtaining opioids form multiple prescribers, recurring emergency department visits for chronic pain management.

  – Aggressive demands for opioids or reflecting subjective behaviors, such as being nervous, overly talkative, agitated, emotionally volatile and evasive.

- Should review and verify the appropriateness of opioid prescriptions and uses with the purpose to identify issues including fraudulent prescription, therapeutic duplication, incorrect dosage or duration of treatment or medically unnecessary care, gross overuse, and patterns of fraud and abuse.

- Should consider dispensing naloxone to patients likely at a higher risk for overdose including, but not limited to, those who have a prior experience of overdose; history of ED visit; and those who are on opioid dose greater than fifty (50) Morphine Milligram Equivalents (MME), or concurrent benzodiazepine use.

- Should perform medication reconciliation in all practice settings, when appropriate and where applicable-clinic, admissions, or outpatient settings.

- Expected to share information, encountered challenges and success stories and important approaches helpful to learn from one another and remediate the problem and facilitate a successful adoption and implementation of policies and procedures.

Department of Health Care Finance (DHCF)

- Develops policies and procedures that govern opioid prescribing and use in consultation with the District's DUR board and subject matter experts.
- Reviews and resolves escalated issues and complaints related to coverage policy, step therapy, clinical, or prior authorization requirements for prescription opioids.
- Receives complaints related to any inappropriate practices, fraud, or abuse case and when necessary, reports the case to concerned parties for auditing or possible fraud and abuse investigations.
- Prepares and compiles annual reports to meet federal and state requirements.
- Oversees the function and compliance of the Pharmacy Benefit Manager (PBM) and the Managed Care Organizations (MCOs) to established standards, policies, and procedures.
- Look for options of service enhancement technologies helpful to identify misuse and potential drug drug-drug interactions (DDI).
- Solicit the potential use of pharmacogenomics testing to improve treatment outcomes, appropriate treatment selection, and dosing for medication-assisted treatment in people with substance use disorders

Drug Utilization Review (DUR) Board

The District's DUR Board was established per to section 1927(g) of the Social Security Act as an interdisciplinary body of medical, pharmacy, nursing, and other health professionals that has the responsibility to:

- Develop a DUR program aimed at reducing inappropriate use of all prescription drugs.
- Interpret patterns of use by doing prospective drug use review and retrospective drug use review.
- Perform data assessment and educational outreach activities.
- Reviews the appropriateness and pattern of opioid prescribing and use with the purpose to identify issues including therapeutic duplication, incorrect dosage or duration of treatment or medically unnecessary care, gross overuse, and patterns of fraud and abuse.
- Identifies interventional tools and recommends, organizes, and facilitates educational outreach activities to providers and beneficiaries upon observing:
  - Seemingly inappropriate opioid prescribing practices.
  - Duplicate opioid prescriptions that may have potential interaction when concurrently used; and
  - The existence of insufficient or lack of coordination and communication among providers.
- Invites subject matter experts to its regular meeting to obtain clarification and share ideas helpful in finding solutions to challenges and problems observed in practice.

Fee for Service Medicaid Pharmacy Benefit Manager (PBM)

- Implements all applicable policies and procedures that govern the opioids prescribing and use.
- Documents and acknowledges prior authorization requests for opioids.
- Performs clinical reviews of prior authorization requests and provides responses to requestors within the established turnaround time.
- Facilitates the process of communication and notification to providers and beneficiaries.
- Creates mechanisms and relevant system edits that help manage the appropriateness of the prescribed opioids.
- Performs audits when deemed necessary and shares and reports any peculiar findings and encounters to both the DHCF and DUR Board.

Managed Care Organization (MCO)

- Develops policies and procedures that govern opioid prescribing and use in consultation with DHCF; and implements all applicable policies and procedures as directed.
- Provides educational outreaches; and facilitates the process of communication and notification to providers and beneficiaries.
- Performs clinical reviews of prior authorization requests and provides response to requestors within the established turnaround time.
- Resolves escalated issues related to coverage, step therapy, clinical, or prior authorization requirements.
- Creates mechanisms and relevant system edits that help manage the appropriateness of the prescribed opioids.
- Prepares and compiles annual reports to meet federal and state requirements
- Performs audits when deemed necessary and shares and reports any findings and encountered problems or learned experiences to DHCF and at the District's DUR Board regular meeting.
- Receives complaints related to any inappropriate practices, fraud, or abuse case and when necessary, reports the case to concerned parties for auditing or possible fraud and abuse investigations.

Other Key Players

Healthcare professional associations, behavioral health, SUD treatment specialists, regulators, social work, housing authority, court system/drug court, prison health care, substance use disorder treatment facilities, and employment services have corresponding roles to play in the management and control of opioid use. They can play roles in areas such as:

- Creating awareness.
- Facilitating the successful adoption and implementation of available policies and procedures.
- Constructing collaborative strategies, initiatives, policies aimed at improving prescriber education, and increasing awareness on using PDMP.
- Developing and maintaining professional competence.
- Educating patients about available treatment options; treatment benefits; risks including addiction, physical dependence, and tolerance, overdosage; potential drug-drug-disease interactions taking into consideration issues that include the patient's learning style, literacy, culture, language, and psychological and physiological barriers etc.
- Sharing, communicating, and reporting when aberrant drug related behaviors are observed
- Providing continuing education programs on opioid use and management.
- Providing evidence-based information regarding prescribing, dispensing, use and management of opioids.
- Creating a care coordination system to maintain continuity of care and patient adherence to prescribed opioids. The purpose is to maintain continuity of care, prevent relapse due to treatment interruption, and provide people with substance use disorders with the opportunities to go into treatment, particularly those with substance use disorders and end up becoming incarcerated and going to and from the prison system.
- Share information, encountered challenges and success stories that may help learn from everyone's perspective are synergistic and important approaches to remediate the problem and facilitate a successful adoption and implementation of policies and procedures.
- Improve treatment outcome and selection and determine an appropriate dosing of a medication-assisted treatment by incorporating pharmacogenomic testing in people with substance use disorders.

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FOOTNOTES

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