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Scott Walker, Governor
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TELECONFERENCE/VIRTUAL MEETING

OPTOMETRY EXAMINING BOARD
Room 121C, 1400 East Washington Avenue, Madison
Contact: Thomas Ryan (608) 266-2112
February 16, 2017

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.

AGENDA

9:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-3)

B. Approval of Minutes – October 27, 2016 (4-6)

C. Conflicts of Interest

D. Administrative Updates (7-12)
1) Department and Staff Updates
2) Introductions, Announcements, and Recognitions
   a. Peter Sorce, Public Member
3) Appointments, Reappointments, and Confirmations
4) Board Member – Term Expiration Date
   a. Ann Carli – 07/01/2014 *(reappointed, not yet confirmed)*
   b. Richard Foss – 07/01/2017
   c. Brian Hammes – 07/01/2019 *(reappointed, not yet confirmed)*
   d. Mark Jinkins – 07/01/2016
   e. Robert Schulz – 07/01/2020 *(reappointed, not yet confirmed)*
   f. Peter Sorce – 07/01/2018
5) Election of Officers
6) Liaison Appointments and Delegated Authorities

E. Legislative and Administrative Rule Matters – Discussion and Consideration (81-191)
1) Proposals for Best Practices for Prescribing Controlled Substances Guidelines – Discussion and Consideration
2) Update on Legislation and Pending or Possible Rulemaking Projects

F. Federation of Associations of Regulatory Boards Advocacy Talking Points – Discussion and Consideration (192-198)

G. Speaking Engagement(s), Travel, or Public Relation Request(s) – Discussion and Consideration (199-201)

1) National Board of Examiners in Optometry (NBEO) and Associated Regulatory Boards of Optometry (ARBO) Annual Meeting – June 18-20, 2017 in Washington, D.C. – Board Consideration of Attendance and Scholarship Offer
2) Citizens Advocacy Center (CAC) Annual Meeting

H. Informational Items

I. Items Added After Preparation of Agenda:

1) Introductions, Announcements and Recognition
2) Nominations, Elections, and Appointments
3) Board Liaison Training and Appointment of Mentors
4) Administrative Updates
5) Education and Examination Matters
6) Credentialing Matters
7) Practice Matters
8) Legislation/Administrative Rule Matters
9) Liaison, Panel, and Committee Report(s)
10) Informational Item(s)
11) Disciplinary Matters
12) Presentations of Petition(s) for Summary Suspension
13) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
14) Presentation of Proposed Decisions
15) Presentation of Interim Order(s)
16) Petitions for Re-Hearing
17) Petitions for Assessments
18) Petitions to Vacate Order(s)
19) Petitions for Designation of Hearing Examiner
20) Requests for Disciplinary Proceeding Presentations
21) Motions
22) Petitions
23) Appearances from Requests Received or Renewed
24) Speaking Engagement(s), Travel, or Public Relation Request(s), and Reports

J. Public Comments

K. Future Agenda Items

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

L. Education and Examination Matters (202-203)

1) ARBO Member Survey – Clinical Skills Exam – NBEO Part III

M. Deliberation of Items Added After Preparation of the Agenda

1) Education and Examination Matters
2) Credentialing Matters
3) Disciplinary Matters

4) Monitoring Matters
5) Professional Assistance Procedure (PAP) Matters
6) Board Liaison Training
7) Petition(s) for Summary Suspensions
8) Proposed Stipulations, Final Decisions and Orders
9) Administrative Warnings
10) Proposed Decisions
11) Matters Relating to Costs
12) Complaints
13) Case Closings
14) Case Status Report
15) Petition(s) for Extension of Time
16) Proposed Interim Orders
17) Petitions for Assessments and Evaluations
18) Petitions to Vacate Orders
19) Remedial Education Cases
20) Motions
21) Petitions for Re-Hearing
22) Appearances from Requests Received or Renewed

N. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

O. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate

P. Open Session Items Noticed Above not Completed in the Initial Open Session

ADJOURNMENT

The Next Scheduled Meeting is March 16, 2017.

OPTOMETRY EXAMINING BOARD
VIRTUAL TELECONFERENCE MEETING MINUTES
OCTOBER 27, 2016

PRESENT: Ann Meier Carli *(via GoToMeeting)*, Richard Foss *(via GoToMeeting)*, Brian Hammes *(via GoToMeeting)*, Mark Jinkins *(via GoToMeeting)*, Robert Schulz *(via GoToMeeting)*

STAFF: Thomas Ryan - Executive Director, Nilajah Hardin - Bureau Assistant, Sharon Henes – Administrative Rules Coordinator and other DSPS Staff

CALL TO ORDER

Ann Meier Carli, Chair, called the meeting to order at 9:00 A.M. A quorum of five (5) members was confirmed.

ADOPTION OF AGENDA

MOTION: Mark Jinkins moved, seconded by Brian Hammes, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES

MOTION: Mark Jinkins moved, seconded by Robert Schulz, to approve the minutes of March 31, 2016 as published. Motion carried unanimously.

PASSING OF DR. VICTOR CONNORS

MOTION: Richard Foss moved, seconded by Brian Hammes, to recognize Dr. Victor Connors for his years of service on the Wisconsin Optometry Examining Board and to send a letter to his family. Motion carried unanimously.

LEGISLATIVE AND ADMINISTRATIVE RULE MATTERS

Adoption Order Clearinghouse Rule 15-079 Relating to Board Organization

MOTION: Mark Jinkins moved, seconded by Ann Meier Carli, to approve the Adoption Order for Clearinghouse Rule 15-079 Relating to Board Organization. Motion carried unanimously.

Adoption Order Clearinghouse Rule 15-078 Relating to Exam, Unprofessional Conduct and Renewal

MOTION: Mark Jinkins moved, seconded by Brian Hammes, to approve the Adoption Order for Clearinghouse Rule 15-078 Relating to Exam, Unprofessional Conduct and Renewal. Motion carried unanimously.

Proposal for Amending Opt 8 Relating to Continuing Education

MOTION: Mark Jinkins moved, seconded by Robert Schulz, to authorize the Chief Presiding Officer to approve the preliminary rule draft of Opt 8 relating to Continuing Education for posting of economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

PUBLIC COMMENTS

Peter Theo, Executive Director of the Wisconsin Optometric Association (WOA) noted his appreciation for Dr. Victor Connors' service on behalf of the citizens of Wisconsin and for his many years of professional service.

CLOSED SESSION MOTION

MOTION: Mark Jinkins moved seconded by Brian Hammes, to convene to closed session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85 (1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.). Ann Meier Carli read the language of the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Ann Meier Carli- yes; Richard Foss-yes; Mark Jinkins-yes; Brian Hammes-yes; Robert Schulz-yes. Motion carried unanimously.

The Board convened into Closed Session at 11:29 a.m.

RECONVENE TO OPEN SESSION

MOTION: Ann Meier Carli moved, seconded by Mark Jinkins to reconvene in Open Session at 11:31 a.m. Motion carried unanimously.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Mark Jinkins moved, seconded by Ann Meier Carli, to affirm all motions made and votes taken in closed session. Motion carried unanimously.

DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Proposed Stipulation(s), Final Decisions and Order(s)

15 OPT 005 – Darwin Chentnik, O.D.

MOTION: Mark Jinkins moved, seconded by Ann Meier Carli, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Darwin Chentnik, O.D., DLSC case number 15 OPT 005. Motion carried unanimously.

MOTION: Ann Meier Carli moved, seconded by Mark Jinkins, to authorize Tom Ryan to sign the Stipulation and Final Decision and Order approved today on behalf of the Chair. Motion carried unanimously.

ADJOURNMENT

MOTION: Brian Hammes moved, seconded by Robert Schulz, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:36 A.M.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Nifty Lynn Dio, Bureau Assistant	01/04/2017 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Optometry Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
02/16/2017	☒ Yes ☐ No	Administrative Updates 1. Election of Officers 2. Liaison Appointments and Delegated Authorities

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes (Fill out Board Appearance Request) ☒ No	N/A

10) Describe the issue and action that should be addressed:

2016 ELECTION RESULTS	
Board Chair	Ann Meier Carli
Vice Chair	Robert Schulz
Secretary	Mark Jinkins

11) Authorization

Nifty Lynn Dio **01/04/2017**

Signature of person making this request — Date

Supervisor (if required) — Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — Date

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

2016 ELECTION RESULTS	
Board Chair	Ann Meier Carli
Vice Chair	Robert Schulz
Secretary	Mark Jinkins

2016 LIAISON APPOINTMENTS	
Professional Assistance Procedure (PAP) Liaison(s)	Mark Jinkins
Monitoring Liaison	Mark Jinkins
Credentialing Liaison(s)	Ann Meier Carli
Education and Exams Liaison(s)	Richard Foss
Prescription Drug Monitoring Program Liaison (PDMP) Liaison(s)	Victor Connors

2016 SCREENING PANEL APPOINTMENTS	
January-December 2016	Richard Foss, Mark Jinkins, Robert Schulz

MOTION: Mark Jinkins moved, seconded by Robert Schulz, to designate the Chair as the legislative liaison regarding telehealth and to speak on behalf of the Board regarding this matter. Motion carried unanimously.

Delegated Authority for Urgent Matters

MOTION: Mark Jinkins moved, seconded by Robert Schulz, that, in order to facilitate the completion of assignments between meetings, the Board delegates its authority by order of succession to the Chair, highest ranking officer, or longest serving member of the Board, to appoint liaisons to the Department to act in urgent matters, make appointments to vacant liaison, panel and committee positions, and to act when knowledge or experience in the profession is required to carry out the duties of the Board in accordance with the law. Motion carried unanimously.

Delegated Authority for Application Denial Reviews

MOTION: Ann Meier Carli moved, seconded by Richard Foss, that the Board counsel or another department attorney is formally authorized to serve as the Board's designee for purposes of Wis. Admin Code § SPS 1.08(1). Motion carried unanimously.

Document Signature Delegation

MOTION: Mark Jinkins moved, seconded by Robert Schulz, to delegate authority to the Chair or chief presiding officer, or longest serving member of the Board, by order of succession, to sign documents on behalf of the Board. In order to carry out duties of the Board, the Chair, chief presiding officer, or longest serving member of the Board, has the ability to delegate this signature authority for purposes of facilitating the completion of assignments during or between meetings. The Chair, chief presiding officer, or longest serving member of the Board delegates the authority to Executive Director or designee to sign the name of any Board member on documents as necessary and appropriate. Motion carried unanimously.

Credentialing Authority Delegations

MOTION: Ann Meier Carli moved, seconded by Robert Schulz, to delegate authority to the Credentialing Liaisons to make all credentialing decisions. Motion carried unanimously.

MOTION: Mark Jinkins moved, seconded by Robert Schulz, to delegate credentialing authority to DSPS for those submitted applications that meet the criteria of Rule and Statute and thereby would not need further Board or Board liaison review. Motion carried unanimously.

Monitoring Delegation

MOTION: Robert Schulz moved, seconded by Ann Meier Carli, to affirm the Chair's appointment of Mark Jinkins as the Monitoring Liaison, to adopt the 'Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor' document as included in the agenda packet. Motion carried unanimously.

PDMP Delegation

MOTION: Ann Meier Carli moved, seconded by Richard Foss, to delegate authority to the Prescription Drug Monitoring Program (PDMP) Liaison for all matters relating to PDMP. Motion carried unanimously.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Kelley Sankbeil Monitoring Supervisor Division of Legal Services and Compliance	January 21, 2017 **Items will be considered late if submitted after 4:30 p.m. and less than:** ▪ **10 work days before the meeting for Medical Board** ▪ **14 work days before the meeting for all others**

3) Name of Board, Committee, Council, Sections:
Optometry Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
February 16, 2017	☒ **Yes** ☐ **No**	Delegation of Authority to Monitoring Liaison and Department Monitor

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ **Open Session** ☐ **Closed Session** ☐ **Both**	☐ **Yes (Fill out Board Appearance Request)** ☒ **No**	

10) Describe the issue and action that should be addressed:

Delegated Authority Motion:

"_____ moved, seconded by _____ to adopt/reject the Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor document as presented in today's agenda packet."

11) **Authorization**

January 21, 2017

Signature of person making this request **Date**

Supervisor (if required) **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:
1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

Roles and Authorities Delegated to the Monitoring Liaison and Department Monitor

The Monitoring Liaison ("Liaison") is a Board/Section designee who works with department monitors to enforce Board/Section orders as explained below.

Current Authorities Delegated to the Monitoring Liaison

The Liaison may take the following actions on behalf of the Board/Section:

1. Grant a temporary reduction in random drug screen frequency upon Respondent's request if he/she is unemployed and is otherwise compliant with Board/Section order. The temporary reduction will be in effect until Respondent secures employment in the profession. The Department Monitor ("Monitor") will draft an order and sign on behalf of the Liaison.

2. Grant a stay of suspension if Respondent is eligible per the Board/Section order. The Monitor will draft an order and sign on behalf of the Liaison.

3. Remove the stay of suspension if there are repeated violations or a substantial violation of the Board/Section order. In conjunction with removal of any stay of suspension, the Liaison may prohibit Respondent from seeking reinstatement of the stay for a specified period of time. The Monitor will draft an order and sign on behalf of the Liaison.

4. Grant or deny approval when Respondent proposes continuing/remedial education courses, treatment providers, mentors, supervisors, change of employment, etc. unless the order specifically requires full-Board/Section approval.

5. Grant a maximum of one 90-day extension, if warranted and requested in writing by Respondent, to complete Board/Section-ordered continuing education.

6. Grant a maximum of one extension or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by Respondent.

7. Grant full reinstatement of licensure if Respondent has fully complied with all terms of the order without deviation. The Monitor will draft an order and obtain the signature or written authorization from the Liaison.

8. Grant or deny a request to appear before the Board/Section in closed session.

9. Dentistry only – delegated authority to the monitoring liaison to approve or deny a request from a respondent.

Current Authorities Delegated to the Department Monitor

The Monitor may take the following actions on behalf of the Board/Section, draft an order and sign:

1. Grant full reinstatement of licensure if CE is the sole condition of the limitation and Respondent has submitted the required proof of completion for approved courses.

2. Suspend the license if Respondent has not completed Board/Section-ordered CE and/or paid costs and forfeitures within the time specified by the Board/Section order. The Monitor may remove the suspension and issue an order when proof completion and/or payment have been received.

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: **Sharon Henes** **Administrative Rules Coordinator**	2) Date When Request Submitted: **18 January 2017** Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Optometry Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
2 February 2017	☐ Yes ☐ No	**Proposals for Best Practices for Prescribing Controlled Substances Guidelines – Discussion and Consideration**

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session ☐ Both	☐ Yes (Fill out Board Appearance Request) ☐ No	

10) Describe the issue and action that should be addressed:

11) Authorization

Sharon Henes *Sharon Henes*

Signature of person making this request Date

Supervisor (if required) Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date

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Kenneth Simons
Chairperson

Timothy Westlake
Vice Chairperson

Mary Jo Capodice
Secretary

WISCONSIN MEDICAL EXAMINING BOARD

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Wisconsin Medical Examining Board Opioid Prescribing Guideline – November 16, 2016

Scope and purpose of the guideline: To help providers make informed decisions about acute and chronic pain treatment -pain lasting longer than three months or past the time of normal tissue healing. The guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care. Although not specifically designed for pediatric pain, many of the principals upon which they are based could be applied there, as well.

Opioids pose a potential risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

Identify and treat the cause of the pain, use non-opioid therapies
Use non-pharmacologic therapies (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) and non-opioid pharmacologic therapies (such as acetaminophen and anti-inflammatories) for acute and chronic pain. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

Start low and go slow
When opioids are used, prescribe the lowest possible effective dosage and start with immediate-release opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain.

Close follow-up
Regularly monitor patients to make sure opioids are improving pain and function without causing harm. If benefits do not outweigh harms, optimize other therapies and work with patients to taper or discontinue opioids, if needed.

What's included in the guideline?
The guideline addresses patient-centered clinical practices including conducting thorough assessments, considering all possible treatments, treating the cause of the pain, closely monitoring risks, and safely discontinuing opioids. The three main focus areas in the guideline include:

1. **Determining when to initiate or continue opioids**
   -Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
   -Establishment of treatment goals
   -Discussion of risks and benefits of therapy with patients

2. **Opioid selection, dosage, duration, follow-up and discontinuation**
   -Selection of immediate-release or extended-release and long-acting opioids
   -Dosage considerations
   -Duration of treatment
   -Considerations for follow-up and discontinuation of opioid therapy

3. **Assessing risk and addressing harms of opioid use**
   -Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk
   -Review of prescription drug monitoring program (PDMP) data
   -Use of urine drug testing
   -Considerations for co-prescribing benzodiazepines
   -Arrangement of treatment for opioid use disorder

Prescription Opioid Guideline

1. Pain is a subjective experience and at present, physicians lack options to objectively quantify pain severity other than by patient reported measures including pain intensity. While accepting the patient's report of pain, the clinician must simultaneously decide if the magnitude of the pain complaint is commensurate with causative factors and if these have been adequately evaluated and addressed with non-opioid therapy.

2. In treating acute pain, if opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and rarely more than 5 days' worth. Left-over pills in medicine cabinets are often the source for illicit opioid abuse in teens and young adults. When prescribing opioids, physicians should consider writing two separate prescriptions for smaller amounts of opioids with specific refill dates, rather than a single large prescription. Most patients do not fill the second prescription, thus limiting opioid excess in a patient's home and potential misuse.

3. A practitioner's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care.

   a. Patients unwilling to obtain definitive treatment for the condition causing their pain should be considered questionable candidates for opioids. If opioids are prescribed to such patients, documentation of clear clinical rationale should exist.

   b. Opioids should not be prescribed unless there is a medical condition present which would reasonably be expected to cause pain severe enough to require an opioid. For conditions where this is questionable, use of other treatments instead of opioids should be strongly considered.

   c. Consultation should be considered if diagnosis of and/or treatment for the condition causing the pain is outside of the scope of the prescribing practitioner.

4. Opioids should not necessarily be the first choice in treating acute or chronic pain.

   a. Acute pain: Evidence for opioids is weak. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments should be attempted prior to initiating opioid therapy. Although opioids could be simultaneously prescribed if it is apparent from

the patient's condition that he/she will need opioids in addition to these. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

b. Acute pain lasting beyond the expected duration: A complication of the acute pain issue (surgical complication, nonunion of fracture, etc.) should be ruled out. If complications are ruled out, a transition to non-opioid therapy (tricyclic antidepressant, serotonin/norepinephrine re-uptake inhibitor, anticonvulsant, etc.) should be attempted.

c. Chronic pain: Evidence for opioids is poor. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) should be utilized. Multiple meta-analyses demonstrate that the benefits of opioids are slight, while annualized mortality rates dramatically increased. There are few if any treatments in medicine with this poor a risk/benefit ratio, and there should be adequate clinical indication to indicate why chronic opioid therapy was chosen in a given patient. **Note:** There is no high-quality evidence to support opioid therapy longer than 6 months in duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior.

d. Patients unwilling to accept non-pharmacological and/or nonnarcotic treatments (or those providing questionably credible justifications for not using them) should not be considered candidates for opioid therapy.

5. Patients should not receive opioid prescriptions from multiple physicians. There should be a dedicated provider such as a primary care or pain specialist to provide all opioids used in treating any patient's chronic pain, with existing pain contracts being honored. Physicians should avoid prescribing controlled substances for patients who have run out of previously prescribed medication or have had previous prescriptions lost or stolen.

6. Physicians should avoid using intravenous or intramuscular opioid injections for patients with exacerbations of chronic non-cancer pain in the emergency department or urgent care setting.

7. Physicians are encouraged to review the patient's history of controlled substance prescriptions using the Wisconsin Prescription Drug Monitoring Program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing any controlled substance for greater than a three-day supply.

8. Pain from acute trauma or chronic degenerative diseases can oftentimes be managed without opioids prior to surgery. Surgical patients using opioids preoperatively have higher complications rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery.

9. Prescribing of opioids is strongly discouraged in patients taking benzodiazepines or other respiratory depressants. Benzodiazepines triple the already high increases in respiratory depression and annual mortality rates from opioids. If they are used concurrently, clear clinical rationale must exist.

10. The use of oxycodone is discouraged. There is no evidence to support that oxycodone is more effective than other oral opioids, while there are multiple studies indicating that oxycodone is more abused and has qualities that would promote addiction to a greater degree than other opioids. As a result, oxycodone should not be considered first-line and should be used only in patients who cannot tolerate other opioids and who have been evaluated for and found not to demonstrate increased risk of abuse.

11. Patients presenting for chronic pain treatment should have a thorough evaluation, which may include the following:

- **a.** Medical history and physical examination targeted to the pain condition.
- **b.** Nature and intensity of the pain.
- **c.** Current and past treatments, with response to each treatment.
- **d.** Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e., renal disease, sleep apnea, chronic obstructive pulmonary disease (COPD), etc.).
- **e.** Effect of pain on physical and psychological functioning.
- **f.** Personal and family history of substance abuse.
- **g.** History of psychiatric disorders associated with opioid abuse (bipolar, attention deficit disorders (ADD/ADHD), sociopathic, borderline, untreated/severe depression).
- **h.** Medical indication(s) for use of opioids.

12. Initiation of opioids for chronic pain should be considered on a trial basis. Prior to starting opioids, objective symptomatic and functional goals should be established with the patient. If after a reasonable trial these goals are not met, then opioids should be weaned or discontinued.

13. Practitioners should always consider the risk-benefit ratio when deciding whether to start or continue opioids. Risks and benefits should be discussed with patients prior to initiating chronic opioid therapy, and continue to be reassessed during that therapy. If evidence of increased risk develops, weaning or discontinuation of opioids should be considered. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be discontinued and the patient should be treated for withdrawal, if needed.

- **a.** Exceptions to this include patients with unstable angina and pregnant patients, especially in the 3rd trimester (withdrawal could precipitate pre-term labor).
- **b.** Components of ongoing assessment of risk include:
  - **i.** Review of the Prescription Drug Monitoring Program (PDMP) information.
  - **ii.** Periodic urine drug testing (including chromatography) – at least yearly in low risk cases, more frequently with evidence of increased risk.
  - **iii.** Periodic pill counts – at least yearly in low risk cases, more frequently if evidence of increased risk.
  - **iv.** Violations of the opioid agreement.

14. All patients on chronic opioid therapy should have informed consent consisting of:

- **a.** Specifically detailing significant possible adverse effects of opioids, including (but not limited to) addiction, overdose, and death.
- **b.** Treatment agreement, documenting the behaviors required of the patient by the prescribing practitioner to ensure that they are remaining safe from these adverse effects.

15. Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long-acting agents for a majority of the daily dose.

16. Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents (MMEs), additional precautions should be implemented (see #13.b. above). Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and appropriate documentation to support such dosing should be present on the chart.

17. The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Individual responses to methadone vary widely; a given dose may have no effect on one patient while causing overdose in another. Metabolism also varies widely and is highly sensitive to multiple drug interactions, which can cause accumulation in the body and overdose. For a given analgesic effect, the respiratory depressant effect is much stronger compared to other opioids. Finally, methadone can have a potent effect on prolonging the QTc, predisposing susceptible patients to potentially fatal arrhythmias.

18. Prescribing of opioids is strongly discouraged for patients abusing illicit drugs. These patients are at extremely high risk for abuse, overdose, and death. If opioids are prescribed to such patients, a clear and compelling justification should be present.

19. During initial opioid titration, practitioners should re-evaluate patients every 1-4 weeks. During chronic therapy, patients should be seen at least every 3 months, more frequently if they demonstrate higher risk.

20. Practitioners should consider prescribing naloxone for home use in case of overdose for patients at higher risk, including:

- **a.** History of overdose (a relative contraindication to chronic opioid therapy).
- **b.** Opioid doses over 50 MMEs/day.
- **c.** Clinical depression.
- **d.** Evidence of increased risk by other measures (behaviors, family history, PDMP, UDS, risk questionnaires, etc.).

The recommended dose is 0.4 mg for IM or intranasal use, with a second dose available if the first is ineffective or wears off before EMS arrives. Family members can be prescribed naloxone for use with the patient.

21. All practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder. As a result, if a patient receiving opioids develops behaviors indicative of opioid use disorder, the practitioner, when possible, should assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an appropriate treatment center or provider willing to accept the patient. Discharging a patient from the provider's practice solely due to an opioid use disorder is not considered acceptable.

22. Discontinuing Opioid Therapy

a. If lack of efficacy of opioid therapy is determined, discontinuation of therapy should be performed.

i. Opioid weaning can be performed by reducing the MED by 10% weekly until 5-10 mg MED remain at which time the opioid can be fully discontinued.

ii. Prescription of clonidine 0.2 mg po BID or tizanidine 2 mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.

b. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered.

i. Opioid weaning can be performed by reducing the MED by 25% weekly until 5-10 mg MED remain at which time the opioid can be fully discontinued.

ii. Prescription of clonidine 0.2 mg po BID or tizanidine 2 mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.

iii. Physicians can consider weekly or bi-monthly follow-up during the weaning process.

c. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be immediately discontinued and the patient should be treated for withdrawal, if needed.

Exceptions to abrupt opioid discontinuation include patients with unstable angina and pregnant patients. These patients should be weaned from the opioid medications in a gradual manner with close follow-up.

Resources

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Board of Nursing
Best Practices for Prescribing Controlled Substances Guidelines

(approved January, 12, 2017)

2015 Wisconsin Act 269 granted authority to the Board of Nursing to issue guidelines regarding best practices in prescribing controlled substances, as defined in s. 961.01 (4), Stats., for persons credentialed by the Board of Nursing who are authorized to prescribe controlled substances.

The purpose of these guidelines are to provide guidance to advanced practice nurse prescribers for prescribing controlled substances. These guidelines are intended to supplement and not replace the individual advanced practice nurse prescriber's clinical judgment. The guidelines are not intended to address prescribing practices related to patients who are in active cancer treatment, palliative care, or end-of-life care.

It is important for advanced practice nurse prescribers to routinely discuss with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to make decisions and to safely operate machinery or a vehicle in any mode of transportation. Patients should be informed that there could be an increased effect when the patient is sick or there is a change in medication dosage.

Prior to prescribing controlled substances, there should be a well-documented evaluation which includes reason to treat and a history and physical. A review of the Prescription Drug Monitoring Program (PDMP) should also be completed. The patient should be provided with education and a notice regarding use of controlled substances including risks, benefits, prohibition on sharing and how to properly dispose of controlled substances.

Opioid Prescribing

1. Non-pharmacologic and/or non-opioid therapy should be strongly considered prior to prescribing opioids. Opioids should be used only if the expected benefits for pain and function outweigh risk to the patient. If opioids are prescribed, non-pharmacologic and/or non-opioid therapy should also be utilized as part of a multimodal approach.

2. Before starting opioid therapy for chronic pain, advance practice nurse prescribers should establish treatment goals with all patients, including realistic goals for pain and function. An advanced practice nurse prescriber should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

3. The advanced practice nurse prescriber should consider a controlled substances agreement in chronic pain situations.

4. The management plan should incorporate strategies to mitigate risk.

5. The advanced practice nurse prescriber may consider ordering naloxone in individual cases based upon the advanced practice nurse prescriber's nursing judgement.

6. Extended-release or long-acting opioids should not be prescribed for acute pain. When starting opioid therapy for chronic pain, advanced practice nurse prescribers should prescribe immediate-release opioids instead of extended-release or long-acting opioids.

7. Advanced practice nurse prescribers utilizing sound clinical judgement should do all of the following:

    a. Use caution when prescribing at any dosage.
    b. Prescribe the lowest effective dosage.
    c. Reassess individual benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents per day.
    d. Avoid increasing to or maintaining dosage at ≥ 90 morphine milligram equivalents per day unless the advanced practice nurse prescriber justifies and documents the decision.
    e. Consider opioid taper, opioid detoxification, or pain management consultation prior to increasing to high doses.

8. When opioids are prescribed for acute pain, the quantity prescribed should be no greater than the expected duration of pain. Three days or less will often be sufficient.

9. If acute pain requires ongoing opioid therapy beyond the expected duration, the patient should be re-evaluated or referred to a pain management specialist.

10. Before opioid dose changes, the advanced practice nurse prescriber should re-evaluate the patient, including benefits, harms and whether another drug is appropriate. The patient should also be re-evaluated at least every 3 months. If the harms outweigh the benefits of continued opioid therapy, the advanced practice nurse prescriber should use other therapies and work with patient to taper opioids to lower dose or discontinue.

11. Advanced practice nurse prescribers should review the patient's history of controlled substance prescriptions through the PDMP to determine whether the patient is receiving opioid dosages or dangerous combinations that put the patient at high risk. The PDMP data should be reviewed prior to starting a patient on opioid therapy and frequently during the opioid therapy. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing any controlled substance for greater than a three day supply.

12. Advanced practice nurse prescribers should use pill counts and/or urine drug testing, including chromatography. The frequency shall be based upon the patient's risk factors. A high risk patient should have observed urine collection.

13. If you have a patient with opioid use disorder, advanced practice nurse prescribers should offer or arrange evidence-based treatment, including methods of detoxification.

14. A patient should not be prescribed opioid and benzodiazepines concurrently, whether the prescribing is done by one practitioner or multiple practitioners. If a patient is taking opioids and benzodiazepines concurrently, clear clinical rationale must exist.

Benzodiazepines Prescribing

1. A trial of non-pharmacologic therapy should be done prior to prescribing benzodiazepines. Benzodiazepines should be used only if the expected benefits outweigh risk to the patient. If benzodiazepines are prescribed, non-pharmacologic therapy should also be utilized as appropriate.

2. Before starting benzodiazepine therapy, advance practice nurse prescribers should establish treatment goals with the patient. The advanced practice nurse prescriber should utilize a controlled substances agreement. An advanced practice nurse prescriber should continue benzodiazepine therapy only if there is clinical benefit that outweighs risks to patient safety.

3. When starting benzodiazepine therapy, advanced practice nurse prescribers should prescribe short-acting benzodiazepines instead of long-acting benzodiazepines.

4. The advanced practice nurse prescriber should continually re-evaluate during benzodiazepine therapy. Consider alternative therapy prior to dose escalation.

5. Advanced practice nurse prescribers should review the patient's history of controlled substance prescriptions through the Prescription Drug Monitoring Program (PDMP) to determine whether the patient is receiving benzodiazepines or dangerous combinations that put the patient at high risk. The PDMP data should be reviewed prior to starting a patient on benzodiazepine therapy and frequently during the benzodiazepine therapy. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing any controlled substance for greater than a three day supply.

6. Advanced practice nurse prescribers should use pill counts and/or urine drug testing, including chromatography. The frequency shall be based upon the patient's risk factors. A high risk patient should have observed urine collection.

7. If you have a patient with substance use disorder, advanced practice nurse prescribers should offer or arrange evidence-based treatment, including methods of detoxification.

8. A patient should not be prescribed benzodiazepines and opioids concurrently, whether the prescribing is done by one practitioner or multiple practitioners. If a patient is taking opioids and benzodiazepines concurrently, clear clinical rationale must exist.

Stimulants Prescribing

1. Advanced practice nurse prescribers should ensure there is adequate testing, assessment and diagnosis prior to prescribing stimulants.

2. Before starting stimulant therapy, advance practice nurse prescribers should establish treatment goals with the patient. The advanced practice nurse prescriber should utilize a controlled substances agreement.

3. Advanced practice nurse prescribers should review the patient's history of controlled substance prescriptions through the PDMP to determine whether the patient is receiving stimulation dosages or dangerous combination that put the patient at high risk. The PDMP data should be reviewed prior to starting a patient on stimulant therapy and frequently during the stimulant therapy. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing any controlled substance for greater than a three day supply.

4. Advanced practice nurse prescribers should use pill counts and/or urine drug testing, including chromatography. The frequency shall be based upon the patient's risk factors. A high risk patient should have observed urine collection.

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

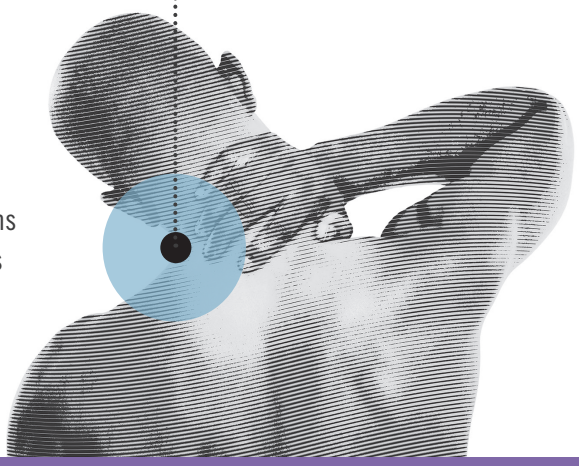
1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic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

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

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

CLINICAL REMINDERS

- **Opioids are not first-line or routine therapy for chronic pain**
- **Establish and measure goals for pain and function**
- **Discuss benefits and risks and availability of nonopioid therapies with patient**



OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed

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

5 When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

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

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

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

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

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

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

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

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

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

Please note: An erratum has been published for this issue. To view the erratum, please click here.

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

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

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Centers for Disease Control and Prevention

CONTENTS

Introduction 1
Guideline Development Methods 4
Summary of the Clinical Evidence Review 8
Summary of the Contextual Evidence Review 11
Recommendations 16
Conclusions and Future Directions 33
References 35

Disclosure of Relationship

The Core Expert Group (CEG) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Pam Archer discloses authorship of the Oklahoma Emergency Department and Urgent Care Clinic Opioid Prescribing Guidelines and the Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office Based Setting; Bonnie Burman discloses authorship of the Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain; Jane Ballantyne discloses that she has served as a paid consultant to Cohen Milstein Sellers & Toll, PLLC, and has special advisory committee responsibilities on the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies committee; Phillip Coffin discloses that in 2012 he provided expert testimony to the California State Assembly regarding a bill to expand naloxone access and reports that he is the principal investigator on a research study of methamphetamine dependence that receives donated injectable naltrexone from Alkermes, Inc.; Gary Franklin discloses authorship of the AMDG Interagency Guideline on Prescribing Opioids for Pain; Erin Krebs discloses that she represented the American College of Physicians at a 2014 Food and Drug Administration meeting on Abuse Deterrent Opioid Formulations; Lewis Nelson discloses his ad-hoc membership on the FDA Drug Safety and Risk Management Advisory Committee; Trupti Patel discloses authorship of the Arizona Opioid Prescribing Guidelines; Robert "Chuck" Rich discloses that he was an author of the 2013 American Academy of Family Physicians position paper on opioids and pain management; Joanna Starrels discloses that she received honoraria from the Betty Ford Institute; Thomas Tape discloses that he was an author of the 2013 American College of Physicians policy position paper on prescription drug abuse. CDC provided 100% of the funding for the supplemental evidence review tasks and meeting support. No foundation or industry support was accepted.

The Opioid Guideline Workgroup (OGW) members disclose that they have no financial conflicts of interest. Experts disclose the following activities related to the content of this guideline: Anne Burns discloses that she participated in a congressional briefing sponsored by Reps. Carter and DeSaulnier on the pharmacist's role of furnishing Naloxone and that she participates on the National Advisory Board for the Prescription Drug Abuse and Heroin Summit. Chinazo Cunningham discloses that her husband is employed by Quest Diagnostics and Dr. Cunningham was recused from any discussion related to urine drug testing. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Erin Krebs discloses that she served on the CDC Opioid Prescribing Guideline CEG. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG. Greg Terman discloses that he serves as the President of the American Pain Society. Mark Wallace discloses that he served on a Kempharma advisory panel for an abuse-deterrent hydrocodone formulation to treat acute postoperative pain and Dr. Wallace was recused form any discussion related to abuse-deterrent drugs.

The NCIPC Board of Scientific Counselors (BSC) members disclose that they have no financial conflicts of interest. Two BSC members, Traci Green and Christina Porucznik, served on the Opioid Guideline Workgroup. Traci Green discloses that she was previously employed by Inflexxion, a small business that conducts Small Business Innovation Research on behavioral interventions for behavioral health and chronic pain and created several psychometric tools for conducting risk assessment for prescription opioid abuse potential. Dr. Green also discloses that while at the hospital where she is employed, she provided consultation to Purdue Pharma Ltd to design overdose prevention brochures for persons who use diverted prescription opioids non-medically with an emphasis on persons who inject prescription drugs, and not for patients using opioid therapy for pain. Dr. Green was recused from any discussion related to risk assessment tools and patient education materials. Christina Porucznik discloses that she served on the CDC Opioid Prescribing Guideline CEG.

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

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Summary

This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guideline addresses 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use. CDC developed the guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, and recommendations are made on the basis of a systematic review of the scientific evidence while considering benefits and harms, values and preferences, and resource allocation. CDC obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee. It is important that patients receive appropriate pain treatment with careful consideration of the benefits and risks of treatment options. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC has provided a checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025) as well as a website (http://www.cdc.gov/drugoverdose/prescribingresources.html) with additional tools to guide clinicians in implementing the recommendations.

Introduction

Background

Opioids are commonly prescribed for pain. An estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription (*1*). In 2012, health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills (*2*). Opioid prescriptions per capita increased 7.3% from 2007 to 2012, with opioid prescribing rates increasing more for family practice, general practice, and internal medicine compared with other specialties (*3*). Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among clinicians on how to use opioid pain medication (*2*).

Prevention, assessment, and treatment of chronic pain are challenges for health providers and systems. Pain might go unrecognized, and patients, particularly members of racial and ethnic minority groups, women, the elderly, persons with cognitive impairment, and those with cancer and at the end of life, can be at risk for inadequate pain treatment (*4*). Patients can experience persistent pain that is not well controlled. There are clinical, psychological, and social consequences associated with chronic pain including limitations in complex activities, lost work productivity, reduced quality of life, and stigma, emphasizing the importance of appropriate and compassionate patient care (*4*). Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options.

Chronic pain has been variably defined but is defined within this guideline as pain that typically lasts >3 months or past the time of normal tissue healing (*5*). Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause (*4*). Estimates of the prevalence of chronic pain vary, but it is clear that the number of persons experiencing chronic pain in the United States is substantial. The 1999–2002 National Health and Nutrition Examination Survey estimated that 14.6% of adults have current widespread or localized pain lasting at least 3 months (*6*). Based on a survey conducted during 2001–2003 (*7*), the overall prevalence of common, predominantly musculoskeletal pain conditions (e.g., arthritis, rheumatism, chronic back or neck problems, and frequent severe headaches) was estimated at 43% among adults in the

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United States, although minimum duration of symptoms was not specified. Most recently, analysis of data from the 2012 National Health Interview Study showed that 11.2% of adults report having daily pain (*8*). Clinicians should consider the full range of therapeutic options for the treatment of chronic pain. However, it is hard to estimate the number of persons who could potentially benefit from opioid pain medication long term. Evidence supports short-term efficacy of opioids for reducing pain and improving function in noncancer nociceptive and neuropathic pain in randomized clinical trials lasting primarily ≤12 weeks (*9*,*10*), and patients receiving opioid therapy for chronic pain report some pain relief when surveyed (*11*–*13*). However, few studies have been conducted to rigorously assess the long-term benefits of opioids for chronic pain (pain lasting >3 months) with outcomes examined at least 1 year later (*14*). On the basis of data available from health systems, researchers estimate that 9.6–11.5 million adults, or approximately 3%–4% of the adult U.S. population, were prescribed long-term opioid therapy in 2005 (*15*).

Opioid pain medication use presents serious risks, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States (*16*). In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly (*17*). Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths (*18*). The Drug Abuse Warning Network estimated that >420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available (*19*). Although clinical criteria have varied over time, opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. This disorder is manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home (*20*). This diagnosis has also been referred to as "abuse or dependence" and "addiction" in the literature, and is different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped), both of which can exist without a diagnosed disorder. In 2013, on the basis of DSM-IV diagnosis criteria, an estimated 1.9 million persons abused or were dependent on prescription opioid pain medication (*21*). Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder (*22*–*24*), highlighting the value of guidance on safer prescribing practices for clinicians. For example, a recent study of patients aged 15–64 years receiving opioids for chronic noncancer pain and followed for up to 13 years revealed that one in 550 patients died from opioid-related overdose at a median of 2.6 years from their first opioid prescription, and one in 32 patients who escalated to opioid dosages >200 morphine milligram equivalents (MME) died from opioid-related overdose (*25*).

This guideline provides recommendations for the prescribing of opioid pain medication by primary care clinicians for chronic pain (i.e., pain conditions that typically last >3 months or past the time of normal tissue healing) in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care. Although the guideline does not focus broadly on pain management, appropriate use of long-term opioid therapy must be considered within the context of all pain management strategies (including nonopioid pain medications and nonpharmacologic treatments). CDC's recommendations are made on the basis of a systematic review of the best available evidence, along with input from experts, and further review and deliberation by a federally chartered advisory committee. The guideline is intended to ensure that clinicians and patients consider safer and more effective treatment, improve patient outcomes such as reduced pain and improved function, and reduce the number of persons who develop opioid use disorder, overdose, or experience other adverse events related to these drugs. Clinical decision making should be based on a relationship between the clinician and patient, and an understanding of the patient's clinical situation, functioning, and life context. The recommendations in the guideline are voluntary, rather than prescriptive standards. They are based on emerging evidence, including observational studies or randomized clinical trials with notable limitations. Clinicians should consider the circumstances and unique needs of each patient when providing care.

Rationale

Primary care clinicians report having concerns about opioid pain medication misuse, find managing patients with chronic pain stressful, express concern about patient addiction, and report insufficient training in prescribing opioids (*26*). Across specialties, physicians believe that opioid pain medication can be effective in controlling pain, that addiction is a common consequence of prolonged use, and that long-term opioid therapy often is overprescribed for patients with chronic noncancer pain (*27*). These attitudes and beliefs, combined with increasing trends in opioid-related overdose, underscore the need for better clinician guidance on opioid prescribing. Clinical practice guidelines focused on prescribing can improve clinician knowledge, change prescribing practices (*28*), and ultimately benefit patient health.

Professional organizations, states, and federal agencies (e.g., the American Pain Society/American Academy of Pain Medicine, 2009; the Washington Agency Medical Directors Group, 2015; and the U.S. Department of Veterans Affairs/Department of Defense, 2010) have developed guidelines for opioid prescribing (*29–31*). Existing guidelines share some common elements, including dosing thresholds, cautious titration, and risk mitigation strategies such as using risk assessment tools, treatment agreements, and urine drug testing. However, there is considerable variability in the specific recommendations (e.g., range of dosing thresholds of 90 MME/day to 200 MME/day), audience (e.g., primary care clinicians versus specialists), use of evidence (e.g., systematic review, grading of evidence and recommendations, and role of expert opinion), and rigor of methods for addressing conflict of interest (*32*). Most guidelines, especially those that are not based on evidence from scientific studies published in 2010 or later, also do not reflect the most recent scientific evidence about risks related to opioid dosage.

This CDC guideline offers clarity on recommendations based on the most recent scientific evidence, informed by expert opinion and stakeholder and public input. Scientific research has identified high-risk prescribing practices that have contributed to the overdose epidemic (e.g., high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting [ER/LA] opioids for acute pain) (*24*,*33*,*34*). Using guidelines to address problematic prescribing has the potential to optimize care and improve patient safety based on evidence-based practice (*28*), as well as reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic.

Scope and Audience

This guideline is intended for primary care clinicians (e.g., family physicians and internists) who are treating patients with chronic pain (i.e., pain lasting >3 months or past the time of normal tissue healing) in outpatient settings. Prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians has been above average (*3*). Primary care clinicians include physicians as well as nurse practitioners and physician assistants. Although the focus is on primary care clinicians, because clinicians work within team-based care, the recommendations refer to and promote integrated pain management and collaborative working relationships with other providers (e.g., behavioral health providers, pharmacists, and pain management specialists). Although the transition from use of opioid therapy for acute pain to use for chronic pain is hard to predict and identify, the guideline is intended to inform clinicians who are considering prescribing opioid pain medication for painful conditions that can or have become chronic.

This guideline is intended to apply to patients aged ≥18 years with chronic pain outside of palliative and end-of-life care. For this guideline, palliative care is defined in a manner consistent with that of the Institute of Medicine as care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness. Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms (*35*). End-of-life care is defined as care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home. Patients within the scope of this guideline include cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, and are under cancer surveillance only. The guideline is not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.

The recommendations address the use of opioid pain medication in certain special populations (e.g., older adults and pregnant women) and in populations with conditions posing special risks (e.g., a history of substance use disorder). The recommendations do not address the use of opioid pain medication in children or adolescents aged <18 years. The available evidence concerning the benefits and harms of long-term opioid therapy in children and adolescents is limited, and few opioid medications provide information on the label regarding safety and effectiveness in pediatric patients. However, observational research shows significant increases in opioid prescriptions for pediatric populations from 2001 to 2010 (*36*), and a large proportion of adolescents are commonly prescribed opioid pain medications for conditions such as headache and sports injuries (e.g., in one study, 50% of adolescents presenting with headache received a prescription for an opioid pain medication [*37*,*38*]). Adolescents who misuse opioid pain medication often misuse medications from their own previous prescriptions (*39*), with an estimated 20% of adolescents with currently prescribed opioid medications reporting using them intentionally to get high or increase the effects of alcohol or other drugs (*40*). Use of prescribed opioid pain medication before high school graduation is associated with a 33% increase in the risk of later opioid misuse (*41*). Misuse of opioid pain medications in adolescence strongly predicts later onset of heroin use (*42*). Thus, risk of opioid medication use in pediatric populations is of great concern. Additional clinical trial and observational research is needed,

and encouraged, to inform development of future guidelines for this critical population.

The recommendations are not intended to provide guidance on use of opioids as part of medication-assisted treatment for opioid use disorder. Some of the recommendations might be relevant for acute care settings or other specialists, such as emergency physicians or dentists, but use in these settings or by other specialists is not the focus of this guideline. Readers are referred to other sources for prescribing recommendations within acute care settings and in dental practice, such as the American College of Emergency Physicians' guideline for prescribing of opioids in the emergency department (*43*); the American Society of Anesthesiologists' guideline for acute pain management in the perioperative setting (*44*); the Washington Agency Medical Directors' Group Interagency Guideline on Prescribing Opioids for Pain, Part II: Prescribing Opioids in the Acute and Subacute Phase (*30*); and the Pennsylvania Guidelines on the Use of Opioids in Dental Practice (*45*). In addition, given the challenges of managing the painful complications of sickle cell disease, readers are referred to the NIH National Heart, Lung, and Blood Institute's Evidence Based Management of Sickle Cell Disease Expert Panel Report for management of sickle cell disease (*46*).

Guideline Development Methods

Guideline Development Using the Grading of Recommendations Assessment, Development, and Evaluation Method

CDC developed this guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method (http://www.gradeworkinggroup.org). This method specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. The method has been adapted by the CDC Advisory Committee on Immunization Practices (ACIP) (*47*). CDC has applied the ACIP translation of the GRADE framework in this guideline. Within the ACIP GRADE framework, the body of evidence is categorized in a hierarchy. This hierarchy reflects degree of confidence in the effect of a clinical action on health outcomes. The categories include type 1 evidence (randomized clinical trials or overwhelming evidence from observational studies), type 2 evidence (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 evidence (observational studies or randomized clinical trials with notable limitations), and type 4 evidence (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). Type of evidence is categorized by study design as well as limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and a constellation of plausible biases that could change observations of effects. Type 1 evidence indicates that one can be very confident that the true effect lies close to that of the estimate of the effect; type 2 evidence means that the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; type 3 evidence means that confidence in the effect estimate is limited and the true effect might be substantially different from the estimate of the effect; and type 4 evidence indicates that one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect (*47*,*48*). When no studies are present, evidence is considered to be insufficient. The ACIP GRADE framework places recommendations in two categories, Category A and Category B. Four major factors determine the category of the recommendation: the quality of evidence, the balance between desirable and undesirable effects, values and preferences, and resource allocation (cost). Category A recommendations apply to all persons in a specified group and indicate that most patients should receive the recommended course of action. Category B recommendations indicate that there should be individual decision making; different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations (*47*). According to the GRADE methodology, a particular quality of evidence does not necessarily imply a particular strength of recommendation (*48*–*50*). Category A recommendations can be made based on type 3 or type 4 evidence when the advantages of a clinical action greatly outweigh the disadvantages based on a consideration of benefits and harms, values and preferences, and costs. Category B recommendations are made when the advantages and disadvantages of a clinical action are more balanced. GRADE methodology is discussed extensively elsewhere (*47*,*51*). The U.S. Preventive Services Task Force (USPSTF) follows different methods for developing and categorizing recommendations (http://www.uspreventiveservicestaskforce.org). USPSTF recommendations focus on preventive services and are categorized as A, B, C, D, and I. Under the Affordable Care Act, all "nongrandfathered" health plans (that is, those health plans not in existence prior to March 23, 2010 or those with significant changes to their coverage) and expanded Medicaid plans are required to cover

preventive services recommended by USPSTF with a category A or B rating with no cost sharing. The coverage requirements went into effect September 23, 2010. Similar requirements are in place for vaccinations recommended by ACIP, but do not exist for other recommendations made by CDC, including recommendations within this guideline.

A previously published systematic review sponsored by the Agency for Healthcare Research and Quality (AHRQ) on the effectiveness and risks of long-term opioid treatment of chronic pain (*14*,*52*) initially served to directly inform the recommendation statements. This systematic clinical evidence review addressed the effectiveness of long-term opioid therapy for outcomes related to pain, function, and quality of life; the comparative effectiveness of different methods for initiating and titrating opioids; the harms and adverse events associated with opioids; and the accuracy of risk-prediction instruments and effectiveness of risk mitigation strategies on outcomes related to overdose, addiction, abuse, or misuse. For the current guideline development, CDC conducted additional literature searches to update the evidence review to include more recently available publications and to answer an additional clinical question about the effect of opioid therapy for acute pain on long-term use. More details about the literature search strategies and GRADE methods applied are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026). CDC developed GRADE evidence tables to illustrate the quality of the evidence for each clinical question.

As identified in the AHRQ-sponsored clinical evidence review, the overall evidence base for the effectiveness and risks of long-term opioid therapy is low in quality per the GRADE criteria. Thus, contextual evidence is needed to provide information about the benefits and harms of nonpharmacologic and nonopioid pharmacologic therapy and the epidemiology of opioid pain medication overdose and inform the recommendations. Further, as elucidated by the GRADE Working Group, supplemental information on clinician and patient values and preferences and resource allocation can inform judgments of benefits and harms and be helpful for translating the evidence into recommendations. CDC conducted a contextual evidence review to supplement the clinical evidence review based on systematic searches of the literature. The review focused on the following four areas: effectiveness of nonpharmacologic and nonopioid pharmacologic treatments; benefits and harms related to opioid therapy (including additional studies not included in the clinical evidence review such as studies that evaluated outcomes at any duration or used observational study designs related to specific opioid pain medications, high-dose opioid therapy, co-prescription of opioids with other controlled substances, duration of opioid use, special populations, risk stratification/mitigation approaches, and effectiveness of treatments for addressing potential harms of opioid therapy); clinician and patient values and preferences; and resource allocation. CDC constructed narrative summaries of this contextual evidence and used the information to support the clinical recommendations. More details on methods for the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

On the basis of a review of the clinical and contextual evidence (review methods are described in more detail in subsequent sections of this report), CDC drafted recommendation statements focused on determining when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. To help assure the draft guideline's integrity and credibility, CDC then began a multistep review process to obtain input from experts, stakeholders, and the public to help refine the recommendations.

Solicitation of Expert Opinion

CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology.* CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

Prior to their participation, CDC asked potential experts to reveal possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Experts could not serve if they had conflicts that might have a direct and predictable effect on the recommendations. CDC excluded experts who had a financial or promotional relationship with a company

* A list of the members appears at the end of this report. The recommendations and all statements included in this guideline are those of CDC and do not necessarily represent the official position of any persons or organizations providing comments on the draft guideline.

that makes a product that might be affected by the guideline. CDC reviewed potential nonfinancial conflicts carefully (e.g., intellectual property, travel, public statements or positions such as congressional testimony) to determine if the activities would have a direct and predictable effect on the recommendations. CDC determined the risk of these types of activities to be minimal for the identified experts. All experts completed a statement certifying that there was no potential or actual conflict of interest. Activities that did not pose a conflict (e.g., participation in Food and Drug Administration [FDA] activities or other guideline efforts) are disclosed.

CDC provided to each expert written summaries of the scientific evidence (both the clinical and contextual evidence reviews conducted for this guideline) and CDC's draft recommendation statements. Experts provided individual ratings for each draft recommendation statement based on the balance of benefits and harms, evidence strength, certainty of values and preferences, cost, recommendation strength, rationale, importance, clarity, and ease of implementation. CDC hosted an in-person meeting of the experts that was held on June 23–24, 2015, in Atlanta, Georgia, to seek their views on the evidence and draft recommendations and to better understand their premeeting ratings. CDC sought the experts' individual opinions at the meeting. Although there was widespread agreement on some of the recommendations, there was disagreement on others. Experts did not vote on the recommendations or seek to come to a consensus. Decisions about recommendations to be included in the guideline, and their rationale, were made by CDC. After revising the guideline, CDC sent written copies of it to each of the experts for review and asked for any additional comments; CDC reviewed these written comments and considered them when making further revisions to the draft guideline. The experts have not reviewed the final version of the guideline.

Federal Partner Engagement

Given the scope of this guideline and the interest of agencies across the federal government in appropriate pain management, opioid prescribing, and related outcomes, CDC invited its National Institute of Occupational Safety and Health and CDC's federal partners to observe the expert meeting, provide written comments on the full draft guideline after the meeting, and review the guideline through an agency clearance process; CDC reviewed comments and incorporated changes. Interagency collaboration will be critical for translating these recommendations into clinical practice. Federal partners included representatives from the Substance Abuse and Mental Health Services Administration, the National Institute on Drug Abuse, FDA, the U.S. Department of Veterans Affairs, the U.S. Department of Defense, the Office of the National Coordinator for Health Information Technology, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, AHRQ, and the Office of National Drug Control Policy.

Stakeholder Comment

Given the importance of the guideline for a wide variety of stakeholders, CDC also invited review from a Stakeholder Review Group (SRG) to provide comment so that CDC could consider modifications that would improve the recommendations' specificity, applicability, and ease of implementation. The SRG included representatives from professional organizations that represent specialties that commonly prescribe opioids (e.g., pain medicine, physical medicine and rehabilitation), delivery systems within which opioid prescribing occurs (e.g., hospitals), and representation from community organizations with interests in pain management and opioid prescribing.* Representatives from each of the SRG organizations were provided a copy of the guideline for comment. Each of these representatives provided written comments. Once input was received from the full SRG, CDC reviewed all comments and carefully considered them when revising the draft guideline.

Constituent Engagement

To obtain initial perspectives from constituents on the recommendation statements, including clinicians and prospective patients, CDC convened a constituent engagement webinar and circulated information about the webinar in advance through announcements to partners. CDC hosted the webinar on September 16 and 17, 2015, provided information about the methodology for developing the guideline, and presented the key recommendations. A fact sheet was posted on the CDC Injury Center website (http://www.cdc.gov/injury) summarizing the guideline development process and clinical practice areas addressed in the guideline; instructions were included on how to submit comments via email. CDC received comments during and for 2 days following the first webinar. Over 1,200 constituent comments were received. Comments were reviewed and carefully considered when revising the draft guideline.

Peer Review

Per the final information quality bulletin for peer review (https://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf), peer review requirements applied to this guideline because it provides influential

scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations.* CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified. CDC placed the names of peer reviewers on the CDC and the National Center for Injury Prevention and Control Peer Review Agenda websites that are used to provide information about the peer review of influential documents. CDC reviewed peer review comments and revised the draft guideline accordingly.

Public Comment

To obtain comments from the public on the full guideline, CDC published a notice in the *Federal Register* (80 FR 77351) announcing the availability of the guideline and the supporting clinical and contextual evidence reviews for public comment. The comment period closed January 13, 2016. CDC received more than 4,350 comments from the general public, including patients with chronic pain, clinicians, families who have lost loved ones to overdose, medical associations, professional organizations, academic institutions, state and local governments, and industry. CDC reviewed each of the comments and carefully considered them when revising the draft guideline.

Federal Advisory Committee Review and Recommendation

The National Center for Injury Prevention and Control (NCIPC) Board of Scientific Counselors (BSC) is a federal advisory committee that advises and makes recommendations to the Secretary of the Department of Health and Human Services, the Director of CDC, and the Director of NCIPC.* The BSC makes recommendations regarding policies, strategies, objectives, and priorities, and reviews progress toward injury and violence prevention. CDC sought the BSC's advice on the draft guideline. BSC members are special government employees appointed as CDC advisory committee members; as such, all members completed an OGE Form 450 to disclose relevant interests. BSC members also reported on their disclosures during meetings. Disclosures for the BSC are reported in the guideline.

To assist in guideline review, on December 14, 2015, via Federal Register notice, CDC announced the intent to form an Opioid Guideline Workgroup (OGW) to provide observations on the draft guideline to the BSC. CDC provided the BSC with the draft guideline as well as summaries of comments provided to CDC by stakeholders, constituents, and peer reviewers, and edits made to the draft guideline in response. During an open meeting held on January 7, 2016, the BSC recommended the formation of the OGW. The OGW included a balance of perspectives from audiences directly affected by the guideline, audiences that would be directly involved with implementing the recommendations, and audiences qualified to provide representation. The OGW comprised clinicians, subject matter experts, and a patient representative, with the following perspectives represented: primary care, pain medicine, public health, behavioral health, substance abuse treatment, pharmacy, patients, and research.* Additional sought-after attributes were appropriate academic and clinical training and relevant clinical experience; high scientific standing; and knowledge of the patient, clinician, and caregiver perspectives. In accordance with CDC policy, two BSC committee members also served as OGW members, with one serving as the OGW Chair. The professional credentials and interests of OGW members were carefully reviewed to identify possible conflicts of interest such as financial relationships with industry, intellectual preconceptions, or previously stated public positions. Only OGW members whose interests were determined to be minimal were selected. When an activity was perceived as having the potential to affect a specific aspect of the recommendations, the activity was disclosed, and the OGW member was recused from discussions related to that specific aspect of the recommendations (e.g., urine drug testing and abuse-deterrent formulations). Disclosures for the OGW are reported. CDC and the OGW identified ad-hoc consultants to supplement the workgroup expertise, when needed, in the areas of pediatrics, occupational medicine, obstetrics and gynecology, medical ethics, addiction psychiatry, physical medicine and rehabilitation, guideline development methodology, and the perspective of a family member who lost a loved one to opioid use disorder or overdose.

The BSC charged the OGW with reviewing the quality of the clinical and contextual evidence reviews and reviewing each of the recommendation statements and accompanying rationales. For each recommendation statement, the OGW considered the quality of the evidence, the balance of benefits and risks, the values and preferences of clinicians and patients, the cost feasibility, and the category designation

Please note: An erratum has been published for this issue. To view the erratum, please click here.

of the recommendation (A or B). The OGW also reviewed supplementary documents, including input provided by the CEG, SRG, peer reviewers, and the public. OGW members discussed the guideline accordingly during virtual meetings and drafted a summary report of members' observations, including points of agreement and disagreement, and delivered the report to the BSC.

NCIPC announced an open meeting of the NCIPC BSC in the Federal Register on January 11, 2015. The BSC met on January 28, 2016, to discuss the OGW report and deliberate on the draft guideline itself. Members of the public provided comments at this meeting. After discussing the OGW report, deliberating on specific issues about the draft guideline identified at the meeting, and hearing public comment, the BSC voted unanimously: to support the observations made by the OGW; that CDC adopt the guideline recommendations that, according to the workgroup's report, had unanimous or majority support; and that CDC further consider the guideline recommendations for which the group had mixed opinions. CDC carefully considered the OGW observations, public comments, and BSC recommendations, and revised the guideline in response.

Summary of the Clinical Evidence Review

Primary Clinical Questions

CDC conducted a clinical systematic review of the scientific evidence to identify the effectiveness, benefits, and harms of long-term opioid therapy for chronic pain, consistent with the GRADE approach (*47*,*48*). Long-term opioid therapy is defined as use of opioids on most days for >3 months. A previously published AHRQ-funded systematic review on the effectiveness and risks of long-term opioid therapy for chronic pain comprehensively addressed four clinical questions (*14*,*52*). CDC, with the assistance of a methodology expert, searched the literature to identify newly published studies on these four original questions. Because long-term opioid use might be affected by use of opioids for acute pain, CDC subsequently developed a fifth clinical question (last in the series below), and in collaboration with a methodologist conducted a systematic review of the scientific evidence to address it. In brief, five clinical questions were addressed:

- The effectiveness of long-term opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for long term (≥1 year) outcomes related to pain, function, and quality of life, and how effectiveness varies according to the type/cause of pain, patient demographics, and patient comorbidities (Key Question [KQ] 1).
- The risks of opioids versus placebo or no opioids on abuse, addiction, overdose, and other harms, and how harms vary according to the type/cause of pain, patient demographics, patient comorbidities, and dose (KQ2).
- The comparative effectiveness of opioid dosing strategies (different methods for initiating and titrating opioids; immediate-release versus ER/LA opioids; different ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled, continuous versus as-needed dosing; dose escalation versus dose maintenance; opioid rotation versus maintenance; different strategies for treating acute exacerbations of chronic pain; decreasing opioid doses or tapering off versus continuation; and different tapering protocols and strategies) (KQ3).
- The accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse; the effectiveness of risk mitigation strategies (use of risk prediction instruments); effectiveness of risk mitigation strategies including opioid management plans, patient education, urine drug testing, prescription drug monitoring program (PDMP) data, monitoring instruments, monitoring intervals, pill counts, and abuse-deterrent formulations for reducing risk for opioid overdose, addiction, abuse, or misuse; and the comparative effectiveness of treatment strategies for managing patients with addiction (KQ4).
- The effects of prescribing opioid therapy versus not prescribing opioid therapy for acute pain on long-term use (KQ5).

The review was focused on the effectiveness of long-term opioid therapy on long-term (>1 year) outcomes related to pain, function, and quality of life to ensure that findings are relevant to patients with chronic pain and long-term opioid prescribing. The effectiveness of short-term opioid therapy has already been established (*10*). However, opioids have unique effects such as tolerance and physical dependence that might influence assessments of benefit over time. These effects raise questions about whether findings on short-term effectiveness of opioid therapy can be extrapolated to estimate benefits of long-term therapy for chronic pain. Thus, it is important to consider studies that provide data on long-term benefit. For certain opioid-related harms (overdose, fractures, falls, motor vehicle crashes), observational studies were included with outcomes measured at shorter intervals because such outcomes can occur early during opioid therapy, and such harms are not captured well in short-term clinical trials. A detailed listing of the key questions is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Clinical Evidence Systematic Review Methods

Complete methods and data for the 2014 AHRQ report, upon which this updated systematic review is based, have been published previously (*14*,*52*). Study authors developed the protocol using a standardized process (*53*) with input from experts and the public and registered the protocol in the PROSPERO database (*54*). For the 2014 AHRQ report, a research librarian searched MEDLINE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, PsycINFO, and CINAHL for English-language articles published January 2008 through August 2014, using search terms for opioid therapy, specific opioids, chronic pain, and comparative study designs. Also included were relevant studies from an earlier review (*10*) in which searches were conducted without a date restriction, reference lists were reviewed, and ClinicalTrials.gov was searched. CDC updated the AHRQ literature search using the same search strategies as in the original review including studies published before April, 2015. Seven additional studies met inclusion criteria and were added to the review. CDC used the GRADE approach outlined in the ACIP Handbook for Developing Evidence-Based Recommendations (*47*) to rate the quality of evidence for the full body of evidence (evidence from the 2014 AHRQ review plus the update) for each clinical question. Evidence was categorized into the following types: type 1 (randomized clinical trials or overwhelming evidence from observational studies), type 2 (randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies), type 3 (observational studies, or randomized clinical trials with notable limitations), or type 4 (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations). When no studies were present, evidence was considered to be insufficient. Per GRADE methods, type of evidence was categorized by study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects. Results were synthesized qualitatively, highlighting new evidence identified during the update process. Meta-analysis was not attempted due to the small numbers of studies, variability in study designs and clinical heterogeneity, and methodological shortcomings of the studies. More detailed information about data sources and searches, study selection, data extraction and quality assessment, data synthesis, and update search yield and new evidence for the current review is provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Summary of Findings for Clinical Questions

The main findings of this updated review are consistent with the findings of the 2014 AHRQ report (*14*). In summary, evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy, though evidence suggests risk for serious harms that appears to be dose-dependent. These findings supplement findings from a previous review of the effectiveness of opioids for adults with chronic noncancer pain. In this previous review, based on randomized trials predominantly ≤12 weeks in duration, opioids were found to be moderately effective for pain relief, with small benefits for functional outcomes; although estimates vary, based on uncontrolled studies, a high percentage of patients discontinued long-term opioid use because of lack of efficacy and because of adverse events (*10*).

The GRADE evidence summary with type of evidence ratings for the five clinical questions for the current evidence review are outlined (Table 1). This summary is based on studies included in the AHRQ 2014 review (35 studies) plus additional studies identified in the updated search (seven studies). Additional details on findings from the original review are provided in the full 2014 AHRQ report (*14*,*52*). Full details on the clinical evidence review findings supporting this guideline are provided in the Clinical Evidence Review (http://stacks.cdc.gov/view/cdc/38026).

Effectiveness

For KQ1, no study of opioid therapy versus placebo, no opioid therapy, or nonopioid therapy for chronic pain evaluated long-term (≥1 year) outcomes related to pain, function, or quality of life. Most placebo-controlled randomized clinical trials were ≤6 weeks in duration. Thus, the body of evidence for KQ1 is rated as insufficient (0 studies contributing) (*14*).

Harms

For KQ2, the body of evidence is rated as type 3 (12 studies contributing; 11 from the original review plus one new study). One fair-quality cohort study found that long-term opioid therapy is associated with increased risk for an opioid abuse or dependence diagnosis (as defined by ICD-9-CM codes) versus no opioid prescription (*22*). Rates of opioid abuse or dependence diagnosis ranged from 0.7% with lower-dose (≤36 MME) chronic therapy to 6.1% with higher-dose (≥120 MME) chronic therapy, versus 0.004% with no opioids prescribed. Ten fair-quality uncontrolled studies reported estimates of opioid abuse, addiction, and related outcomes (*55*–*65*). In primary care settings, prevalence of opioid dependence

(using DSM-IV criteria) ranged from 3% to 26% (*55*,*56*,*59*). In pain clinic settings, prevalence of addiction ranged from 2% to 14% (*57*,*58*,*60*,*61*,*63–65*).

Factors associated with increased risk for misuse included history of substance use disorder, younger age, major depression, and use of psychotropic medications (*55*,*62*). Two studies reported on the association between opioid use and risk for overdose (*66*,*67*). One large fair-quality retrospective cohort study found that recent opioid use was associated with increased risk for any overdose events and serious overdose events versus nonuse (*66*). It also found higher doses associated with increased risk. Relative to 1–19 MME/day, the adjusted hazard ratio (HR) for any overdose event (consisting of mostly nonfatal overdose) was 1.44 for 20 to 49 MME/day, 3.73 for 50–99 MME/day, and 8.87 for ≥100 MME/day. A similar pattern was observed for serious overdose. A good-quality population-based, nested case-control study also found a dose-dependent association with risk for overdose death (*67*). Relative to 1–19 MME/day, the adjusted odds ratio (OR) was 1.32 for 20–49 MME/day, 1.92 for 50–99 MME/day, 2.04 for 100–199 MME/day, and 2.88 for ≥200 MME/day.

Findings of increased fracture risk for current opioid use, versus nonuse, were mixed in two studies (*68*,*69*). Two studies found an association between opioid use and increased risk for cardiovascular events (*70*,*71*). Indirect evidence was found for endocrinologic harms (increased use of medications for erectile dysfunction or testosterone from one previously included study; laboratory-defined androgen deficiency from one newly reviewed study) (*72*,*73*). One study found that opioid dosages ≥20 MME/day were associated with increased odds of road trauma among drivers (*74*).

Opioid Dosing Strategies

For KQ3, the body of evidence is rated as type 4 (14 studies contributing; 12 from the original review plus two new studies). For initiation and titration of opioids, the 2014 AHRQ report found insufficient evidence from three fair-quality, open-label trials to determine comparative effectiveness of ER/LA versus immediate-release opioids for titrating patients to stable pain control (*75*,*76*). One new fair-quality cohort study of Veterans Affairs patients found initiation of therapy with an ER/LA opioid associated with greater risk for nonfatal overdose than initiation with an immediate-release opioid, with risk greatest in the first 2 weeks after initiation of treatment (*77*).

For comparative effectiveness and harms of ER/LA opioids, the 2014 AHRQ report included three randomized, head-to-head trials of various ER/LA opioids that found no clear differences in 1-year outcomes related to pain or function (*78–80*) but had methodological shortcomings. A fair-quality retrospective cohort study based on national Veterans Health Administration system pharmacy data found that methadone was associated with lower overall risk for all-cause mortality versus morphine (*81*), and a fair-quality retrospective cohort study based on Oregon Medicaid data found no statistically significant differences between methadone and long-acting morphine in risk for death or overdose symptoms (*82*). However, a new observational study (*83*) found methadone associated with increased risk for overdose versus sustained-release morphine among Tennessee Medicaid patients. The observed inconsistency in study findings suggests that risks of methadone might vary in different settings as a function of different monitoring and management protocols, though more research is needed to understand factors associated with safer methadone prescribing.

For dose escalation, the 2014 AHRQ report included one fair-quality randomized trial that found no differences between more liberal dose escalation and maintenance of current doses after 12 months in pain, function, all-cause withdrawals, or withdrawals due to opioid misuse (*84*). However, the difference in opioid dosages prescribed at the end of the trial was relatively small (mean 52 MME/day with more liberal dosing versus 40 MME/day). Evidence on other comparisons related to opioid dosing strategies (ER/LA versus immediate-release opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled continuous dosing versus as-needed dosing; or opioid rotation versus maintenance of current therapy; long-term effects of strategies for treating acute exacerbations of chronic pain) was not available or too limited to determine effects on long-term clinical outcomes. For example, evidence on the comparative effectiveness of opioid tapering or discontinuation versus maintenance, and of different opioid tapering strategies, was limited to small, poor-quality studies (*85–87*).

Risk Assessment and Mitigation

For KQ4, the body of evidence is rated as type 3 for the accuracy of risk assessment tools and insufficient for the effectiveness of use of risk assessment tools and mitigation strategies in reducing harms (six studies contributing; four from the original review plus two new studies). The 2014 AHRQ report included four studies (*88–91*) on the accuracy of risk assessment instruments, administered prior to opioid therapy initiation, for predicting opioid abuse or misuse. Results for the Opioid Risk Tool (ORT) (*89–91*) were extremely inconsistent; evidence for other risk assessment instruments was very sparse, and studies had serious methodological shortcomings. One additional fair-quality (*92*) and one poor-quality (*93*) study identified for this update compared the predictive accuracy of the ORT, the Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP-R), and the Brief Risk Interview.

For the ORT, sensitivity was 0.58 and 0.75 and specificity 0.54 and 0.86; for the SOAPP-R, sensitivity was 0.53 and 0.25 and specificity 0.62 and 0.73; and for the Brief Risk Interview, sensitivity was 0.73 and 0.83 and specificity 0.43 and 0.88. For the ORT, positive likelihood ratios ranged from noninformative (positive likelihood ratio close to 1) to moderately useful (positive likelihood ratio >5). The SOAPP-R was associated with noninformative likelihood ratios (estimates close to 1) in both studies.

No study evaluated the effectiveness of risk mitigation strategies (use of risk assessment instruments, opioid management plans, patient education, urine drug testing, use of PDMP data, use of monitoring instruments, more frequent monitoring intervals, pill counts, or use of abuse-deterrent formulations) for improving outcomes related to overdose, addiction, abuse, or misuse.

Effects of Opioid Therapy for Acute Pain on Long-Term Use

For KQ5, the body of evidence is rated as type 3 (two new studies contributing). Two fair-quality retrospective cohort studies found opioid therapy prescribed for acute pain associated with greater likelihood of long-term use. One study evaluated opioid-naïve patients who had undergone low-risk surgery, such as cataract surgery and varicose vein stripping (*94*). Use of opioids within 7 days of surgery was associated with increased risk for use at 1 year. The other study found that among patients with a workers' compensation claim for acute low back pain, compared to patients who did not receive opioids early after injury (defined as use within 15 days following onset of pain), patients who did receive early opioids had an increased likelihood of receiving five or more opioid prescriptions 30–730 days following onset that increased with greater early exposure. Versus no early opioid use, the adjusted OR was 2.08 (95% CI = 1.55–2.78) for 1–140 MME/day and increased to 6.14 (95% confidence interval [CI] = 4.92–7.66) for ≥450 MME/day (*95*).

Summary of the Contextual Evidence Review

Primary Areas of Focus

Contextual evidence is complementary information that assists in translating the clinical research findings into recommendations. CDC conducted contextual evidence reviews on four topics to supplement the clinical evidence review findings:

- Effectiveness of nonpharmacologic (e.g., cognitive behavioral therapy [CBT], exercise therapy, interventional treatments, and multimodal pain treatment) and nonopioid pharmacologic treatments (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], antidepressants, and anticonvulsants), including studies of any duration.
- Benefits and harms of opioid therapy (including additional studies not included in the clinical evidence review, such as studies that were not restricted to patients with chronic pain, evaluated outcomes at any duration, performed ecological analyses, or used observational study designs other than cohort and case-cohort control studies) related to specific opioids, high-dose therapy, co-prescription with other controlled substances, duration of use, special populations, and potential usefulness of risk stratification/mitigation approaches, in addition to effectiveness of treatments associated with addressing potential harms of opioid therapy (opioid use disorder).
- Clinician and patient values and preferences related to opioids and medication risks, benefits, and use.
- Resource allocation including costs and economic efficiency of opioid therapy and risk mitigation strategies.

CDC also reviewed clinical guidelines that were relevant to opioid prescribing and could inform or complement the CDC recommendations under development (e.g., guidelines on nonpharmacologic and nonopioid pharmacologic treatments and guidelines with recommendations related to specific clinician actions such as urine drug testing or opioid tapering protocols).

Contextual Evidence Review Methods

CDC conducted a contextual evidence review to assist in developing the recommendations by providing an assessment of the balance of benefits and harms, values and preferences, and cost, consistent with the GRADE approach. Given the public health urgency for developing opioid prescribing recommendations, a rapid review was required for the contextual evidence review for the current guideline. Rapid reviews are used when there is a need to streamline the systematic review process to obtain evidence quickly (*96*). Methods used to streamline the process include limiting searches by databases, years, and languages considered, and truncating quality assessment and data abstraction protocols. CDC conducted "rapid reviews" of the contextual evidence on nonpharmacologic and nonopioid pharmacologic treatments, benefits and harms, values and preferences, and resource allocation.

Detailed information about contextual evidence data sources and searches, inclusion criteria, study selection, and

data extraction and synthesis are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). In brief, CDC conducted systematic literature searches to identify original studies, systematic reviews, and clinical guidelines, depending on the topic being searched. CDC also solicited publication referrals from subject matter experts. Given the need for a rapid review process, grey literature (e.g., literature by academia, organizations, or government in the forms of reports, documents, or proceedings not published by commercial publishers) was not systematically searched. Database sources, including MEDLINE, PsycINFO, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews, varied by topic. Multiple reviewers scanned study abstracts identified through the database searches and extracted relevant studies for review. CDC constructed narrative summaries and tables based on relevant articles that met inclusion criteria, which are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Findings from the contextual reviews provide indirect evidence and should be interpreted accordingly. CDC did not formally rate the quality of evidence for the studies included in the contextual evidence review using the GRADE method. The studies that addressed benefits and harms, values and preferences, and resource allocation most often employed observational methods, used short follow-up periods, and evaluated selected samples. Therefore the strength of the evidence from these contextual review areas was considered to be low, comparable to type 3 or type 4 evidence. The quality of evidence for nonopioid pharmacologic and nonpharmacologic pain treatments was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines (e.g., for treatment of chronic neuropathic pain, low back pain, osteoarthritis, and fibromyalgia). Similarly, the quality of evidence on pharmacologic and psychosocial opioid use disorder treatment was generally rated as moderate, comparable to type 2 evidence, in systematic reviews and clinical guidelines.

Summary of Findings for Contextual Areas

Full narrative reviews and tables that summarize key findings from the contextual evidence review are provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027).

Effectiveness of Nonpharmacologic and Nonopioid Pharmacologic Treatments

Several nonpharmacologic and nonopioid pharmacologic treatments have been shown to be effective in managing chronic pain in studies ranging in duration from 2 weeks to 6 months. For example, CBT that trains patients in behavioral techniques and helps patients modify situational factors and cognitive processes that exacerbate pain has small positive effects on disability and catastrophic thinking (*97*). Exercise therapy can help reduce pain and improve function in chronic low back pain (*98*), improve function and reduce pain in osteoarthritis of the knee (*99*) and hip (*100*), and improve well-being, fibromyalgia symptoms, and physical function in fibromyalgia (*101*). Multimodal and multidisciplinary therapies (e.g., therapies that combine exercise and related therapies with psychologically based approaches) can help reduce pain and improve function more effectively than single modalities (*102*,*103*). Nonopioid pharmacologic approaches used for pain include analgesics such as acetaminophen, NSAIDs, and cyclooxygenase 2 (COX-2) inhibitors; selected anticonvulsants; and selected antidepressants (particularly tricyclics and serotonin and norepinephrine reuptake inhibitors [SNRIs]). Multiple guidelines recommend acetaminophen as first-line pharmacotherapy for osteoarthritis (*104*–*109*) or for low back pain (*110*) but note that it should be avoided in liver failure and that dosage should be reduced in patients with hepatic insufficiency or a history of alcohol abuse (*109*). Although guidelines also recommend NSAIDs as first-line treatment for osteoarthritis or low back pain (*106*,*110*), NSAIDs and COX-2 inhibitors do have risks, including gastrointestinal bleeding or perforation as well as renal and cardiovascular risks (*111*). FDA has recently strengthened existing label warnings that NSAIDs increase risks for heart attack and stroke, including that these risks might increase with longer use or at higher doses (*112*). Several guidelines agree that first- and second-line drugs for neuropathic pain include anticonvulsants (gabapentin or pregabalin), tricyclic antidepressants, and SNRIs (*113*–*116*). Interventional approaches such as epidural injection for certain conditions (e.g., lumbar radiculopathy) can provide short-term improvement in pain (*117*–*119*). Epidural injection has been associated with rare but serious adverse events, including loss of vision, stroke, paralysis, and death (*120*).

Benefits and Harms of Opioid Therapy

Balance between benefits and harms is a critical factor influencing the strength of clinical recommendations. In particular, CDC considered what is known from the epidemiology research about benefits and harms related to specific opioids and formulations, high dose therapy, co-prescription with other controlled substances, duration of use, special populations, and risk stratification and mitigation approaches. Additional information on benefits and harms of long-term opioid therapy from studies meeting rigorous selection criteria is provided in the clinical evidence review (e.g., see KQ2). CDC also considered the number of persons experiencing chronic pain, numbers potentially benefiting

from opioids, and numbers affected by opioid-related harms. A review of these data is presented in the background section of this document, with detailed information provided in the Contextual Evidence Review (http://stacks.cdc.gov/view/cdc/38027). Finally, CDC considered the effectiveness of treatments that addressed potential harms of opioid therapy (opioid use disorder).

Regarding specific opioids and formulations, as noted by FDA, there are serious risks of ER/LA opioids, and the indication for this class of medications is for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment in patients for whom other treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain (*121*). Time-scheduled opioid use was associated with substantially higher average daily opioid dosage than as-needed opioid use in one study (*122*). Methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for pain. Methadone has been found to account for as much as a third of opioid-related overdose deaths involving single or multiple drugs in states that participated in the Drug Abuse Warning Network, which was more than any opioid other than oxycodone, despite representing <2% of opioid prescriptions outside of opioid treatment programs in the United States; further, methadone was involved in twice as many single-drug deaths as any other prescription opioid (*123*).

Regarding high-dose therapy, several epidemiologic studies that were excluded from the clinical evidence review because patient samples were not restricted to patients with chronic pain also examined the association between opioid dosage and overdose risk (*23*,*24*,*124*–*126*). Consistent with the clinical evidence review, the contextual review found that opioid-related overdose risk is dose-dependent, with higher opioid dosages associated with increased overdose risk. Two of these studies (*23*,*24*), as well as the two studies in the clinical evidence review (*66*,*67*), evaluated similar MME/day dose ranges for association with overdose risk. In these four studies, compared with opioids prescribed at <20 MME/day, the odds of overdose among patients prescribed opioids for chronic nonmalignant pain were between 1.3 (*67*) and 1.9 (*24*) for dosages of 20 to <50 MME/day, between 1.9 (*67*) and 4.6 (*24*) for dosages of 50 to <100 MME/day, and between 2.0 (*67*) and 8.9 (*66*) for dosages of ≥100 MME/day. Compared with dosages of 1–<20 MME/day, absolute risk difference approximation for 50–<100 MME/day was 0.15% for fatal overdose (*24*) and 1.40% for any overdose (*66*), and for ≥100 MME/day was 0.25% for fatal overdose (*24*) and 4.04% for any overdose (*66*). A recent study of Veterans Health Administration patients with chronic pain found that patients who died of overdoses related to opioids were prescribed higher opioid dosages (mean: 98 MME/day; median: 60 MME/day) than controls (mean: 48 MME/day, median: 25 MME/day) (*127*). Finally, another recent study of overdose deaths among state residents with and without opioid prescriptions revealed that prescription opioid-related overdose mortality rates rose rapidly up to prescribed doses of 200 MME/day, after which the mortality rates continued to increase but grew more gradually (*128*). A listing of common opioid medications and their MME equivalents is provided (Table 2).

Regarding coprescription of opioids with benzodiazepines, epidemiologic studies suggest that concurrent use of benzodiazepines and opioids might put patients at greater risk for potentially fatal overdose. Three studies of fatal overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents (*67*,*128*,*129*). In one of these studies (*67*), among decedents who received an opioid prescription, those whose deaths were related to opioids were more likely to have obtained opioids from multiple physicians and pharmacies than decedents whose deaths were not related to opioids.

Regarding duration of use, patients can experience tolerance and loss of effectiveness of opioids over time (*130*). Patients who do not experience clinically meaningful pain relief early in treatment (i.e., within 1 month) are unlikely to experience pain relief with longer-term use (*131*).

Regarding populations potentially at greater risk for harm, risk is greater for patients with sleep apnea or other causes of sleep-disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders. Interpretation of clinical data on the effects of opioids on sleep-disordered breathing is difficult because of the types of study designs and methods employed, and there is no clear consensus regarding association with risk for developing obstructive sleep apnea syndrome (*132*). However, opioid therapy can decrease respiratory drive, a high percentage of patients on long-term opioid therapy have been reported to have an abnormal apnea-hypopnea index (*133*), opioid therapy can worsen central sleep apnea in obstructive sleep apnea patients, and it can cause further desaturation in obstructive sleep apnea patients not on continuous positive airway pressure (CPAP) (*31*). Reduced renal or hepatic function can result in greater peak effect and longer duration of action and reduce the dose at which respiratory depression and overdose occurs (*134*). Age-related changes in patients aged ≥65 years, such as reduced renal function and medication clearance, even in the absence of renal disease (*135*), result in a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose. Older adults might also be at increased risk for falls and fractures related to opioids (*136*–*138*). Opioids used

in pregnancy can be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with birth defects, including neural tube defects (*139*,*140*), congenital heart defects (*140*), and gastroschisis (*140*); preterm delivery (*141*), poor fetal growth (*141*), and stillbirth (*141*). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome (*142*). Patients with mental health comorbidities and patients with histories of substance use disorders might be at higher risk than other patients for opioid use disorder (*62*,*143*,*144*). Recent analyses found that depressed patients were at higher risk for drug overdose than patients without depression, particularly at higher opioid dosages, although investigators were unable to distinguish unintentional overdose from suicide attempts (*145*). In case-control and case-cohort studies, substance abuse/dependence was more prevalent among patients experiencing overdose than among patients not experiencing overdose (12% versus 6% [*66*], 40% versus 10% [*24*], and 26% versus 9% [*23*]).

Regarding risk stratification approaches, limited evidence was found regarding benefits and harms. Potential benefits of PDMPs and urine drug testing include the ability to identify patients who might be at higher risk for opioid overdose or opioid use disorder, and help determine which patients will benefit from greater caution and increased monitoring or interventions when risk factors are present. For example, one study found that most fatal overdoses could be identified retrospectively on the basis of two pieces of information, multiple prescribers and high total daily opioid dosage, both important risk factors for overdose (*124*,*146*) that are available to prescribers in the PDMP (*124*). However, limited evaluation of PDMPs at the state level has revealed mixed effects on changes in prescribing and mortality outcomes (*28*). Potential harms of risk stratification include underestimation of risks of opioid therapy when screening tools are not adequately sensitive, as well as potential overestimation of risk, which could lead to inappropriate clinical decisions.

Regarding risk mitigation approaches, limited evidence was found regarding benefits and harms. Although no studies were found to examine prescribing of naloxone with opioid pain medication in primary care settings, naloxone distribution through community-based programs providing prevention services for substance users has been demonstrated to be associated with decreased risk for opioid overdose death at the community level (*147*).

Concerns have been raised that prescribing changes such as dose reduction might be associated with unintended negative consequences, such as patients seeking heroin or other illicitly obtained opioids (*148*) or interference with appropriate pain treatment (*149*). With the exception of a study noting an association between an abuse-deterrent formulation of OxyContin and heroin use, showing that some patients in qualitative interviews reported switching to another opioid, including heroin, for many reasons, including cost and availability as well as ease of use (*150*), CDC did not identify studies evaluating these potential outcomes.

Finally, regarding the effectiveness of opioid use disorder treatments, methadone and buprenorphine for opioid use disorder have been found to increase retention in treatment and to decrease illicit opioid use among patients with opioid use disorder involving heroin (*151*–*153*). Although findings are mixed, some studies suggest that effectiveness is enhanced when psychosocial treatments (e.g., contingency management, community reinforcement, psychotherapeutic counseling, and family therapy) are used in conjunction with medication-assisted therapy; for example, by reducing opioid misuse and increasing retention during maintenance therapy, and improving compliance after detoxification (*154*,*155*).

Clinician and Patient Values and Preferences

Clinician and patient values and preferences can inform how benefits and harms of long-term opioid therapy are weighted and estimate the effort and resources required to effectively provide implementation support. Many physicians lack confidence in their ability to prescribe opioids safely (*156*), to predict (*157*) or detect (*158*) prescription drug abuse, and to discuss abuse with their patients (*158*). Although clinicians have reported favorable beliefs and attitudes about improvements in pain and quality of life attributed to opioids (*159*), most consider prescription drug abuse to be a "moderate" or "big" problem in their community, and large proportions are "very" concerned about opioid addiction (55%) and death (48%) (*160*). Clinicians do not consistently use practices intended to decrease the risk for misuse, such as PDMPs (*161*,*162*), urine drug testing (*163*), and opioid treatment agreements (*164*). This is likely due in part to challenges related to registering for PDMP access and logging into the PDMP (which can interrupt normal clinical workflow if data are not integrated into electronic health record systems) (*165*), competing clinical demands, perceived inadequate time to discuss the rationale for urine drug testing and to order confirmatory testing, and feeling unprepared to interpret and address results (*166*).

Many patients do not have an opinion about "opioids" or know what this term means (*167*). Most are familiar with the term "narcotics." About a third associated "narcotics" with addiction or abuse, and about half feared "addiction" from long-term "narcotic" use (*168*). Most patients taking opioids experience side effects (73% of patients taking hydrocodone for noncancer pain [*11*], 96% of patients taking opioids for chronic pain [*12*]), and side effects, rather than pain relief,

have been found to explain most of the variation in patients' preferences related to taking opioids (*12*). For example, patients taking hydrocodone for noncancer pain commonly reported side effects including dizziness, headache, fatigue, drowsiness, nausea, vomiting, and constipation (*11*). Patients with chronic pain in focus groups emphasized effectiveness of goal setting for increasing motivation and functioning (*168*). Patients taking high dosages report reliance on opioids despite ambivalence about their benefits (*169*) and regardless of pain reduction, reported problems, concerns, side effects, or perceived helpfulness (*13*).

Resource Allocation

Resource allocation (cost) is an important consideration in understanding the feasibility of clinical recommendations. CDC searched for evidence on opioid therapy compared with other treatments; costs of misuse, abuse, and overdose from prescription opioids; and costs of specific risk mitigation strategies (e.g., urine drug testing). Yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be $53.4 billion for nonmedical use of prescription opioids (*170*); $55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids (*171*); and $20.4 billion for direct and indirect costs related to opioid-related overdose alone (*172*). In 2012, total expenses for outpatient prescription opioids were estimated at $9.0 billion, an increase of 120% from 2002 (*173*). Although there are perceptions that opioid therapy for chronic pain is less expensive than more time-intensive nonpharmacologic management approaches, many pain treatments, including acetaminophen, NSAIDs, tricyclic antidepressants, and massage therapy, are associated with lower mean and median annual costs compared with opioid therapy (*174*). COX-2 inhibitors, SNRIs, anticonvulsants, topical analgesics, physical therapy, and CBT are also associated with lower median annual costs compared with opioid therapy (*174*). Limited information was found on costs of strategies to decrease risks associated with opioid therapy; however, urine drug testing, including screening and confirmatory tests, has been estimated to cost $211–$363 per test (*175*).

Recommendations

The recommendations are grouped into three areas for consideration:

- Determining when to initiate or continue opioids for chronic pain.
- Opioid selection, dosage, duration, follow-up, and discontinuation.
- Assessing risk and addressing harms of opioid use.

There are 12 recommendations (Box 1). Each recommendation is followed by a rationale for the recommendation, with considerations for implementation noted. In accordance with the ACIP GRADE process, CDC based the recommendations on consideration of the clinical evidence, contextual evidence (including benefits and harms, values and preferences, resource allocation), and expert opinion. For each recommendation statement, CDC notes the recommendation category (A or B) and the type of the evidence (1, 2, 3, or 4) supporting the statement (Box 2). Expert opinion is reflected within each of the recommendation rationales. While there was not an attempt to reach consensus among experts, experts from the Core Expert Group and from the Opioid Guideline Workgroup ("experts") expressed overall, general support for all recommendations. Where differences in expert opinion emerged for detailed actions within the clinical recommendations or for implementation considerations, CDC notes the differences of opinion in the supporting rationale statements.

Category A recommendations indicate that most patients should receive the recommended course of action; category B recommendations indicate that different choices will be appropriate for different patients, requiring clinicians to help patients arrive at a decision consistent with patient values and preferences and specific clinical situations. Consistent with the ACIP (*47*) and GRADE process (*48*), category A recommendations were made, even with type 3 and 4 evidence, when there was broad agreement that the advantages of a clinical action greatly outweighed the disadvantages based on a consideration of benefits and harms, values and preferences, and resource allocation. Category B recommendations were made when there was broad agreement that the advantages and disadvantages of a clinical action were more balanced, but advantages were significant enough to warrant a recommendation. All recommendations are category A recommendations, with the exception of recommendation 10, which is rated as category B. Recommendations were associated with a range of evidence types, from type 2 to type 4.

In summary, the categorization of recommendations was based on the following assessment:

- No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤6 weeks in duration).
- Extensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury).
- Extensive evidence suggests some benefits of nonpharmacologic and nonopioid pharmacologic treatments compared with long-term opioid therapy, with less harm.

BOX 1. CDC recommendations for prescribing opioids for chronic pain outside of active cancer, palliative, and end-of-life care

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

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

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

* All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

BOX 2. Interpretation of recommendation categories and evidence type

Recommendation Categories

Based on evidence type, balance between desirable and undesirable effects, values and preferences, and resource allocation (cost).

Category A recommendation: Applies to all persons; most patients should receive the recommended course of action.

Category B recommendation: Individual decision making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.

Evidence Type

Based on study design as well as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects.

Type 1 evidence: Randomized clinical trials or overwhelming evidence from observational studies.

Type 2 evidence: Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.

Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.

Type 4 evidence: Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

Determining When to Initiate or Continue Opioids for Chronic Pain

1. **Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (recommendation category: A, evidence type: 3).**

Patients with pain should receive treatment that provides the greatest benefits relative to risks. The contextual evidence review found that many nonpharmacologic therapies, including physical therapy, weight loss for knee osteoarthritis, psychological therapies such as CBT, and certain interventional procedures can ameliorate chronic pain. There is high-quality evidence that exercise therapy (a prominent modality in physical therapy) for hip (*100*) or knee (*99*) osteoarthritis reduces pain and improves function immediately after treatment and that the improvements are sustained for at least 2–6 months. Previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*). Exercise therapy also can help reduce pain and improve function in low back pain and can improve global well-being and physical function in fibromyalgia (*98*,*101*). Multimodal therapies and multidisciplinary biopsychosocial rehabilitation-combining approaches (e.g., psychological therapies with exercise) can reduce long-term pain and disability compared with usual care and compared with physical treatments (e.g., exercise) alone. Multimodal therapies are not always available or reimbursed by insurance and can be time-consuming and costly for patients. Interventional approaches such as arthrocentesis and intraarticular glucocorticoid injection for pain associated with rheumatoid arthritis (*117*) or osteoarthritis (*118*) and subacromial corticosteroid injection for rotator cuff disease (*119*) can provide short-term improvement in pain and function. Evidence is insufficient to determine the extent to which repeated glucocorticoid injection increases potential risks such as articular cartilage changes (in osteoarthritis) and sepsis (*118*). Serious adverse events are rare but have been reported with epidural injection (*120*).

Several nonopioid pharmacologic therapies (including acetaminophen, NSAIDs, and selected antidepressants and anticonvulsants) are effective for chronic pain. In particular, acetaminophen and NSAIDs can be useful for arthritis and low back pain. Selected anticonvulsants such as pregabalin and gabapentin can improve pain in diabetic neuropathy and post-herpetic neuralgia (contextual evidence review). Pregabalin, gabapentin, and carbamazepine are FDA-approved for treatment of certain neuropathic pain conditions, and pregabalin is FDA approved for fibromyalgia management. In patients with or without depression, tricyclic antidepressants and SNRIs provide effective analgesia for neuropathic pain conditions including diabetic neuropathy and post-herpetic neuralgia, often at lower dosages and with a shorter time to onset of effect than for treatment of depression (see contextual evidence review). Tricyclics and SNRIs can also relieve fibromyalgia symptoms. The SNRI duloxetine is FDA-approved for the treatment of diabetic neuropathy and fibromyalgia. Because patients with chronic pain often suffer from concurrent depression (*144*), and depression can exacerbate physical symptoms including pain (*177*), patients with co-occurring pain and depression are especially likely to benefit from antidepressant medication (see Recommendation 8). Nonopioid pharmacologic therapies

are not generally associated with substance use disorder, and the numbers of fatal overdoses associated with nonopioid medications are a fraction of those associated with opioid medications (contextual evidence review). For example, acetaminophen, NSAIDs, and opioid pain medication were involved in 881, 228, and 16,651 pharmaceutical overdose deaths in the United States in 2010 (*178*). However, nonopioid pharmacologic therapies are associated with certain risks, particularly in older patients, pregnant patients, and patients with certain co-morbidities such as cardiovascular, renal, gastrointestinal, and liver disease (see contextual evidence review). For example, acetaminophen can be hepatotoxic at dosages of >3–4 grams/day and at lower dosages in patients with chronic alcohol use or liver disease (*109*). NSAID use has been associated with gastritis, peptic ulcer disease, cardiovascular events (*111*,*112*), and fluid retention, and most NSAIDs (choline magnesium trilisate and selective COX-2 inhibitors are exceptions) interfere with platelet aggregation (*179*). Clinicians should review FDA-approved labeling including boxed warnings before initiating treatment with any pharmacologic therapy.

Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy (KQ1). While benefits for pain relief, function, and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant. Based on the clinical evidence review, long-term opioid use for chronic pain is associated with serious risks including increased risk for opioid use disorder, overdose, myocardial infarction, and motor vehicle injury (KQ2). At a population level, more than 165,000 persons in the United States have died from opioid pain-medication-related overdoses since 1999 (see Contextual Evidence Review).

Integrated pain management requires coordination of medical, psychological, and social aspects of health care and includes primary care, mental health care, and specialist services when needed (*180*). Nonpharmacologic physical and psychological treatments such as exercise and CBT are approaches that encourage active patient participation in the care plan, address the effects of pain in the patient's life, and can result in sustained improvements in pain and function without apparent risks. Despite this, these therapies are not always or fully covered by insurance, and access and cost can be barriers for patients. For many patients, aspects of these approaches can be used even when there is limited access to specialty care. For example, previous guidelines have strongly recommended aerobic, aquatic, and/or resistance exercises for patients with osteoarthritis of the knee or hip (*176*) and maintenance of activity for patients with low back pain (*110*). A randomized trial found no difference in reduced chronic low back pain intensity, frequency or disability between patients assigned to relatively low-cost group aerobics and individual physiotherapy or muscle reconditioning sessions (*181*). Low-cost options to integrate exercise include brisk walking in public spaces or use of public recreation facilities for group exercise. CBT addresses psychosocial contributors to pain and improves function (*97*). Primary care clinicians can integrate elements of a cognitive behavioral approach into their practice by encouraging patients to take an active role in the care plan, by supporting patients in engaging in beneficial but potentially anxiety-provoking activities, such as exercise (*179*), or by providing education in relaxation techniques and coping strategies. In many locations, there are free or low-cost patient support, self-help, and educational community-based programs that can provide stress reduction and other mental health benefits. Patients with more entrenched anxiety or fear related to pain, or other significant psychological distress, can be referred for formal therapy with a mental health specialist (e.g., psychologist, psychiatrist, clinical social worker). Multimodal therapies should be considered for patients not responding to single-modality therapy, and combinations should be tailored depending on patient needs, cost, and convenience.

To guide patient-specific selection of therapy, clinicians should evaluate patients and establish or confirm the diagnosis. Detailed recommendations on diagnosis are provided in other guidelines (*110*,*179*), but evaluation should generally include a focused history, including history and characteristics of pain and potentially contributing factors (e.g., function, psychosocial stressors, sleep) and physical exam, with imaging or other diagnostic testing only if indicated (e.g., if severe or progressive neurologic deficits are present or if serious underlying conditions are suspected) (*110*,*179*). For complex pain syndromes, pain specialty consultation can be considered to assist with diagnosis as well as management. Diagnosis can help identify disease-specific interventions to reverse or ameliorate pain; for example, improving glucose control to prevent progression of diabetic neuropathy; immune-modulating agents for rheumatoid arthritis; physical or occupational therapy to address posture, muscle weakness, or repetitive occupational motions that contribute to musculoskeletal pain; or surgical intervention to relieve mechanical/compressive pain (*179*). The underlying mechanism for most pain syndromes can be categorized as neuropathic (e.g., diabetic neuropathy, postherpetic neuralgia, fibromyalgia), or nociceptive (e.g., osteoarthritis, muscular back pain). The diagnosis and pathophysiologic mechanism of pain have implications for symptomatic pain treatment with medication. For example, evidence is limited or insufficient

for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain (*182*), headache (*183*), and fibromyalgia (*184*). Although NSAIDs can be used for exacerbations of nociceptive pain, other medications (e.g., tricyclics, selected anticonvulsants, or transdermal lidocaine) generally are recommended for neuropathic pain. In addition, improvement of neuropathic pain can begin weeks or longer after symptomatic treatment is initiated (*179*). Medications should be used only after assessment and determination that expected benefits outweigh risks given patient-specific factors. For example, clinicians should consider falls risk when selecting and dosing potentially sedating medications such as tricyclics, anticonvulsants, or opioids, and should weigh risks and benefits of use, dose, and duration of NSAIDs when treating older adults as well as patients with hypertension, renal insufficiency, or heart failure, or those with risk for peptic ulcer disease or cardiovascular disease. Some guidelines recommend topical NSAIDs for localized osteoarthritis (e.g., knee osteoarthritis) over oral NSAIDs in patients aged ≥75 years to minimize systemic effects (*176*).

Experts agreed that opioids should not be considered first-line or routine therapy for chronic pain (i.e., pain continuing or expected to continue >3 months or past the time of normal tissue healing) outside of active cancer, palliative, and end-of-life care, given small to moderate short-term benefits, uncertain long-term benefits, and potential for serious harms; although evidence on long-term benefits of nonopioid therapies is also limited, these therapies are also associated with short-term benefits, and risks are much lower. This does not mean that patients should be required to sequentially "fail" nonpharmacologic and nonopioid pharmacologic therapy before proceeding to opioid therapy. Rather, expected benefits specific to the clinical context should be weighed against risks before initiating therapy. In some clinical contexts (e.g., headache or fibromyalgia), expected benefits of initiating opioids are unlikely to outweigh risks regardless of previous nonpharmacologic and nonopioid pharmacologic therapies used. In other situations (e.g., serious illness in a patient with poor prognosis for return to previous level of function, contraindications to other therapies, and clinician and patient agreement that the overriding goal is patient comfort), opioids might be appropriate regardless of previous therapies used. In addition, when opioid pain medication is used, it is more likely to be effective if integrated with nonpharmacologic therapy. Nonpharmacologic approaches such as exercise and CBT should be used to reduce pain and improve function in patients with chronic pain. Nonopioid pharmacologic therapy should be used when benefits outweigh risks and should be combined with nonpharmacologic therapy to reduce pain and improve function. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate, to provide greater benefits to patients in improving pain and function.

2. **Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).**

The clinical evidence review found insufficient evidence to determine long-term benefits of opioid therapy for chronic pain and found an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent. In addition, studies on currently available risk assessment instruments were sparse and showed inconsistent results (KQ4). The clinical evidence review for the current guideline considered studies with outcomes examined at ≥1 year that compared opioid use versus nonuse or placebo. Studies of opioid therapy for chronic pain that did not have a nonopioid control group have found that although many patients discontinue opioid therapy for chronic noncancer pain due to adverse effects or insufficient pain relief, there is weak evidence that patients who are able to continue opioid therapy for at least 6 months can experience clinically significant pain relief and insufficient evidence that function or quality of life improves (*185*). These findings suggest that it is very difficult for clinicians to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients. Opioid therapy should not be initiated without consideration of an "exit strategy" to be used if the therapy is unsuccessful.

Experts agreed that before opioid therapy is initiated for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should determine how effectiveness will be evaluated and should establish treatment goals with patients. Because the line between acute pain and initial chronic pain is not always clear, it might be difficult for clinicians to determine when they are initiating opioids for chronic pain rather than treating acute pain. Pain lasting longer than 3 months or past the time of normal tissue healing (which could be substantially shorter than 3 months, depending on the condition) is generally no longer considered acute. However, establishing treatment goals with a patient who has already received opioid therapy for 3 months would defer this discussion well past the point of

initiation of opioid therapy for chronic pain. Clinicians often write prescriptions for long-term use in 30-day increments, and opioid prescriptions written for ≥30 days are likely to represent initiation or continuation of long-term opioid therapy. Before writing an opioid prescription for ≥30 days, clinicians should establish treatment goals with patients. Clinicians seeing new patients already receiving opioids should establish treatment goals for continued opioid therapy. Although the clinical evidence review did not find studies evaluating the effectiveness of written agreements or treatment plans (KQ4), clinicians and patients who set a plan in advance will clarify expectations regarding how opioids will be prescribed and monitored, as well as situations in which opioids will be discontinued or doses tapered (e.g., if treatment goals are not met, opioids are no longer needed, or adverse events put the patient at risk) to improve patient safety.

Experts thought that goals should include improvement in both pain relief and function (and therefore in quality of life). However, there are some clinical circumstances under which reductions in pain without improvement in physical function might be a more realistic goal (e.g., diseases typically associated with progressive functional impairment or catastrophic injuries such as spinal cord trauma). Experts noted that function can include emotional and social as well as physical dimensions. In addition, experts emphasized that mood has important interactions with pain and function. Experts agreed that clinicians may use validated instruments such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) to track patient outcomes. Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function (*187*). Monitoring progress toward patient-centered functional goals (e.g., walking the dog or walking around the block, returning to part-time work, attending family sports or recreational activities) can also contribute to the assessment of functional improvement. Clinicians should use these goals in assessing benefits of opioid therapy for individual patients and in weighing benefits against risks of continued opioid therapy (see Recommendation 7, including recommended intervals for follow-up). Because depression, anxiety, and other psychological co-morbidities often coexist with and can interfere with resolution of pain, clinicians should use validated instruments to assess for these conditions (see Recommendation 8) and ensure that treatment for these conditions is optimized. If patients receiving opioid therapy for chronic pain do not experience meaningful improvements in both pain and function compared with prior to initiation of opioid therapy, clinicians should consider working with patients to taper and discontinue opioids (see Recommendation 7) and should use nonpharmacologic and nonopioid pharmacologic approaches to pain management (see Recommendation 1).

3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3).

The clinical evidence review did not find studies evaluating effectiveness of patient education or opioid treatment plans as risk-mitigation strategies (KQ4). However, the contextual evidence review found that many patients lack information about opioids and identified concerns that some clinicians miss opportunities to effectively communicate about safety. Given the substantial evidence gaps on opioids, uncertain benefits of long-term use, and potential for serious harms, patient education and discussion before starting opioid therapy are critical so that patient preferences and values can be understood and used to inform clinical decisions. Experts agreed that essential elements to communicate to patients before starting and periodically during opioid therapy include realistic expected benefits, common and serious harms, and expectations for clinician and patient responsibilities to mitigate risks of opioid therapy.

Clinicians should involve patients in decisions about whether to start or continue opioid therapy. Given potentially serious risks of long-term opioid therapy, clinicians should ensure that patients are aware of potential benefits of, harms of, and alternatives to opioids before starting or continuing opioid therapy. Clinicians are encouraged to have open and honest discussions with patients to inform mutual decisions about whether to start or continue opioid therapy. Important considerations include the following:

- Be explicit and realistic about expected benefits of opioids, explaining that while opioids can reduce pain during short-term use, there is no good evidence that opioids improve pain or function with long-term use, and that complete relief of pain is unlikely (clinical evidence review, KQ1).
- Emphasize improvement in function as a primary goal and that function can improve even when pain is still present.
- Advise patients about serious adverse effects of opioids, including potentially fatal respiratory depression and development of a potentially serious lifelong opioid use disorder that can cause distress and inability to fulfill major role obligations.
- Advise patients about common effects of opioids, such as constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids. To prevent constipation associated with opioid use, advise patients to increase

hydration and fiber intake and to maintain or increase physical activity. Stool softeners or laxatives might be needed.
- Discuss effects that opioids might have on ability to safely operate a vehicle, particularly when opioids are initiated, when dosages are increased, or when other central nervous system depressants, such as benzodiazepines or alcohol, are used concurrently.
- Discuss increased risks for opioid use disorder, respiratory depression, and death at higher dosages, along with the importance of taking only the amount of opioids prescribed, i.e., not taking more opioids or taking them more often.
- Review increased risks for respiratory depression when opioids are taken with benzodiazepines, other sedatives, alcohol, illicit drugs such as heroin, or other opioids.
- Discuss risks to household members and other individuals if opioids are intentionally or unintentionally shared with others for whom they are not prescribed, including the possibility that others might experience overdose at the same or at lower dosage than prescribed for the patient, and that young children are susceptible to unintentional ingestion. Discuss storage of opioids in a secure, preferably locked location and options for safe disposal of unused opioids (*188*).
- Discuss the importance of periodic reassessment to ensure that opioids are helping to meet patient goals and to allow opportunities for opioid discontinuation and consideration of additional nonpharmacologic or nonopioid pharmacologic treatment options if opioids are not effective or are harmful.
- Discuss planned use of precautions to reduce risks, including use of prescription drug monitoring program information (see Recommendation 9) and urine drug testing (see Recommendation 10). Consider including discussion of naloxone use for overdose reversal (see Recommendation 8).
- Consider whether cognitive limitations might interfere with management of opioid therapy (for older adults in particular) and, if so, determine whether a caregiver can responsibly co-manage medication therapy. Discuss the importance of reassessing safer medication use with both the patient and caregiver.

Given the possibility that benefits of opioid therapy might diminish or that risks might become more prominent over time, it is important that clinicians review expected benefits and risks of continued opioid therapy with patients periodically, at least every 3 months (see Recommendation 7).

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

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

ER/LA opioids include methadone, transdermal fentanyl, and extended-release versions of opioids such as oxycodone, oxymorphone, hydrocodone, and morphine. The clinical evidence review found a fair-quality study showing a higher risk for overdose among patients initiating treatment with ER/LA opioids than among those initiating treatment with immediate-release opioids (*77*). The clinical evidence review did not find evidence that continuous, time-scheduled use of ER/LA opioids is more effective or safer than intermittent use of immediate-release opioids or that time-scheduled use of ER/LA opioids reduces risks for opioid misuse or addiction (KQ3).

In 2014, the FDA modified the labeling for ER/LA opioid pain medications, noting serious risks and recommending that ER/LA opioids be reserved for "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment" when "alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain" and not used as "as needed" pain relievers (*121*). FDA has also noted that some ER/LA opioids are only appropriate for opioid-tolerant patients, defined as patients who have received certain dosages of opioids (e.g., 60 mg daily of oral morphine, 30 mg daily of oral oxycodone, or equianalgesic dosages of other opioids) for at least 1 week (*189*). Time-scheduled opioid use can be associated with greater total average daily opioid dosage compared with intermittent, as-needed opioid use (contextual evidence review). In addition, experts indicated that there was not enough evidence to determine the safety of using immediate-release opioids for breakthrough pain when ER/LA opioids are used for chronic pain outside of active cancer pain, palliative care, or end-of-life care, and that this practice might be associated with dose escalation.

Abuse-deterrent technologies have been employed to prevent manipulation intended to defeat extended-release properties of ER/LA opioids and to prevent opioid use by unintended routes of administration, such as injection of oral opioids. As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids (*190*), although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent

opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes. The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

In comparing different ER/LA formulations, the clinical evidence review found inconsistent results for overdose risk with methadone versus other ER/LA opioids used for chronic pain (KQ3). The contextual evidence review found that methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for chronic pain. In addition, methadone is associated with cardiac arrhythmias along with QT prolongation on the electrocardiogram, and it has complicated pharmacokinetics and pharmacodynamics, including a long and variable half-life and peak respiratory depressant effect occurring later and lasting longer than peak analgesic effect. Experts noted that the pharmacodynamics of methadone are subject to more inter-individual variability than other opioids. In regard to other ER/LA opioid formulations, experts noted that the absorption and pharmacodynamics of transdermal fentanyl are complex, with gradually increasing serum concentration during the first part of the 72-hour dosing interval, as well as variable absorption based on factors such as external heat. In addition, the dosing of transdermal fentanyl in mcg/hour, which is not typical for a drug used by outpatients, can be confusing. Experts thought that these complexities might increase the risk for fatal overdose when methadone or transdermal fentanyl is prescribed to a patient who has not used it previously or by clinicians who are not familiar with its effects.

Experts agreed that for patients not already receiving opioids, clinicians should not initiate opioid treatment with ER/LA opioids and should not prescribe ER/LA opioids for intermittent use. ER/LA opioids should be reserved for severe, continuous pain and should be considered only for patients who have received immediate-release opioids daily for at least 1 week. When changing to an ER/LA opioid for a patient previously receiving a different immediate-release opioid, clinicians should consult product labeling and reduce total daily dosage to account for incomplete opioid cross-tolerance. Clinicians should use additional caution with ER/LA opioids and consider a longer dosing interval when prescribing to patients with renal or hepatic dysfunction because decreased clearance of drugs among these patients can lead to accumulation of drugs to toxic levels and persistence in the body for longer durations. Although there might be situations in which clinicians need to prescribe immediate-release and ER/LA opioids together (e.g., transitioning patients from ER/LA opioids to immediate-release opioids by temporarily using lower dosages of both), in general, avoiding the use of immediate-release opioids in combination with ER/LA opioids is preferable, given potentially increased risk and diminishing returns of such an approach for chronic pain.

When an ER/LA opioid is prescribed, using one with predictable pharmacokinetics and pharmacodynamics is preferred to minimize unintentional overdose risk. In particular, unusual characteristics of methadone and of transdermal fentanyl make safe prescribing of these medications for pain especially challenging.

- Methadone should not be the first choice for an ER/LA opioid. Only clinicians who are familiar with methadone's unique risk profile and who are prepared to educate and closely monitor their patients, including risk assessment for QT prolongation and consideration of electrocardiographic monitoring, should consider prescribing methadone for pain. A clinical practice guideline that contains further guidance regarding methadone prescribing for pain has been published previously (*191*).
- Because dosing effects of transdermal fentanyl are often misunderstood by both clinicians and patients, only clinicians who are familiar with the dosing and absorption properties of transdermal fentanyl and are prepared to educate their patients about its use should consider prescribing it.

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day (recommendation category: A, evidence type: 3).

Benefits of high-dose opioids for chronic pain are not established. The clinical evidence review found only one study (*84*) addressing effectiveness of dose titration for outcomes related to pain control, function, and quality of life (KQ3). This randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage. (These groups were prescribed average dosages of 52 and 40 MME/day, respectively, at the end of the trial.) At the same time, risks for serious harms

related to opioid therapy increase at higher opioid dosage. The clinical evidence review found that higher opioid dosages are associated with increased risks for motor vehicle injury, opioid use disorder, and overdose (KQ2). The clinical and contextual evidence reviews found that opioid overdose risk increases in a dose-response manner, that dosages of 50–<100 MME/day have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages of 1–<20 MME/day, and that dosages ≥100 MME/day are associated with increased risks of overdose 2.0–8.9 times the risk at 1–<20 MME/day. In a national sample of Veterans Health Administration patients with chronic pain who were prescribed opioids, mean prescribed opioid dosage among patients who died from opioid overdose was 98 MME (median 60 MME) compared with mean prescribed opioid dosage of 48 MME (median 25 MME) among patients not experiencing fatal overdose (*127*).

The contextual evidence review found that although there is not a single dosage threshold below which overdose risk is eliminated, holding dosages <50 MME/day would likely reduce risk among a large proportion of patients who would experience fatal overdose at higher prescribed dosages. Experts agreed that lower dosages of opioids reduce the risk for overdose, but that a single dosage threshold for safe opioid use could not be identified. Experts noted that daily opioid dosages close to or greater than 100 MME/day are associated with significant risks, that dosages <50 MME/day are safer than dosages of 50–100 MME/day, and that dosages <20 MME/day are safer than dosages of 20–50 MME/day. One expert thought that a specific dosage at which the benefit/risk ratio of opioid therapy decreases could not be identified. Most experts agreed that, in general, increasing dosages to 50 or more MME/day increases overdose risk without necessarily adding benefits for pain control or function and that clinicians should carefully reassess evidence of individual benefits and risks when considering increasing opioid dosages to ≥50 MME/day. Most experts also agreed that opioid dosages should not be increased to ≥90 MME/day without careful justification based on diagnosis and on individualized assessment of benefits and risks.

When opioids are used for chronic pain outside of active cancer, palliative, and end-of-life care, clinicians should start opioids at the lowest possible effective dosage (the lowest starting dosage on product labeling for patients not already taking opioids and according to product labeling guidance regarding tolerance for patients already taking opioids). Clinicians should use additional caution when initiating opioids for patients aged ≥65 years and for patients with renal or hepatic insufficiency because decreased clearance of drugs in these patients can result in accumulation of drugs to toxic levels. Clinicians should use caution when increasing opioid dosages and increase dosage by the smallest practical amount because overdose risk increases with increases in opioid dosage. Although there is limited evidence to recommend specific intervals for dosage titration, a previous guideline recommended waiting at least five half-lives before increasing dosage and waiting at least a week before increasing dosage of methadone to make sure that full effects of the previous dosage are evident (*31*). Clinicians should re-evaluate patients after increasing dosage for changes in pain, function, and risk for harm (see Recommendation 7). Before increasing total opioid dosage to ≥50 MME/day, clinicians should reassess whether opioid treatment is meeting the patient's treatment goals (see Recommendation 2). If a patient's opioid dosage for all sources of opioids combined reaches or exceeds 50 MME/day, clinicians should implement additional precautions, including increased frequency of follow-up (see Recommendation 7) and considering offering naloxone and overdose prevention education to both patients and the patients' household members (see Recommendation 8). Clinicians should avoid increasing opioid dosages to ≥90 MME/day or should carefully justify a decision to increase dosage to ≥90 MME/day based on individualized assessment of benefits and risks and weighing factors such as diagnosis, incremental benefits for pain and function relative to harms as dosages approach 90 MME/day, other treatments and effectiveness, and recommendations based on consultation with pain specialists. If patients do not experience improvement in pain and function at ≥90 MME/day, or if there are escalating dosage requirements, clinicians should discuss other approaches to pain management with the patient, consider working with patients to taper opioids to a lower dosage or to taper and discontinue opioids (see Recommendation 7), and consider consulting a pain specialist. Some states require clinicians to implement clinical protocols at specific dosage levels. For example, before increasing long-term opioid therapy dosage to >120 MME/day, clinicians in Washington state must obtain consultation from a pain specialist who agrees that this is indicated and appropriate (*30*). Clinicians should be aware of rules related to MME thresholds and associated clinical protocols established by their states.

Established patients already taking high dosages of opioids, as well as patients transferring from other clinicians, might consider the possibility of opioid dosage reduction to be anxiety-provoking, and tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence. However, these patients should be offered the opportunity to re-evaluate their continued use of opioids at high dosages in light of recent evidence regarding the association of opioid dosage and overdose risk. Clinicians should explain in a nonjudgmental manner to patients already taking high opioid dosages (≥90 MME/day) that there is

now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages. Clinicians should empathically review benefits and risks of continued high-dosage opioid therapy and should offer to work with the patient to taper opioids to safer dosages. For patients who agree to taper opioids to lower dosages, clinicians should collaborate with the patient on a tapering plan (see Recommendation 7). Experts noted that patients tapering opioids after taking them for years might require very slow opioid tapers as well as pauses in the taper to allow gradual accommodation to lower opioid dosages. Clinicians should remain alert to signs of anxiety, depression, and opioid use disorder (see Recommendations 8 and 12) that might be unmasked by an opioid taper and arrange for management of these co-morbidities. For patients agreeing to taper to lower opioid dosages as well as for those remaining on high opioid dosages, clinicians should establish goals with the patient for continued opioid therapy (see Recommendation 2), maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1), and consider consulting a pain specialist as needed to assist with pain management.

6. **Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed (recommendation category: A, evidence type: 4).**

The clinical evidence review found that opioid use for acute pain (i.e., pain with abrupt onset and caused by an injury or other process that is not ongoing) is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use (KQ5). Several guidelines on opioid prescribing for acute pain from emergency departments (*192*–*194*) and other settings (*195*,*196*) have recommended prescribing ≤3 days of opioids in most cases, whereas others have recommended ≤7 days (*197*) or <14 days (*30*). Because physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days (contextual evidence review), limiting days of opioids prescribed also should minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms. Experts noted that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion.

Experts agreed that when opioids are needed for acute pain, clinicians should prescribe opioids at the lowest effective dose and for no longer than the expected duration of pain severe enough to require opioids to minimize unintentional initiation of long-term opioid use. The lowest effective dose can be determined using product labeling as a starting point with calibration as needed based on the severity of pain and on other clinical factors such as renal or hepatic insufficiency (see Recommendation 8). Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤3 days' supply of opioids will be sufficient. For example, in one study of the course of acute low back pain (not associated with malignancies, infections, spondylarthropathies, fractures, or neurological signs) in a primary care setting, there was a large decrease in pain until the fourth day after treatment with paracetamol, with smaller decreases thereafter (*198*). Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3–5 days or ≤3–7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

Acute pain can often be managed without opioids. It is important to evaluate the patient for reversible causes of pain, for underlying etiologies with potentially serious sequelae, and to determine appropriate treatment. When the diagnosis and severity of nontraumatic, nonsurgical acute pain are reasonably assumed to warrant the use of opioids, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids, often 3 days or less, unless circumstances clearly warrant additional opioid therapy. More than 7 days will rarely be needed. Opioid treatment for post-surgical pain is outside the scope of this guideline but has been addressed elsewhere (*30*). Clinicians should not prescribe additional opioids to patients "just in case" pain continues longer than expected. Clinicians should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly. Given longer half-lives and longer duration of effects (e.g., respiratory depression) with ER/LA opioids such as methadone, fentanyl patches, or extended release versions of opioids such as oxycodone, oxymorphone, or morphine, clinicians should not prescribe ER/LA opioids for the treatment of acute pain.

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

Although the clinical evidence review did not find studies evaluating the effectiveness of more frequent monitoring intervals (KQ4), it did find that continuing opioid therapy for 3 months substantially increases risk for opioid use disorder (KQ2); therefore, follow-up earlier than 3 months might be necessary to provide the greatest opportunity to prevent the development of opioid use disorder. In addition, risk for overdose associated with ER/LA opioids might be particularly high during the first 2 weeks of treatment (KQ3). The contextual evidence review found that patients who do not have pain relief with opioids at 1 month are unlikely to experience pain relief with opioids at 6 months. Although evidence is insufficient to determine at what point within the first 3 months of opioid therapy the risks for opioid use disorder increase, reassessment of pain and function within 1 month of initiating opioids provides an opportunity to minimize risks of long-term opioid use by discontinuing opioids among patients not receiving a clear benefit from these medications. Experts noted that risks for opioid overdose are greatest during the first 3–7 days after opioid initiation or increase in dosage, particularly when methadone or transdermal fentanyl are prescribed; that follow-up within 3 days is appropriate when initiating or increasing the dosage of methadone; and that follow-up within 1 week might be appropriate when initiating or increasing the dosage of other ER/LA opioids.

Clinicians should evaluate patients to assess benefits and harms of opioids within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation. Clinicians should consider follow-up intervals within the lower end of this range when ER/LA opioids are started or increased or when total daily opioid dosage is ≥50 MME/day. Shorter follow-up intervals (within 3 days) should be strongly considered when starting or increasing the dosage of methadone. At follow up, clinicians should assess benefits in function, pain control, and quality of life using tools such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale (*186*) and/or asking patients about progress toward functional goals that have meaning for them (see Recommendation 2). Clinicians should also ask patients about common adverse effects such as constipation and drowsiness (see Recommendation 3), as well as asking about and assessing for effects that might be early warning signs for more serious problems such as overdose (e.g., sedation or slurred speech) or opioid use disorder (e.g., craving, wanting to take opioids in greater quantities or more frequently than prescribed, or difficulty controlling use). Clinicians should ask patients about their preferences for continuing opioids, given their effects on pain and function relative to any adverse effects experienced.

Because of potential changes in the balance of benefits and risks of opioid therapy over time, clinicians should regularly reassess all patients receiving long-term opioid therapy, including patients who are new to the clinician but on long-term opioid therapy, at least every 3 months. At reassessment, clinicians should determine whether opioids continue to meet treatment goals, including sustained improvement in pain and function, whether the patient has experienced common or serious adverse events or early warning signs of serious adverse events, signs of opioid use disorder (e.g., difficulty controlling use, work or family problems related to opioid use), whether benefits of opioids continue to outweigh risks, and whether opioid dosage can be reduced or opioids can be discontinued. Ideally, these reassessments would take place in person and be conducted by the prescribing clinician. In practice contexts where virtual visits are part of standard care (e.g., in remote areas where distance or other issues make follow-up visits challenging), follow-up assessments that allow the clinician to communicate with and observe the patient through video and audio could be conducted, with in-person visits occurring at least once per year. Clinicians should re-evaluate patients who are exposed to greater risk of opioid use disorder or overdose (e.g., patients with depression or other mental health conditions, a history of substance use disorder, a history of overdose, taking ≥50 MME/day, or taking other central nervous system depressants with opioids) more frequently than every 3 months. If clinically meaningful improvements in pain and function are not sustained, if patients are taking high-risk regimens (e.g., dosages ≥50 MME/day or opioids combined with benzodiazepines) without evidence of benefit, if patients believe benefits no longer outweigh risks or if they request dosage reduction or discontinuation, or if patients experience overdose or other serious adverse events (e.g., an event leading to hospitalization or disability) or warning signs of serious adverse events, clinicians should work with patients to reduce opioid dosage or to discontinue opioids when possible. Clinicians should maximize pain treatment with nonpharmacologic and nonopioid pharmacologic treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to assist with pain management.

Considerations for Tapering Opioids

Although the clinical evidence review did not find high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued (KQ3), tapers reducing weekly dosage by 10%–50% of the original dosage have been recommended by other clinical guidelines (*199*), and a rapid taper over 2–3 weeks has been recommended in the case of a severe adverse event such as overdose (*30*). Experts noted that tapers slower than 10% per week (e.g., 10% per month) also might be appropriate and better tolerated than more rapid tapers, particularly when patients have been taking opioids for longer durations (e.g., for years). Opioid withdrawal during pregnancy has been associated with spontaneous abortion and premature labor.

When opioids are reduced or discontinued, a taper slow enough to minimize symptoms and signs of opioid withdrawal (e.g., drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, diaphoresis, mydriasis, tremor, tachycardia, or piloerection) should be used. A decrease of 10% of the original dose per week is a reasonable starting point; experts agreed that tapering plans may be individualized based on patient goals and concerns. Experts noted that at times, tapers might have to be paused and restarted again when the patient is ready and might have to be slowed once patients reach low dosages. Tapers may be considered successful as long as the patient is making progress. Once the smallest available dose is reached, the interval between doses can be extended. Opioids may be stopped when taken less frequently than once a day. More rapid tapers might be needed for patient safety under certain circumstances (e.g., for patients who have experienced overdose on their current dosage). Ultrarapid detoxification under anesthesia is associated with substantial risks, including death, and should not be used (*200*). Clinicians should access appropriate expertise if considering tapering opioids during pregnancy because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal. Patients who are not taking opioids (including patients who are diverting all opioids they obtain) do not require tapers. Clinicians should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose. Primary care clinicians should collaborate with mental health providers and with other specialists as needed to optimize nonopioid pain management (see Recommendation 1), as well as psychosocial support for anxiety related to the taper. More detailed guidance on tapering, including management of withdrawal symptoms has been published previously (*30*,*201*). If a patient exhibits signs of opioid use disorder, clinicians should offer or arrange for treatment of opioid use disorder (see Recommendation 12) and consider offering naloxone for overdose prevention (see Recommendation 8).

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on patient demographics or patient comorbidities (KQ2). However, based on the contextual evidence review and expert opinion, certain risk factors are likely to increase susceptibility to opioid-associated harms and warrant incorporation of additional strategies into the management plan to mitigate risk. Clinicians should assess these risk factors periodically, with frequency varying by risk factor and patient characteristics. For example, factors that vary more frequently over time, such as alcohol use, require more frequent follow up. In addition, clinicians should consider offering naloxone, re-evaluating patients more frequently (see Recommendation 7), and referring to pain and/or behavioral health specialists when factors that increase risk for harm, such as history of overdose, history of substance use disorder, higher dosages of opioids (≥50 MME/day), and concurrent use of benzodiazepines with opioids, are present.

Patients with Sleep-Disordered Breathing, Including Sleep Apnea

Risk factors for sleep-disordered breathing include congestive heart failure, and obesity. Experts noted that careful monitoring and cautious dose titration should be used if opioids are prescribed for patients with mild sleep-disordered breathing. Clinicians should avoid prescribing opioids to patients with moderate or severe sleep-disordered breathing whenever possible to minimize risks for opioid overdose (contextual evidence review).

Pregnant Women

Opioids used in pregnancy might be associated with additional risks to both mother and fetus. Some studies have shown an association of opioid use in pregnancy with stillbirth, poor fetal growth, pre-term delivery, and birth defects (contextual evidence review). Importantly, in some cases, opioid use during pregnancy leads to neonatal opioid withdrawal syndrome. Clinicians and patients together should carefully weigh risks and benefits when making decisions

about whether to initiate opioid therapy for chronic pain during pregnancy. In addition, before initiating opioid therapy for chronic pain for reproductive-age women, clinicians should discuss family planning and how long-term opioid use might affect any future pregnancy. For pregnant women already receiving opioids, clinicians should access appropriate expertise if considering tapering opioids because of possible risk to the pregnant patient and to the fetus if the patient goes into withdrawal (see Recommendation 7). For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine or methadone has been associated with improved maternal outcomes and should be offered (*202*) (see Recommendation 12). Clinicians caring for pregnant women receiving opioids for pain or receiving buprenorphine or methadone for opioid use disorder should arrange for delivery at a facility prepared to monitor, evaluate for, and treat neonatal opioid withdrawal syndrome. In instances when travel to such a facility would present an undue burden on the pregnant woman, it is appropriate to deliver locally, monitor and evaluate the newborn for neonatal opioid withdrawal syndrome, and transfer the newborn for additional treatment if needed. Neonatal toxicity and death have been reported in breast-feeding infants whose mothers are taking codeine (contextual evidence review); previous guidelines have recommended that codeine be avoided whenever possible among mothers who are breast feeding and, if used, should be limited to the lowest possible dose and to a 4-day supply (*203*).

Patients with Renal or Hepatic Insufficiency

Clinicians should use additional caution and increased monitoring (see Recommendation 7) to minimize risks of opioids prescribed for patients with renal or hepatic insufficiency, given their decreased ability to process and excrete drugs, susceptibility to accumulation of opioids, and reduced therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review; see Recommendations 4, 5, and 7).

Patients Aged ≥65 Years

Inadequate pain treatment among persons aged ≥65 years has been documented (*204*). Pain management for older patients can be challenging given increased risks of both nonopioid pharmacologic therapies (see Recommendation 1) and opioid therapy in this population. Given reduced renal function and medication clearance even in the absence of renal disease, patients aged ≥65 years might have increased susceptibility to accumulation of opioids and a smaller therapeutic window between safe dosages and dosages associated with respiratory depression and overdose (contextual evidence review). Some older adults suffer from cognitive impairment, which can increase risk for medication errors and make opioid-related confusion more dangerous. In addition, older adults are more likely than younger adults to experience co-morbid medical conditions and more likely to receive multiple medications, some of which might interact with opioids (such as benzodiazepines). Clinicians should use additional caution and increased monitoring (see Recommendations 4, 5, and 7) to minimize risks of opioids prescribed for patients aged ≥65 years. Experts suggested that clinicians educate older adults receiving opioids to avoid risky medication-related behaviors such as obtaining controlled medications from multiple prescribers and saving unused medications. Clinicians should also implement interventions to mitigate common risks of opioid therapy among older adults, such as exercise or bowel regimens to prevent constipation, risk assessment for falls, and patient monitoring for cognitive impairment.

Patients with Mental Health Conditions

Because psychological distress frequently interferes with improvement of pain and function in patients with chronic pain, using validated instruments such as the Generalized Anxiety Disorder (GAD)-7 and the Patient Health Questionnaire (PHQ)-9 or the PHQ-4 to assess for anxiety, post-traumatic stress disorder, and/or depression (*205*), might help clinicians improve overall pain treatment outcomes. Experts noted that clinicians should use additional caution and increased monitoring (see Recommendation 7) to lessen the increased risk for opioid use disorder among patients with mental health conditions (including depression, anxiety disorders, and PTSD), as well as increased risk for drug overdose among patients with depression. Previous guidelines have noted that opioid therapy should not be initiated during acute psychiatric instability or uncontrolled suicide risk, and that clinicians should consider behavioral health specialist consultation for any patient with a history of suicide attempt or psychiatric disorder (*31*). In addition, patients with anxiety disorders and other mental health conditions are more likely to receive benzodiazepines, which can exacerbate opioid-induced respiratory depression and increase risk for overdose (see Recommendation 11). Clinicians should ensure that treatment for depression and other mental health conditions is optimized, consulting with behavioral health specialists when needed. Treatment for depression can improve pain symptoms as well as depression and might decrease overdose risk (contextual evidence review). For treatment of chronic pain in patients with depression, clinicians should strongly consider using tricyclic or SNRI antidepressants for analgesic as well as antidepressant effects if these medications are not otherwise contraindicated (see Recommendation 1).

Patients with Substance Use Disorder

Illicit drugs and alcohol are listed as contributory factors on a substantial proportion of death certificates for opioid-related overdose deaths (contextual evidence review). Previous guidelines have recommended screening or risk assessment tools to identify patients at higher risk for misuse or abuse of opioids. However, the clinical evidence review found that currently available risk-stratification tools (e.g., Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain Version 1, SOAPP-R, and Brief Risk Interview) show insufficient accuracy for classification of patients as at low or high risk for abuse or misuse (KQ4). Clinicians should always exercise caution when considering or prescribing opioids for any patient with chronic pain outside of active cancer, palliative, and end-of-life care and should not overestimate the ability of these tools to rule out risks from long-term opioid therapy.

Clinicians should ask patients about their drug and alcohol use. Single screening questions can be used (*206*). For example, the question "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?" (with an answer of one or more considered positive) was found in a primary care setting to be 100% sensitive and 73.5% specific for the detection of a drug use disorder compared with a standardized diagnostic interview (*207*). Validated screening tools such as the Drug Abuse Screening Test (DAST) (*208*) and the Alcohol Use Disorders Identification Test (AUDIT) (*209*) can also be used. Clinicians should use PDMP data (see Recommendation 9) and drug testing (see Recommendation 10) as appropriate to assess for concurrent substance use that might place patients at higher risk for opioid use disorder and overdose. Clinicians should also provide specific counseling on increased risks for overdose when opioids are combined with other drugs or alcohol (see Recommendation 3) and ensure that patients receive effective treatment for substance use disorders when needed (see Recommendation 12).

The clinical evidence review found insufficient evidence to determine how harms of opioids differ depending on past or current substance use disorder (KQ2), although a history of substance use disorder was associated with misuse. Similarly, based on contextual evidence, patients with drug or alcohol use disorders are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions. If clinicians consider opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care for patients with drug or alcohol use disorders, they should discuss increased risks for opioid use disorder and overdose with patients, carefully consider whether benefits of opioids outweigh increased risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed. Because pain management in patients with substance use disorder can be complex, clinicians should consider consulting substance use disorder specialists and pain specialists regarding pain management for persons with active or recent past history of substance abuse. Experts also noted that clinicians should communicate with patients' substance use disorder treatment providers if opioids are prescribed.

Patients with Prior Nonfatal Overdose

Although studies were not identified that directly addressed the risk for overdose among patients with prior nonfatal overdose who are prescribed opioids, based on clinical experience, experts thought that prior nonfatal overdose would substantially increase risk for future nonfatal or fatal opioid overdose. If patients experience nonfatal opioid overdose, clinicians should work with them to reduce opioid dosage and to discontinue opioids when possible (see Recommendation 7). If clinicians continue opioid therapy for chronic pain outside of active cancer, palliative, and end-of-life care in patients with prior opioid overdose, they should discuss increased risks for overdose with patients, carefully consider whether benefits of opioids outweigh substantial risks, and incorporate strategies to mitigate risk into the management plan, such as considering offering naloxone (see Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present) and increasing frequency of monitoring (see Recommendation 7) when opioids are prescribed.

Offering Naloxone to Patients When Factors That Increase Risk for Opioid-Related Harms Are Present

Naloxone is an opioid antagonist that can reverse severe respiratory depression; its administration by lay persons, such as friends and family of persons who experience opioid overdose, can save lives. Naloxone precipitates acute withdrawal among patients physically dependent on opioids. Serious adverse effects, such as pulmonary edema, cardiovascular instability, and seizures, have been reported but are rare at doses consistent with labeled use for opioid overdose (*210*). The contextual evidence review did not find any studies on effectiveness of prescribing naloxone for overdose prevention among patients prescribed opioids for chronic pain. However, there is evidence for effectiveness of naloxone provision in preventing opioid-related overdose death at the community level through community-based distribution (e.g., through overdose education and naloxone distribution programs in community service agencies) to persons at risk for overdose

(mostly due to illicit opiate use), and it is plausible that effectiveness would be observed when naloxone is provided in the clinical setting as well. Experts agreed that it is preferable not to initiate opioid treatment when factors that increase risk for opioid-related harms are present. Opinions diverged about the likelihood of naloxone being useful to patients and the circumstances under which it should be offered. However, most experts agreed that clinicians should consider offering naloxone when prescribing opioids to patients at increased risk for overdose, including patients with a history of overdose, patients with a history of substance use disorder, patients taking benzodiazepines with opioids (see Recommendation 11), patients at risk for returning to a high dose to which they are no longer tolerant (e.g., patients recently released from prison), and patients taking higher dosages of opioids (≥50 MME/day). Practices should provide education on overdose prevention and naloxone use to patients receiving naloxone prescriptions and to members of their households. Experts noted that naloxone co-prescribing can be facilitated by clinics or practices with resources to provide naloxone training and by collaborative practice models with pharmacists. Resources for prescribing naloxone in primary care settings can be found through Prescribe to Prevent at http://prescribetoprevent.org.

9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).

PDMPs are state-based databases that collect information on controlled prescription drugs dispensed by pharmacies in most states and, in select states, by dispensing physicians as well. In addition, some clinicians employed by the federal government, including some clinicians in the Indian Health Care Delivery System, are not licensed in the states where they practice, and do not have access to PDMP data. Certain states require clinicians to review PDMP data prior to writing each opioid prescription (see state-level PDMP-related policies on the National Alliance for Model State Drug Laws website at http://www.namsdl.org/prescription-monitoring-programs.cfm). The clinical evidence review did not find studies evaluating the effectiveness of PDMPs on outcomes related to overdose, addiction, abuse, or misuse (KQ4). However, even though evidence is limited on the effectiveness of PDMP implementation at the state level on prescribing and mortality outcomes (*28*), the contextual evidence review found that most fatal overdoses were associated with patients receiving opioids from multiple prescribers and/or with patients receiving high total daily opioid dosages; information on both of these risk factors for overdose are available to prescribers in the PDMP. PDMP data also can be helpful when patient medication history is not otherwise available (e.g., for patients from other locales) and when patients transition care to a new clinician. The contextual evidence review also found that PDMP information could be used in a way that is harmful to patients. For example, it has been used to dismiss patients from clinician practices (*211*), which might adversely affect patient safety.

The contextual review found variation in state policies that affect timeliness of PDMP data (and therefore benefits of reviewing PDMP data) as well as time and workload for clinicians in accessing PDMP data. In states that permit delegating access to other members of the health care team, workload for prescribers can be reduced. These differences might result in a different balance of benefits to clinician workload in different states. Experts agreed that PDMPs are useful tools that should be consulted when starting a patient on opioid therapy and periodically during long-term opioid therapy. However, experts disagreed on how frequently clinicians should check the PDMP during long-term opioid therapy, given PDMP access issues and the lag time in reporting in some states. Most experts agreed that PDMP data should be reviewed every 3 months or more frequently during long-term opioid therapy. A minority of experts noted that, given the current burden of accessing PDMP data in some states and the lack of evidence surrounding the most effective interval for PDMP review to improve patient outcomes, annual review of PDMP data during long-term opioid therapy would be reasonable when factors that increase risk for opioid-related harms are not present.

Clinicians should review PDMP data for opioids and other controlled medications patients might have received from additional prescribers to determine whether a patient is receiving high total opioid dosages or dangerous combinations (e.g., opioids combined with benzodiazepines) that put him or her at high risk for overdose. Ideally, PDMP data should be reviewed before every opioid prescription. This is recommended in all states with well-functioning PDMPs and where PDMP access policies make this practicable (e.g., clinician and delegate access permitted), but it is not currently possible in states without functional PDMPs or in those that do not permit certain prescribers to access them. As vendors and practices facilitate integration of PDMP information into regular clinical workflow (e.g., data made available in electronic health records), clinicians' ease of access in reviewing PDMP data is expected to improve.

In addition, improved timeliness of PDMP data will improve their value in identifying patient risks.

If patients are found to have high opioid dosages, dangerous combinations of medications, or multiple controlled substance prescriptions written by different clinicians, several actions can be taken to augment clinicians' abilities to improve patient safety:

- Clinicians should discuss information from the PDMP with their patient and confirm that the patient is aware of the additional prescriptions. Occasionally, PDMP information can be incorrect (e.g., if the wrong name or birthdate has been entered, the patient uses a nickname or maiden name, or another person has used the patient's identity to obtain prescriptions).
- Clinicians should discuss safety concerns, including increased risk for respiratory depression and overdose, with patients found to be receiving opioids from more than one prescriber or receiving medications that increase risk when combined with opioids (e.g., benzodiazepines) and consider offering naloxone (see Recommendation 8).
- Clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. Clinicians should communicate with others managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care (see Recommendation 11).
- Clinicians should calculate the total MME/day for concurrent opioid prescriptions to help assess the patient's overdose risk (see Recommendation 5). If patients are found to be receiving high total daily dosages of opioids, clinicians should discuss their safety concerns with the patient, consider tapering to a safer dosage (see Recommendations 5 and 7), and consider offering naloxone (see Recommendation 8).
- Clinicians should discuss safety concerns with other clinicians who are prescribing controlled substances for their patient. Ideally clinicians should first discuss concerns with their patient and inform him or her that they plan to coordinate care with the patient's other prescribers to improve the patient's safety.
- Clinicians should consider the possibility of a substance use disorder and discuss concerns with their patient (see Recommendation 12).
- If clinicians suspect their patient might be sharing or selling opioids and not taking them, clinicians should consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal (see Recommendations 7 and 10). A negative drug test for prescribed opioids might indicate the patient is not taking prescribed opioids, although clinicians should consider other possible reasons for this test result (see Recommendation 10).

Experts agreed that clinicians should not dismiss patients from their practice on the basis of PDMP information. Doing so can adversely affect patient safety, could represent patient abandonment, and could result in missed opportunities to provide potentially lifesaving information (e.g., about risks of opioids and overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment [see Recommendation 1], naloxone [see Recommendation 8], and effective treatment for substance use disorder [see Recommendation 12]).

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

Concurrent use of opioid pain medications with other opioid pain medications, benzodiazepines, or heroin can increase patients' risk for overdose. Urine drug tests can provide information about drug use that is not reported by the patient. In addition, urine drug tests can assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects. Urine drug tests do not provide accurate information about how much or what dose of opioids or other drugs a patient took. The clinical evidence review did not find studies evaluating the effectiveness of urine drug screening for risk mitigation during opioid prescribing for pain (KQ4). The contextual evidence review found that urine drug testing can provide useful information about patients assumed not to be using unreported drugs. Urine drug testing results can be subject to misinterpretation and might sometimes be associated with practices that might harm patients (e.g., stigmatization, inappropriate termination from care). Routine use of urine drug tests with standardized policies at the practice or clinic level might destigmatize their use. Although random drug testing also might destigmatize urine drug testing, experts thought that truly random testing was not feasible in clinical practice. Some clinics obtain a urine specimen at every visit, but only send it for testing on a random schedule. Experts noted that in addition to direct costs of urine drug testing, which often are not covered fully by insurance and can be a burden for patients, clinician time is needed to interpret, confirm, and communicate results.

Experts agreed that prior to starting opioids for chronic pain and periodically during opioid therapy, clinicians should

use urine drug testing to assess for prescribed opioids as well as other controlled substances and illicit drugs that increase risk for overdose when combined with opioids, including nonprescribed opioids, benzodiazepines, and heroin. There was some difference of opinion among experts as to whether this recommendation should apply to all patients, or whether this recommendation should entail individual decision making with different choices for different patients based on values, preferences, and clinical situations. While experts agreed that clinicians should use urine drug testing before initiating opioid therapy for chronic pain, they disagreed on how frequently urine drug testing should be conducted during long-term opioid therapy. Most experts agreed that urine drug testing at least annually for all patients was reasonable. Some experts noted that this interval might be too long in some cases and too short in others, and that the follow-up interval should be left to the discretion of the clinician. Previous guidelines have recommended more frequent urine drug testing in patients thought to be at higher risk for substance use disorder (*30*). However, experts thought that predicting risk prior to urine drug testing is challenging and that currently available tools do not allow clinicians to reliably identify patients who are at low risk for substance use disorder.

In most situations, initial urine drug testing can be performed with a relatively inexpensive immunoassay panel for commonly prescribed opioids and illicit drugs. Patients prescribed less commonly used opioids might require specific testing for those agents. The use of confirmatory testing adds substantial costs and should be based on the need to detect specific opioids that cannot be identified on standard immunoassays or on the presence of unexpected urine drug test results. Clinicians should be familiar with the drugs included in urine drug testing panels used in their practice and should understand how to interpret results for these drugs. For example, a positive "opiates" immunoassay detects morphine, which might reflect patient use of morphine, codeine, or heroin, but this immunoassay does not detect synthetic opioids (e.g., fentanyl or methadone) and might not detect semisynthetic opioids (e.g., oxycodone). However, many laboratories use an oxycodone immunoassay that detects oxycodone and oxymorphone. In some cases, positive results for specific opioids might reflect metabolites from opioids the patient is taking and might not mean the patient is taking the specific opioid for which the test was positive. For example, hydromorphone is a metabolite of hydrocodone, and oxymorphone is a metabolite of oxycodone. Detailed guidance on interpretation of urine drug test results, including which tests to order and expected results, drug detection time in urine, drug metabolism, and other considerations has been published previously (*30*). Clinicians should not test for substances for which results would not affect patient management or for which implications for patient management are unclear. For example, experts noted that there might be uncertainty about the clinical implications of a positive urine drug test for tetrahyrdocannabinol (THC). In addition, restricting confirmatory testing to situations and substances for which results can reasonably be expected to affect patient management can reduce costs of urine drug testing, given the substantial costs associated with confirmatory testing methods. Before ordering urine drug testing, clinicians should have a plan for responding to unexpected results. Clinicians should explain to patients that urine drug testing is intended to improve their safety and should also explain expected results (e.g., presence of prescribed medication and absence of drugs, including illicit drugs, not reported by the patient). Clinicians should ask patients about use of prescribed and other drugs and ask whether there might be unexpected results. This will provide an opportunity for patients to provide information about changes in their use of prescribed opioids or other drugs. Clinicians should discuss unexpected results with the local laboratory or toxicologist and with the patient. Discussion with patients prior to specific confirmatory testing can sometimes yield a candid explanation of why a particular substance is present or absent and obviate the need for expensive confirmatory testing on that visit. For example, a patient might explain that the test is negative for prescribed opioids because she felt opioids were no longer helping and discontinued them. If unexpected results are not explained, a confirmatory test using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography/mass spectrometry) might be warranted to clarify the situation.

Clinicians should use unexpected results to improve patient safety (e.g., change in pain management strategy [see Recommendation 1], tapering or discontinuation of opioids [see Recommendation 7], more frequent re-evaluation [see Recommendation 7], offering naloxone [see Recommendation 8], or referral for treatment for substance use disorder [see Recommendation 12], all as appropriate). If tests for prescribed opioids are repeatedly negative, confirming that the patient is not taking the prescribed opioid, clinicians can discontinue the prescription without a taper. Clinicians should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently

whenever possible (recommendation category: A, evidence type: 3).

Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive. Concurrent use is likely to put patients at greater risk for potentially fatal overdose. The clinical evidence review did not address risks of benzodiazepine co-prescription among patients prescribed opioids. However, the contextual evidence review found evidence in epidemiologic series of concurrent benzodiazepine use in large proportions of opioid-related overdose deaths, and a case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone (*212*). Experts agreed that although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. In addition, given that other central nervous system depressants (e.g., muscle relaxants, hypnotics) can potentiate central nervous system depression associated with opioids, clinicians should consider whether benefits outweigh risks of concurrent use of these drugs. Clinicians should check the PDMP for concurrent controlled medications prescribed by other clinicians (see Recommendation 9) and should consider involving pharmacists and pain specialists as part of the management team when opioids are co-prescribed with other central nervous system depressants. Because of greater risks of benzodiazepine withdrawal relative to opioid withdrawal, and because tapering opioids can be associated with anxiety, when patients receiving both benzodiazepines and opioids require tapering to reduce risk for fatal respiratory depression, it might be safer and more practical to taper opioids first (see Recommendation 7). Clinicians should taper benzodiazepines gradually if discontinued because abrupt withdrawal can be associated with rebound anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death (contextual evidence review). A commonly used tapering schedule that has been used safely and with moderate success is a reduction of the benzodiazepine dose by 25% every 1–2 weeks (*213*,*214*). CBT increases tapering success rates and might be particularly helpful for patients struggling with a benzodiazepine taper (*213*). If benzodiazepines prescribed for anxiety are tapered or discontinued, or if patients receiving opioids require treatment for anxiety, evidence-based psychotherapies (e.g., CBT) and/or specific anti-depressants or other nonbenzodiazepine medications approved for anxiety should be offered. Experts emphasized that clinicians should communicate with mental health professionals managing the patient to discuss the patient's needs, prioritize patient goals, weigh risks of concurrent benzodiazepine and opioid exposure, and coordinate care.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 2).

Opioid use disorder (previously classified as opioid abuse or opioid dependence) is defined in the *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition (DSM-5) as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within a year (http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf) (*20*).

The clinical evidence review found prevalence of opioid dependence (using DSM-IV diagnosis criteria) in primary care settings among patients with chronic pain on opioid therapy to be 3%–26% (KQ2). As found in the contextual evidence review and supported by moderate quality evidence, opioid agonist or partial agonist treatment with methadone maintenance therapy or buprenorphine has been shown to be more effective in preventing relapse among patients with opioid use disorder (*151–153*). Some studies suggest that using behavioral therapies in combination with these treatments can reduce opioid misuse and increase retention during maintenance therapy and improve compliance after detoxification (*154*,*155*); behavioral therapies are also recommended by clinical practice guidelines (*215*). The cited studies primarily evaluated patients with a history of illicit opioid use, rather than prescription opioid use for chronic pain. Recent studies among patients with prescription opioid dependence (based on DSM-IV criteria) have found maintenance therapy with buprenorphine and buprenorphine-naloxone effective in preventing relapse (*216*,*217*). Treatment need in a community is often not met by capacity to provide buprenorphine or methadone maintenance therapy (*218*), and patient cost can be a barrier to buprenorphine treatment because insurance coverage of buprenorphine for opioid use disorder is often limited (*219*). Oral or long-acting injectable formulations of naltrexone can also be used as medication-assisted treatment for opioid use disorder in nonpregnant adults, particularly for highly motivated persons (*220*,*221*). Experts agreed that clinicians prescribing opioids should identify treatment resources for opioid use disorder in the community and should work together to ensure sufficient treatment capacity for opioid use disorder at the practice level.

If clinicians suspect opioid use disorder based on patient concerns or behaviors or on findings in prescription drug monitoring program data (see Recommendation 9) or from urine drug testing (see Recommendation 10), they should discuss their concern with their patient and provide an opportunity for the patient to disclose related concerns or problems. Clinicians should assess for the presence of opioid use disorder using DSM-5 criteria (*20*). Alternatively, clinicians can arrange for a substance use disorder treatment specialist to assess for the presence of opioid use disorder. For patients meeting criteria for opioid use disorder, clinicians should offer or arrange for patients to receive evidence-based treatment, usually medication-assisted treatment with buprenorphine or methadone maintenance therapy in combination with behavioral therapies. Oral or long-acting injectable naltrexone, a long-acting opioid antagonist, can also be used in non-pregnant adults. Naltrexone blocks the effects of opioids if they are used but requires adherence to daily oral therapy or monthly injections. For pregnant women with opioid use disorder, medication-assisted therapy with buprenorphine (without naloxone) or methadone has been associated with improved maternal outcomes and should be offered (see Recommendation 8). Clinicians should also consider offering naloxone for overdose prevention to patients with opioid use disorder (see Recommendation 8). For patients with problematic opioid use that does not meet criteria for opioid use disorder, experts noted that clinicians can offer to taper and discontinue opioids (see Recommendation 7). For patients who choose to but are unable to taper, clinicians may reassess for opioid use disorder and offer opioid agonist therapy if criteria are met.

Physicians not already certified to provide buprenorphine in an office-based setting can undergo training to receive a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) that allows them to prescribe buprenorphine to treat patients with opioid use disorder. Physicians prescribing opioids in communities without sufficient treatment capacity for opioid use disorder should strongly consider obtaining this waiver. Information about qualifications and the process to obtain a waiver are available from SAMHSA (*222*). Clinicians do not need a waiver to offer naltrexone for opioid use disorder as part of their practice.

Additional guidance has been published previously (*215*) on induction, use, and monitoring of buprenorphine treatment (see Part 5) and naltrexone treatment (see Part 6) for opioid use disorder and on goals, components of, and types of effective psychosocial treatment that are recommended in conjunction with pharmacological treatment of opioid use disorder (see Part 7). Clinicians unable to provide treatment themselves should arrange for patients with opioid use disorder to receive care from a substance use disorder treatment specialist, such as an office-based buprenorphine or naltrexone treatment provider, or from an opioid treatment program certified by SAMHSA to provide supervised medication-assisted treatment for patients with opioid use disorder. Clinicians should assist patients in finding qualified treatment providers and should arrange for patients to follow up with these providers, as well as arranging for ongoing coordination of care. Clinicians should not dismiss patients from their practice because of a substance use disorder because this can adversely affect patient safety and could represent patient abandonment. Identification of substance use disorder represents an opportunity for a clinician to initiate potentially life-saving interventions, and it is important for the clinician to collaborate with the patient regarding their safety to increase the likelihood of successful treatment. In addition, although identification of an opioid use disorder can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. Clinicians should continue to use nonpharmacologic and nonopioid pharmacologic pain treatments as appropriate (see Recommendation 1) and consider consulting a pain specialist as needed to provide optimal pain management.

Resources to help with arranging for treatment include SAMHSA's buprenorphine physician locator (http://buprenorphine.samhsa.gov/bwns_locator); SAMHSA's Opioid Treatment Program Directory (http://dpt2.samhsa.gov/treatment/directory.aspx); SAMHSA's Provider Clinical Support System for Opioid Therapies (http://pcss-o.org), which offers extensive experience in the treatment of substance use disorders and specifically of opioid use disorder, as well as expertise on the interface of pain and opioid misuse; and SAMHSA's Provider's Clinical Support System for Medication-Assisted Treatment (http://pcssmat.org), which offers expert physician mentors to answer questions about assessment for and treatment of substance use disorders.

Conclusions and Future Directions

Clinical guidelines represent one strategy for improving prescribing practices and health outcomes. Efforts are required to disseminate the guideline and achieve widespread adoption and implementation of the recommendations in clinical settings. CDC will translate this guideline into user-friendly materials for distribution and use by health systems, medical professional societies, insurers, public health departments, health information technology developers, and clinicians and engage in dissemination efforts. CDC has provided a

checklist for prescribing opioids for chronic pain (http://stacks.cdc.gov/view/cdc/38025), additional resources such as fact sheets (http://www.cdc.gov/drugoverdose/prescribing/resources.html), and will provide a mobile application to guide clinicians in implementing the recommendations. CDC will also work with partners to support clinician education on pain management options, opioid therapy, and risk mitigation strategies (e.g., urine drug testing). Activities such as development of clinical decision support in electronic health records to assist clinicians' treatment decisions at the point of care; identification of mechanisms that insurers and pharmacy benefit plan managers can use to promote safer prescribing within plans; and development of clinical quality improvement measures and initiatives to improve prescribing and patient care within health systems have promise for increasing guideline adoption and improving practice. In addition, policy initiatives that address barriers to implementation of the guidelines, such as increasing accessibility of PDMP data within and across states, e-prescribing, and availability of clinicians who can offer medication-assisted treatment for opioid use disorder, are strategies to consider to enhance implementation of the recommended practices. CDC will work with federal partners and payers to evaluate strategies such as payment reform and health care delivery models that could improve patient health and safety. For example, strategies might include strengthened coverage for nonpharmacologic treatments, appropriate urine drug testing, and medication-assisted treatment; reimbursable time for patient counseling; and payment models that improve access to interdisciplinary, coordinated care.

As highlighted in the forthcoming report on the National Pain Strategy, an overarching federal effort that outlines a comprehensive population-level health strategy for addressing pain as a public health problem, clinical guidelines complement other strategies aimed at preventing illnesses and injuries that lead to pain. A draft of the National Pain Strategy has been published previously (*180*). These strategies include strengthening the evidence base for pain prevention and treatment strategies, reducing disparities in pain treatment, improving service delivery and reimbursement, supporting professional education and training, and providing public education. It is important that overall improvements be made in developing the workforce to address pain management in general, in addition to opioid prescribing specifically. This guideline also complements other federal efforts focused on addressing the opioid overdose epidemic including prescriber training and education, improving access to treatment for opioid use disorder, safe storage and disposal programs, utilization management mechanisms, naloxone distribution programs, law enforcement and supply reduction efforts, prescription drug monitoring program improvements, and support for community coalitions and state prevention programs.

This guideline provides recommendations that are based on the best available evidence that was interpreted and informed by expert opinion. The clinical scientific evidence informing the recommendations is low in quality. To inform future guideline development, more research is necessary to fill in critical evidence gaps. The evidence reviews forming the basis of this guideline clearly illustrate that there is much yet to be learned about the effectiveness, safety, and economic efficiency of long-term opioid therapy. As highlighted by an expert panel in a recent workshop sponsored by the National Institutes of Health on the role of opioid pain medications in the treatment of chronic pain, "evidence is insufficient for every clinical decision that a provider needs to make about the use of opioids for chronic pain" (*223*). The National Institutes of Health panel recommended that research is needed to improve our understanding of which types of pain, specific diseases, and patients are most likely to be associated with benefit and harm from opioid pain medications; evaluate multidisciplinary pain interventions; estimate cost-benefit; develop and validate tools for identification of patient risk and outcomes; assess the effectiveness and harms of opioid pain medications with alternative study designs; and investigate risk identification and mitigation strategies and their effects on patient and public health outcomes. It is also important to obtain data to inform the cost feasibility and cost-effectiveness of recommended actions, such as use of nonpharmacologic therapy and urine drug testing. Research that contributes to safer and more effective pain treatment can be implemented across public health entities and federal agencies (*4*). Additional research can inform the development of future guidelines for special populations that could not be adequately addressed in this guideline, such as children and adolescents, where evidence and guidance is needed but currently lacking. CDC is committed to working with partners to identify the highest priority research areas to build the evidence base. Yet, given that chronic pain is recognized as a significant public health problem, the risks associated with long-term opioid therapy, the availability of effective nonpharmacological and nonopioid pharmacologic treatment options for pain, and the potential for improvement in the quality of health care with the implementation of recommended practices, a guideline for prescribing is warranted with the evidence that is currently available. The balance between the benefits and the risks of long-term opioid therapy for chronic pain based on both clinical and contextual evidence is strong enough to support the issuance of category A recommendations in most cases.

CDC will revisit this guideline as new evidence becomes available to determine when evidence gaps have been sufficiently closed to warrant an update of the guideline. Until this research is conducted, clinical practice guidelines will have to be based on the best available evidence and expert opinion. This guideline is intended to improve communication between clinicians and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death. CDC is committed to evaluating the guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted.

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TABLE 1. Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness and comparative effectiveness (KQ1)							
Effectiveness of long-term opioid therapy versus placebo or no opioid therapy for long-term (≥1 year) outcomes							
Pain, function, and quality of life	None	—[†]	—	—	Insufficient	—	No evidence
Harms and adverse events (KQ2)							
Risks of opioids versus placebo or no opioids on opioid abuse, addiction, and related outcomes; overdose; and other harms							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found long-term use of prescribed opioids associated with an increased risk of abuse or dependence diagnosis versus no opioid use (adjusted OR ranged from 14.9 to 122.5, depending on dose).
Abuse or addiction	10 uncontrolled studies (n = 3,780)	Very serious limitations	Very serious inconsistency	No imprecision	4	None identified	In primary care settings, prevalence of opioid abuse ranged from 0.6% to 8% and prevalence of dependence from 3% to 26%. In pain clinic settings, prevalence of misuse ranged from 8% to 16% and addiction from 2% to 14%. Prevalence of aberrant drug-related behaviors ranged from 6% to 37%.
Overdose	1 cohort study (n = 9,940)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Current opioid use associated with increased risk of any overdose events (adjusted HR 5.2, 95% CI = 2.1–12) and serious overdose events (adjusted HR 8.4, 95% CI = 2.5–28) versus current nonuse.
Fractures	1 cohort study (n = 2,341) and 1 case–control study (n = 21,739 case patients)	Serious limitations	No inconsistency	No imprecision	3	None identified	Opioid use associated with increased risk of fracture in 1 cohort study (adjusted HR 1.28, 95% CI = 0.99–1.64) and 1 case-control study (adjusted OR 1.27, 95% CI = 1.21–1.33).
Myocardial infarction	1 cohort study (n = 426,124) and 1 case–control study (n = 11,693 case patients)	No limitations	No inconsistency	No imprecision	3	None identified	Current opioid use associated with increased risk of myocardial infarction versus nonuse (adjusted OR 1.28, 95% CI = 1.19–1.37 and incidence rate ratio 2.66, 95% CI = 2.30–3.08).
Endocrinologic harms	1 cross-sectional study (n = 11,327)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Long-term opioid use associated with increased risk for use of medications for erectile dysfunction or testosterone replacement versus nonuse (adjusted OR 1.5, 95% CI = 1.1–1.9).
How do harms vary depending on the opioid dose used?							
Abuse or addiction	1 cohort study (n = 568,640)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	One retrospective cohort study found higher doses of long-term opioid therapy associated with increased risk of opioid abuse or dependence than lower doses. Compared to no opioid prescription, the adjusted odds ratios were 15 (95% CI = 10–21) for 1 to 36 MME/day, 29 (95 % CI = 20–41) for 36 to120 MME/day, and 122 (95 % CI = 73–205) for ≥120 MME/day.
Overdose	1 cohort study (n = 9,940) and 1 case–control study (n = 593 case patients in primary analysis)	Serious limitations	No inconsistency	No imprecision	3	Magnitude of effect, dose response relationship	Versus 1 to <20 MME/day, one cohort study found an adjusted HR for an overdose event of 1.44 (95% CI = 0.57–3.62) for 20 to <50 MME/day that increased to 8.87 (95% CI = 3.99–19.72) at ≥100 MME/day; one case-control study found an adjusted OR for an opioid-related death of 1.32 (95% CI = 0.94–1.84) for 20 to 49 MME/day that increased to 2.88 (95% CI = 1.79–4.63) at ≥200 MME/day.
Fractures	1 cohort study (n = 2,341)	Serious limitations	Unknown (1 study)	Serious imprecision	3	None identified	Risk of fracture increased from an adjusted HR of 1.20 (95% CI = 0.92–1.56) at 1 to <20 MME/day to 2.00 (95% CI = 1.24–3.24) at ≥50 MME/day; the trend was of borderline statistical significance.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Myocardial infarction	1 cohort study (n = 426,124)	Serious limitations	Unknown (1 study)	No imprecision	3	None identified	Relative to a cumulative dose of 0 to 1,350 MME during a 90-day period, the incidence rate ratio for myocardial infarction for 1350 to <2700 MME was 1.21 (95% CI = 1.02–1.45), for 2,700 to <8,100 MME was 1.42 (95% CI = 1.21–1.67), for 8,100 to <18,000 MME was 1.89 (95% CI = 1.54–2.33), and for ≥18,000 MME was 1.73 (95% CI = 1.32–2.26).
Motor vehicle crash injuries	1 case–control study (n = 5,300 case patients)	No limitations	Unknown (1 study)	No imprecision	3	None identified	No association between opioid dose and risk of motor vehicle crash injuries even though opioid doses >20 MME/day were associated with increased odds of road trauma among drivers.
Endocrinologic harms	1 cross-sectional study (n = 11,327) New for update: 1 additional cross-sectional study (n=1,585)	Serious limitations	Consistent	No imprecision	3	None identified	Relative to 0 to <20 MME/day, the adjusted OR for ≥120 MME/day for use of medications for erectile dysfunction or testosterone replacement was 1.6 (95% CI = 1.0–2.4). One new cross-sectional study found higher-dose long-term opioid therapy associated with increased risk of androgen deficiency among men receiving immediate-release opioids (adjusted OR per 10 MME/day 1.16, 95% CI = 1.09–1.23), but the dose response was very weak among men receiving ER/LA opioids.
Dosing strategies (KQ3)							
Comparative effectiveness of different methods for initiating opioid therapy and titrating doses							
Pain	3 randomized trials (n = 93)	Serious limitations	Serious inconsistency	Very serious imprecision	4	None identified	Trials on effects of titration with immediate-release versus ER/LA opioids reported inconsistent results and had additional differences between treatment arms in dosing protocols (titrated versus fixed dosing) and doses of opioids used.
Overdose	New for update: 1 cohort study (n = 840,606)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One new cross-sectional study found initiation of therapy with an ER/LA opioid associated with increased risk of overdose versus initiation with an immediate-release opioid (adjusted HR 2.33, 95% CI = 1.26–4.32).
Comparative effectiveness of different ER/LA opioids							
Pain and function	3 randomized trials (n = 1,850)	Serious limitations	No inconsistency	No imprecision	3	None identified	No differences
All-cause mortality	1 cohort study (n = 108,492) New for update: 1 cohort study (n = 38,756)	Serious limitations	Serious inconsistency	No imprecision	4	None identified	One cohort study found methadone to be associated with lower all-cause mortality risk than sustained-release morphine in a propensity-adjusted analysis (adjusted HR 0.56, 95% CI = 0.51–0.62) and one cohort study among Tennessee Medicaid patients found methadone to be associated with higher risk of all-cause mortality than sustained-release morphine (adjusted HR 1.46, 95% CI = 1.17–1.73).
Abuse and related outcomes	1 cohort study (n = 5,684)	Serious limitations	Unknown (1 study)	Serious imprecision	4	None identified	One cohort study found some differences between ER/LA opioids in rates of adverse outcomes related to abuse, but outcomes were nonspecific for opioid-related adverse events, precluding reliable conclusions.
ER/LA versus immediate-release opioids							
Endocrinologic harms	New for update: 1 cross-sectional study (n = 1,585)	Serious limitations	Unknown (1 study)	No imprecision	4	None identified	One cross-sectional study found ER/LA opioids associated with increased risk of androgen deficiency versus immediate-release opioids (adjusted OR 3.39, 95% CI = 2.39–4.77).

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Dose escalation versus dose maintenance or use of dose thresholds							
Pain, function, or withdrawal due to opioid misuse	1 randomized trial (n = 140)	Serious limitations	Unknown (1 study)	Very serious imprecision	3	None identified	No difference between more liberal dose escalation versus maintenance of current doses in pain, function, or risk of withdrawal due to opioid misuse, but there was limited separation in opioid doses between groups (52 versus 40 MME/day at the end of the trial).
Immediate-release versus ER/LA opioids; immediate-release plus ER/LA opioids versus ER/LA opioids alone; scheduled and continuous versus as-needed dosing of opioids; or opioid rotation versus maintenance of current therapy							
Pain, function, quality of life, and outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of decreasing or tapering opioid doses versus continuation of opioid therapy							
Pain and function	1 randomized trial (n = 10)	Very serious limitations	Unknown (1 study)	Very serious imprecision	4	None identified	Abrupt cessation of morphine was associated with increased pain and decreased function compared with continuation of morphine.
Comparative effectiveness of different tapering protocols and strategies							
Opioid abstinence	2 nonrandomized trials (n = 150)	Very serious limitations	No inconsistency	Very serious imprecision	4	None identified	No clear differences between different methods for opioid discontinuation or tapering in likelihood of opioid abstinence after 3–6 months
Risk assessment and risk mitigation strategies (KQ4)							
Diagnostic accuracy of instruments for predicting risk for opioid overdose, addiction, abuse, or misuse among patients with chronic pain being considered for long-term opioid therapy							
Opioid risk tool	3 studies of diagnostic accuracy (n = 496) New for update: 2 studies of diagnostic accuracy (n = 320)	Serious limitations	Very serious inconsistency	Serious imprecision	4	None identified	Based on a cutoff score of >4 (or unspecified), five studies (two fair-quality, three poor-quality) reported sensitivity that ranged from 0.20 to 0.99 and specificity that ranged from 0.16 to 0.88.
Screener and Opioid Assessment for Patients with Pain, Version 1	2 studies of diagnostic accuracy (n = 203)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of ≥8, sensitivity was 0.68 and specificity was 0.38 in one study, for a positive likelihood ratio of 1.11 and a negative likelihood ratio of 0.83. Based on a cutoff score of >6, sensitivity was 0.73 in one study.
Screener and Opioid Assessment for Patients with Pain-Revised	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a cutoff score of >3 or unspecified, sensitivity was 0.25 and 0.53 and specificity was 0.62 and 0.73 in two studies, for likelihood ratios close to 1.
Brief Risk Interview	New for update: 2 studies of diagnostic accuracy (n = 320)	Very serious limitations	No inconsistency	Serious imprecision	3	None identified	Based on a "high risk" assessment, sensitivity was 0.73 and 0.83 and specificity was 0.43 and 0.88 in two studies, for positive likelihood ratios of 1.28 and 7.18 and negative likelihood ratios of 0.63 and 0.19.

See table footnotes on page 47.

TABLE 1. (*Continued*) Grading of Recommendations Assessment, Development and Evaluation (GRADE) clinical evidence review ratings of the evidence for the key clinical questions regarding effectiveness and risks of long-term opioid therapy for chronic pain

Outcome	Studies	Limitations	Inconsistency	Imprecision	Type of evidence	Other factors	Estimates of effect/findings
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk prediction instruments on outcomes related to overdose, addiction, abuse, or misuse in patients with chronic pain							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effectiveness of risk mitigation strategies, including opioid management plans, patient education, urine drug screening, use of prescription drug monitoring program data, use of monitoring instruments, more frequent monitoring intervals, pill counts, and use of abuse-deterrent formulations, on outcomes related to overdose, addiction, abuse, or misuse							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Comparative effectiveness of treatment strategies for managing patients with addiction to prescription opioids							
Outcomes related to abuse	None	—	—	—	Insufficient	—	No evidence
Effects of opioid therapy for acute pain on long-term use (KQ5)							
Long-term opioid use	New for update: 2 cohort studies (n = 399,852)	Serious limitations	No inconsistency	No imprecision	3	None identified	One study found use of opioids within 7 days of low-risk surgery associated with increased likelihood of opioid use at 1 year (adjusted OR 1.44, 95% CI = 1.39–1.50), and one study found use of opioids within 15 days of onset of low back pain among workers with a compensation claim associated with increased risk of late opioid use (adjusted OR 2.08, 95% CI = 1.55–2.78 for 1 to 140 MME/day and OR 6.14, 95% CI = 4.92–7.66 for ≥450 MME/day).

Abbreviations: CI = confidence interval; ER/LA = extended release/long-acting; HR = hazard ratio; MME = morphine milligram equivalents; OR = odds ratio.
* Ratings were made per GRADE quality assessment criteria; "no limitations" indicates that limitations assessed through the GRADE method were not identified.
† Not applicable as no evidence was available for rating.

TABLE 2. Morphine milligram equivalent (MME) doses for commonly prescribed opioids

Opioid	Conversion factor*
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1–20 mg/day	4
21–40 mg/day	8
41–60 mg/day	10
≥61–80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3
Tapentadol†	0.4

Source: Adapted from Von Korff M, Saunders K, Ray GT, et al. Clin J Pain 2008;24:521–7 and Washington State Interagency Guideline on Prescribing Opioids for Pain (http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf).

* Multiply the dose for each opioid by the conversion factor to determine the dose in MMEs. For example, tablets containing hydrocodone 5 mg and acetaminophen 300 mg taken four times a day would contain a total of 20 mg of hydrocodone daily, equivalent to 20 MME daily; extended-release tablets containing oxycodone 10mg and taken twice a day would contain a total of 20mg of oxycodone daily, equivalent to 30 MME daily. The following cautions should be noted: 1) All doses are in mg/day except for fentanyl, which is mcg/hr. 2) Equianalgesic dose conversions are only estimates and cannot account for individual variability in genetics and pharmacokinetics. 3) Do not use the calculated dose in MMEs to determine the doses to use when converting opioid to another; when converting opioids the new opioid is typically dosed at substantially lower than the calculated MME dose to avoid accidental overdose due to incomplete cross-tolerance and individual variability in opioid pharmacokinetics. 4) Use particular caution with methadone dose conversions because the conversion factor increases at higher doses. 5) Use particular caution with fentanyl since it is dosed in mcg/hr instead of mg/day, and its absorption is affected by heat and other factors.

† Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. MMEs are based on degree of mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists.

Please note: An erratum has been published for this issue. To view the erratum, please click here.

Steering Committee and Core Expert Group Members

Steering Committee: *Deborah Dowell, MD, Tamara M. Haegerich, PhD; Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC; Roger Chou, MD; on detail to CDC under contract.*

Core Expert Group Members: *Pam Archer, MPH, Oklahoma State Department of Health; Jane Ballantyne, MD; University of Washington (retired); Amy Bohnert, PhD; University of Michigan; Bonnie Burman, ScD; Ohio Department on Aging; Roger Chou, MD; on detail to CDC under contract; Phillip Coffin, MD, San Francisco Department of Public Health; Gary Franklin, MD, MPH; Washington State Department of Labor and Industries/University of Washington; Erin Krebs, MDH; Minneapolis VA Health Care System/University of Minnesota; Mitchel Mutter, MD, Tennessee Department of Health; Lewis Nelson, MD; New York University School of Medicine; Trupti Patel, MD, Arizona Department of Health Services; Christina A. Porucznik, PhD, University of Utah; Robert "Chuck" Rich, MD, FAAFP, American Academy of Family Physicians; Joanna Starrels, MD, Albert Einstein College of Medicine of Yeshiva University; Michael Steinman, MD, Society of General Internal Medicine; Thomas Tape, MD, American College of Physicians; Judith Turner, PhD, University of Washington.*

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Workgroup Members: *Anne Burns, RPh; Penney Cowan; Chinazo Cunningham, MD, MS; Katherine Galluzzi, DO; Traci Green, PhD, MSC; Mitchell Katz, MD; Erin Krebs, MD, MPH; Gregory Terman, MD, PhD; Mark Wallace, MD. Workgroup Consultants: Roger Chou, MD; Edward Covington, MD; Diana Eppolito; Michael Greene, MD; Steven Stanos, DO.*

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National Transportation Safety Board
Washington, DC 20594

Office of the Chairman

November 12, 2015

The Honorable Scott Walker
Governor of Wisconsin
Office of the Governor
115 East Capitol
Madison, WI 53702

Dear Governor Walker:

The National Transportation Safety Board (NTSB) is an independent federal agency charged by Congress with investigating every civil aviation accident in the United States and significant accidents in other modes of transportation—railroad, highway, marine, and pipeline. We determine the probable cause of the accidents and issue safety recommendations aimed at preventing future accidents. In addition, we conduct special studies concerning transportation safety and coordinate the resources of the federal government and other organizations to provide assistance to victims and their family members impacted by major transportation disasters.

This letter addresses NTSB Safety Recommendations I-14-1 and -2. We issued these recommendations to the state of Wisconsin on September 23, 2014, as a result of our safety study *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*, SS 14/01, available at http://www.ntsb.gov/safety/safety-studies/Documents/SS1401.pdf. For your convenience, the background and bases for the recommendations may be found on pages 36-38 of the report.

I-14-1

Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

I-14-2

Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

We are interested in knowing whether and how our recommendations are implemented, both to ensure that the traveling public is provided the highest level of safety and to identify creative solutions that might be shared with others, and we normally expect actions to address our recommendations to be completed within 3 to 5 years. As we issued this recommendation more than a year ago and we have yet to hear from you regarding it, we would appreciate receiving a response within 90 days indicating actions you have taken or plan to take to implement it. In the meantime, the recommendation will retain its current classification of "Open—Await Response."

Please reply at correspondence@ntsb.gov. If your response, including attachments, exceeds 10 megabytes, please e-mail us at the same address for instructions. Please do not submit both an electronic and a hard copy of the same response.

If you have any questions, please contact Mr. Jeffrey Marcus, Safety Recommendation Specialist, at marcusj@ntsb.gov.

Thank you for your assistance in this matter.

Sincerely,

Christopher A. Hart
Chairman

cc: Mr. Thomas Ryan
Executive Director
Wisconsin Medical Examining Board
thomas.ryan@wisconsin.gov

Mr. Dan Williams
Bureau Director
Wisconsin Department of Safety and
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dsps@wisconsin.gov

Mr. Dan Williams
Executive Director
Wisconsin Pharmacy Examining Board
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Guidelines for Prescribing for the Treatment of Pain
Optometry Practice

These practice guidelines represent points of reference for authorized optometric prescribers of opioids, other controlled substances and the prescription medication tramadol to focus provider attention on accepted and prevailing standards of care and board rules governing the treatment of pain. These guidelines are not an endorsement by the board to utilize opioids, other controlled substances or tramadol in the treatment of pain.

Ohio professional licensing boards, including the Ohio Board of Optometry, have been active participants in the various working groups led by the Governor's Cabinet Opiate Action Team (GCOAT) in efforts to address public safety concerns associated with inappropriate prescribing of opioids, other controlled substances, and tramadol. These efforts include urging licensing boards to publish prescribing guidelines as an educational tool to supplement, but not replace the individual provider's clinical judgment when treating pain. In addition, House Bill 93 of the 129th General Assembly directed the Optometry Board to adopt a rule on the use of the Ohio Automated Rx Reporting System (OARRS).

Optometrists are in a unique position to provide a point of contact and care when treating acute pain issues on a short term, non-chronic basis. Optometrists who have a **valid DEA license number** may only prescribe when treating pain based on the patient's presenting symptoms, overall condition, clinical examination and risk for addiction. While prevailing standards of care permit the prescription of narcotic medications in the legitimate treatment of severe pain, health care providers are not obligated to use opioids, other controlled substances or tramadol when a favorable risk-benefit balance cannot be documented.

In Ohio Administrative Code Rule 4725-16-03, the Board established that prescriptive treatment for pain may only be initiated if the product's FDA approved labeling contains an indication that it may be used for pain. **The rule is clear in stating that authorized optometric prescribers may *not* prescribe the following medications in the following dosages and in quantities that exceed a four day supply when treating an individual episode of optometric related illness or injury**:

- ✓ any schedule II narcotic;
- ✓ any medication or narcotic preparation that contains more than 60 mg of codeine per dosage unit and that also contains other active non-narcotic ingredients (e.g., acetaminophen or aspirin) in a recognized therapeutic amount consistent with the recognized standard of care;
- ✓ and, any medication or narcotic preparation that contains more than 7.5 mg of hydrocodone per dosage unit and that also contains other active non-narcotic ingredients (e.g., acetaminophen, aspirin or ibuprofen) in a recognized therapeutic amount consistent with the recognized standard of care.

Providers can minimize the potential for prescription drug abuse and misuse and help reduce the number of unintentional complications associated with pain medications by recognizing times at which they may utilize OARRS as an additional check on patient use and compliance with other prescriptive therapies (please see recently proposed Ohio Administrative Code Rule 4725-16-04).

OARRS prescription history reports are an important component of delivering and coordinating patient-centered care. The reports should be interpreted within the context of a patient's on-going medical history. Prescription history reports: (1) assist providers in better management of a patient's prescription regimen; (2) are a screening tool for signs of potential abuse, addiction and diversion; and (3) highlight patient risk for future addiction or abuse when used in conjunction with a patient's medical history.

To register for OARRS and to obtain additional information about OARRS, go to https://www.ohiopmp.gov/Portal/Brochure.pdf.

Acute Pain Prescribing Guidelines

A companion to Ohio's Guidelines for the Management of Acute Pain Outside of Emergency Departments

These guidelines are to be used as a clinical tool, but they do not replace clinician judgment.

Patient Presents with Acute Pain

❶ Pain Assessment:

- Medical history and physical examination, including pregnancy status
- Location, intensity, severity; and associated symptoms
- Quality of pain (somatic, visceral or neuropathic)
- Psychological factors, personal/family history of addiction

❷ Develop a Plan:

- Educate patient and family and negotiate goals of treatment
- Discuss risks/benefits of non-pharmacologic & pharmacologic therapies
- Set patient expectations for the degree and the duration of the pain

GOAL: Improvement of function to baseline as opposed to complete resolution of pain

Options

Non-Pharmacologic Treatment

- Ice, heat, positioning, bracing, wrapping, splints, stretching
- Massage therapy, tactile stimulation, acupuncture/acupressure, chiropractic adjustment, osteopathic neuromusculoskeletal medicine
- Biofeedback
- Directed exercise such as physical therapy

Non-Opioid Pharmacologic Treatment

Role in Therapy	Somatic (Sharp or Stabbing)	Visceral (Ache or Pressure)	Neuropathic (Burning or Tingling)
First Line	Acetaminophen, NSAIDs, Corticosteroids		Gabapentin/pregabalin/TCAs/ SNRIs
Alternatives	Gabapentin/pregabalin, skeletal muscle relaxants, SSRIs/SNRIs/TCAs	SNRIs/TCAs, dicyclomine	Anti-epileptics, baclofen, bupropion, low-concentration capsaicin, SSRIs, topical lidocaine

Opioid Pharmacologic Treatment

For All Opioids:

- **Complete risk screening** (e.g. age, pregnancy, high-risk psychosocial environment, personal/family history of substance use disorder).
- **Provide the patient with the least potent opioid** to effectively manage pain (e.g. APAP/codeine instead of oxycodone). **Refer to Morphine Equivalence Table.**
- **Prescribe the minimum quantity needed with no refills.**
- **Consider checking OARRS** for all patients who will receive an opioid prescription. (OARRS report is required for most prescriptions of 7 days or more.)
- **Avoid prescribing long-acting opioids** for acute pain (e.g. methadone, oxycodone).
- **Use caution when prescribing opioids** with patients on benzodiazepines and sedative-hypnotics or patients known to use alcohol.
- **Discuss how to safely and effectively wean** patient off opioid medication.
- **Remind that it is a unsafe and unlawful** to give away or sell their opioids.
- **Discuss proper storage and disposal of opioid medications.**
- **Coordinate care and communication** of complex patients with other clinicians.

Morphine Equivalence Table

Opioid Naive: Morphine Equivalence*	Notable NSAIDS
Most Potent	
Buprenorphine sublinguam 42:1	
Hydromorphone PO 4:1	
Oxymorphone 3:1	
Hydrocodone 1:1	
Morphine 1:1	
	Meloxicam 0.67:1
	Diclofenac 0.2:1
Codeine 0.15:1	
Tramadol 0.1:1	Celecoxib 0.1:1
Least Potent	

*Source: CDC, 5/2014

14 Days (Key Checkpoint)

Reassess patient within an appropriate time NOT exceeding 14 days

If pain is unresolved, reassess:

- Pain, consider standardized tool (e.g. Oswestry Disability Index for back pain)
- Treatment method
- Context and reason for continued pain
- Additional treatment options, including consultation

Six Weeks (Key Checkpoint)

- If pain is unresolved:
- Repeat the prior step
- Refer to Chronic Pain Guideline

July 2015

Open Letter to the General Public on the Quad-Regulator Joint Policy for Prescribing and Dispensing Opioids

October 15, 2014

Dear Colorado citizens:

We, the Chairs and Presidents of the regulatory Boards for dental, medical, nursing and pharmacy in Colorado and the Nurse-Physician Advisory Taskforce for Colorado Healthcare, encouraged the development of the joint *Policy for Prescribing and Dispensing Opioids* to support practitioner to compassionately treat pain while addressing the prescription drug abuse crisis in our State. This letter discusses the history of the policy and some of the categories of comments received by stakeholders. We hope it provides useful background to the public about our decisions, and we look forward to continuing to work with the community to address this important challenge facing our State.

History

Facilitated by the Nurse-Physician Advisory Task Force for Colorado Healthcare (NPATCH) at the Department of Regulatory Agencies, the Quad-Regulator Boards of Dental, Medical, Nursing and Pharmacy held a workshop in September 2013 to discuss the growing concern of access to pain management and prescription drug misuse and abuse in Colorado. At this workshop, and in conjunction with the recently published Colorado Plan to Reduce Prescription Drug Abuse issued by the Governor as part of his commitment to make Colorado the healthiest state, the Quad-Regulator Boards agreed to pursue a joint policy for prescribing and dispensing painkillers. We agreed that as healthcare increasingly is being delivered in team-based settings, so should the State's regulation keep pace, and that shared guidance to address such an important public health problem would be a vital step to support Colorado's practitioners to effectively and safely treat pain. This effort at a joint regulatory policy across professional licensing Boards is the first of its kind in the nation.

A number of drafts of the policy were vetted by the Boards over the course of 16 public meetings during a four month period throughout the winter and spring of 2014 in which written comments and testimony were accepted. The Boards made multiple changes as a result of stakeholder comments to address both general concerns and specific word changes. The policy was revised based on suggestions by multiple representatives from the Colorado Consortium to Reduce Prescription Drug Abuse.

The final draft of the policy was unanimously adopted by the four Boards in June and July 2014. Subsequently it was adopted by the Optometry and Podiatry Boards and endorsed by the Veterinary Board. Collectively, these are all of the Boards in the State with authority over practitioner prescribing and dispensing.

Stakeholder views and comments were essential to the crafting of this policy. The following discussion presents some of the categories of comments received, and how the Boards incorporated those comments in the final policy.

Categories of Comments

Bright Line Thresholds: No other topic was so intensely debated among stakeholders throughout the public consideration of the policy than the bright line thresholds. The thresholds in the policy are duration, dosage and formulation. Specifically, the policy recommends additional safeguards be put in place when prescribing and dispensing exceeds the following evidence-based thresholds that have been associated with adverse outcomes:

- 90 days in duration,
- 120 milligram morphine equivalents dosages, or
- certain formulations such as transdermal or long-acting preparations.

Chronic pain patients in particular expressed concern about drawing any line that could be interpreted to suggest the arbitrary discontinuation of opioid therapy.

We want to ensure that the Board's message with this policy is clear -- the policy does not draw any line, but rather seeks to educate the practitioner of evidence-based thresholds above which safeguards are indicated. Prescribing and dispensing above the certain thresholds is more likely dangerous indicating additional safeguards to protect the patient. The policy does not suggest the discontinuation of opioid therapy after a threshold is crossed. It does recommend the practitioner closely monitor the pain to detect contraindications such as decreased function or quality of life. Also, by issuing these bright line thresholds in policy rather than Board rule, the Boards acknowledge the importance of clinical judgment in the treatment of pain.

The evidence-based, bright line thresholds are intended in particular to assist the group of practitioners that find themselves treating pain without specializing in pain. Short-term treatment of pain can often lead into longer-term treatment, and at higher doses or riskier delivery methods. These bright lines caution the practitioner to pause, re-evaluate treatment, and institute additional safeguards. Not all patients requiring pain therapy can reasonably be referred to pain specialists, given the number of pain specialists in the State. Thus the policy recommends additional safeguards when crossing the bright line thresholds, and draws on practices established by pain specialists, such as treatment agreements and monitoring, in making these recommendations.

Assessing Risk: Stakeholders raised concerns about the policy's guidance to conduct a patient risk assessment in all prescribing situations. The Boards received comments that, in some situations, conducting a risk assessment may not be in the best interest of the patient or would be burdensome to workflow. Other concerns were raised that the recommended risk assessment was not specific enough to adequately screen for substance and alcohol use.

The Boards determined that the policy should include guidance to conduct a brief risk assessment before initiating opioid therapy, even for very short-term treatment of acute pain, such as dental procedures. Simply put, the risk for adverse outcomes is too high when opioids are used in the presence of evidence-based risk factors, such as history of substance use, or currently prescribed benzodiazepines. Protecting the patient from adverse outcomes is in the best interest of the patient. Items flagged during a brief risk assessment may point to the need for a more sophisticated screening. Practitioners will utilize clinical judgment to tailor the risk assessment to each patient and practice setting, and the policy appendix provides resources for risk assessment instruments.

Classifying Pain: The Boards received a number of comments and requests to define and distinguish the type of pain addressed in this policy, particularly acute versus chronic. Suggestions included limiting the policy to treatment of "chronic" pain.

Because pain can evolve from a more acute phase to a chronic phase, the Boards determined that it was most appropriate to craft a policy that applied to more than just chronic pain. The Boards

determined that risk screening, including checking the PDMP, is essential before prescribing even a few pills for an acute condition.

Moreover, because of the lack of uniformity around what constitutes chronic treatment, the Boards through their examination of many complaints about treatment, determined that many practitioners do not recognize when they have crossed one of the bright lines for which prescribing opioids has been associated with adverse outcomes (dosage, formulation, and duration).

For these reasons, the Boards did not limit the policy to treatment of chronic pain. Note, however, that the Boards did exclude treatment of cancer pain and similar conditions.)

On-going evaluation

The *Quad-Regulator Policy for Prescribing and Dispensing Opioids* is written to address today's crisis in prescription drug misuse and abuse in Colorado. We, the Chairs and Presidents of the Quad-Regulator Boards are pleased to present a policy that is authentically Coloradan, addressing Colorado's unique patients, practitioners and settings. It is a living document; however, as science, pharmaceuticals, illness and technology all evolve over time, demanding changes to the way we practice. The Boards are committed to evaluate the effectiveness and usefulness of the policy, including responding to any unintended consequences it may create. Continued collaboration with other state agencies, researchers, practitioners, and patients, facilitated by the 200-member strong Colorado Consortium for Prescription Drug Abuse Prevention, will help to identify and evaluate the outcomes of this policy. Likewise, we welcome continued feedback from all members of the public. Thank you for your interest.

Sincerely (in alphabetical order by Board),

Steven Tilliss, DDS, MS
President, Colorado Dental Board

Mark Watts, MD
President, Colorado Medical Board

Vicki Erickson, RN, NP, PhD
President, State Board of Nursing

Luis Rivera-Lleras, RPh
President, State Board of Pharmacy

Mary Ciambelli, RN, CNS, PhD
Co-Chair, Nurse-Physician Advisory Task Force for Colorado Healthcare

Susan Townsend, MD
Co-Chair, Nurse-Physician Advisory Task Force for Colorado Healthcare

COLORADO

Department of Regulatory Agencies

Division of Professions and Occupations

Policy for Prescribing and Dispensing Opioids

Colorado Dental Board, Colorado Medical Board, State Board of Nursing, and State Board of Pharmacy

In collaboration with the Nurse-Physician Advisory Task Force for Colorado Healthcare

PREAMBLE

Prescribing and dispensing medication for the appropriate treatment of pain is a priority for Colorado healthcare providers. However, in 2013 the misuse and abuse of prescription opioids became a public health epidemic in the United States in general, and Colorado in particular, leading to drug addiction, death from overdose, and increased costs to society.

In order to address this crisis, the Colorado Dental Board, Colorado Medical Board, State Board of Nursing, State Board of Pharmacy, and the Nurse-Physician Advisory Task Force for Colorado Healthcare collaborated to identify opportunities and provide meaningful guidance to prescribers and dispensers in Colorado.

The Boards recognize that reversing the trend of opioid misuse and abuse requires coordinated efforts to increase public awareness, take-back events for safe disposal, addiction treatment and recovery options, and enforcement, among others. The Boards and the practitioners they license are one part of a multi-pronged solution.

The Boards recognize the complexities faced by prescribers in the appropriate management of pain.[1] The demands on practitioners considering opioid prescribing differ depending on patient diagnosis, practice settings, and/or conditions. Importantly, long-term therapies addressing cancer-related treatment, palliative and/or hospice care involve different considerations from short-term therapies appropriate for acute or chronic non-cancer pain.

Pain and addiction specialists play an important role in healthcare and the communities they serve to compassionately and safely care for patients. Many of the tools and practices referenced in this policy were developed by such specialists. The need for therapeutic care of pain in Colorado patients exceeds the supply of specialists in the state. However, other types of providers can successfully treat many painful conditions and achieve the function and relief the patient seeks. Accordingly, this policy is intended to educate prescribers and dispensers broadly by providing useful tools that may be utilized at the point-of-care to support clinical decision making.

The Boards further recognize that decreasing opioid misuse and abuse in Colorado should be addressed by collaborative and constructive policies aimed at improving prescriber education and practice, decreasing diversion, and establishing the same guidelines for all opioid prescribers and dispensers. This includes opioid therapies for both acute and chronic non-cancer pain, [2] because

[1] "Boards" as used in this policy means the Boards overseeing prescribing and dispensing of opioids and involved in the drafting of this policy: the Colorado Medical Board, State Board of Nursing, Colorado Dental Board, and the State Board of Pharmacy.

[2] Pain is categorized by a number of descriptors ranging from duration, impact, or physiological response, among others. For the purpose of this policy, the term "chronic, non-cancer pain" is utilized to refer to pain

the Boards find that treatment for pain often does not fall clearly into one category or another.

Diversion and "doctor shopping" accounts for 40% of drug overdose deaths.[3] To address the dual issues of access to appropriate pain management and opioid-related adverse outcomes, prescribers have dual obligations: to manage pain and improve function while reducing problems resulting from misuse and abuse of prescription opioids in the patient and community. Pharmacists share a corresponding responsibility with the prescriber to assure that a prescription order is valid in all respects and is appropriate for the patient and condition being treated.

Therefore, the Boards have agreed to the following guidelines regarding opioid prescriptions in Colorado. Providers prescribing and/or dispensing opioids should:

- Follow the same guidelines
- Use the Colorado Prescription Drug Monitoring Program (PDMP)
- Be informed about evidence-based practices for opioid use in healthcare and risk mitigation
- Educate patients on appropriate use, storage and disposal of opioids, risks and the potential for diversion
- Collaborate within the integrated healthcare team to decrease over-prescribing, misuse and abuse of opioids.

Opioid prescribers and dispensers must conform to the regulations set forth by the respective licensing board and other laws.

To this end, we, the Boards regulating the prescribers and dispensers in Colorado, have developed this joint policy incorporating the guidelines above.

This policy provides guidelines, and does not set a standard of care for prescribers and dispensers. This policy represents the Boards' current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind Boards or the public. Prescribers may use an alternative approach if the approach satisfies the requirements of the applicable statutes, regulations, and standard of care. The Boards will refer to current clinical practice guidelines and expert review in approaching cases involving the management of pain. [4]

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that lasts longer than 90 days and is non-terminal. It does not include conditions such as cancer, scleroderma, multiple sclerosis, muscular dystrophy, or rheumatoid arthritis.

[3] Paulozzi, L., Baldwin, G., Franklin, G., Ghiya, N., & Popovic, T. (2012). CDC Grand Rounds: Prescription drug overdoses — a U.S. epidemic. *Center for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR)*, *61*(01), 10-13. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm

[4] A "policy" is adopted by a board to provide guidance to licensees regarding the board's position on various subjects. Policies are unlike statutes or rules in that they are not law. Conversely, "board rules" have the force of law and set forth requirements to which licensees must adhere.

Table of Contents

BEFORE PRESCRIBING OR DISPENSING 1
WHEN PRESCRIBING OR DISPENSING 2
PRESCRIBING AND DISPENSING FOR ADVANCED DOSAGE, FORMULATION OR DURATION 4
PATIENT EDUCATION 5
DISCONTINUING OPIOID THERAPY 5

BEFORE PRESCRIBING OR DISPENSING

Develop and maintain competence

Prescribers, including prescribers who dispense, must maintain competence to assess and treat pain to improve function. This includes understanding current, evidenced-based practices and using other resources and tools related to opioid prescribing and dispensing. In some clinical situations consultation with a specialist is appropriate. Pharmacists must maintain competence in the appropriateness of therapy. See the Appendix for a list of resources and tools for developing and maintaining competence.

Utilize safeguards for the initiation of pain management

The decision to prescribe or dispense opioid medication for outpatient use may be made only after a proper diagnosis and complete evaluation which should include a risk assessment, pain assessment, and review of relevant PDMP data. These safeguards apply to acute and chronic, non-cancer pain but not to palliative end-of-life care.

Not all pain requires opioid treatment. Prescribers should not prescribe opioids when non-opioid medication is both effective and appropriate for the level of pain.

1. Diagnose

Prescribers should establish a diagnosis and legitimate medical purpose appropriate for opioid therapy through a history, physical exam, and/or laboratory, imaging or other studies. A bona fide provider-patient relationship must exist.

2. Assess Risk

Prescribers should conduct a risk assessment prior to prescribing opioids for outpatient use and again before increasing dosage or duration. Risk assessment is defined as identification of factors that may lead to adverse outcomes and may include:

- Patient and family history of substance use (drugs including alcohol and marijuana)
- Patient medication history (among other reasons, this is taken to avoid unsafe combinations of opioids with sedative-hypnotics, benzodiazepines, barbiturates, muscle relaxants or to determine other drug-drug interactions)
- Mental health/psychological conditions and history

- Abuse history including physical, emotional or sexual
- Health conditions that could aggravate adverse reactions (including COPD, CHF, sleep apnea, elderly, or history of renal or hepatic dysfunction)
- Prescribers and dispensers should observe the patient for any aberrant drug-related behavior and follow-up appropriately when aberrant drug-related behavior is presented. See the Appendix for a description of such behaviors.

See the Appendix for additional resources related to assessment, including resources for alcohol and substance use screening and guidelines for treating patients with risk factors.

If the assessment identifies risk factors, prescribers should exercise greater caution before prescribing opioids as detailed in subsequent sections, consider conducting a drug test or consulting a specialist and put in place additional safeguards as part of the treatment plan.

3. Assess Pain

An appropriate pain assessment should include an evaluation of the patient's pain for the:

- Nature and intensity
- Type
- Pattern/frequency
- Duration
- Past and current treatments
- Underlying or co-morbid disorders or conditions
- Impact on physical and psychological functioning

4. Review PDMP

Prescribers and dispensers should utilize the Prescription Drug Monitoring Program (PDMP) prior to prescribing or dispensing opioids.

Collaborate with the healthcare team

Prescribers and dispensers should collaborate within the healthcare team to prevent under-prescribing, over-prescribing, misuse and abuse of opioids. See the Appendix for additional resources.

WHEN PRESCRIBING OR DISPENSING

Verify a provider-patient relationship

A bona fide provider-patient relationship must exist. The prescriber or dispenser should verify the patient's identification prior to prescribing or dispensing opioids to a new or unknown patient.

For pharmacists, this includes exercising judgment and conducting research if appropriate (such as use of the PDMP or communication with the prescriber or relevant pharmacies) when the prescription order is:

- For a new or unknown patient
- For a weekend or late day prescription
- Issued far from the location of the pharmacy or patient's residential address
- Denied by another pharmacist.

Additional Safeguards

Ensure the dose, quantity, and refills for prescription opioids are appropriate to improve the function and condition of the patient, at the lowest effective dose and quantity, in order to avoid over-prescribing opioids.

Factors that have been associated with adverse outcomes include: 1) opioid doses greater than 120 mg morphine equivalents per day 2) certain formulations and 3) treatment exceeding 90 days. Additional safeguards have been found to reduce these risks.

Dosage

Opioid doses >120 mg morphine equivalents per day is a dosage that the Boards agree is more likely dangerous for the average adult (chances for unintended death are higher) over which prescribers should use clinical judgment, put in place additional safeguards for the treatment plan (such as utilizing a treatment agreement), consult a specialist or refer the patient; and dispensers should be more cautious.[5] Benzodiazepines are known to potentiate the effects of opioids and may increase the risk of adverse outcomes. See the Appendix for additional resources on dose calculators

Formulation

In addition to noting and responding to this dosage marker, prescribers and dispensers must use clinical judgment regardless of dose, especially when:

- The prescription is considered an outlier to what is normally prescribed, or

[5] Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: a cohort study. Ann Intern Med 2010;152(2):85-92.

- Transdermal, extended relief or long-acting preparation is prescribed.

Duration

Treatment **exceeding 90 days** should be re-evaluated as opioids may no longer be as effective.

One way to distinguish pain is as either acute (that lasting less than 90 days) or chronic (that lasting 90 days or greater). Management of each presents its own unique challenges. The overwhelming majority of prescribers treat patients with acute pain; in fact the pain for these patients lasts considerably less than 90 days.

If a prescriber extends short-term treatment, and results in exceeding 90 days, prescribers should re-conduct the risk and pain assessments, review the PDMP and undertake the additional safeguards.

PRESCRIBING AND DISPENSING FOR ADVANCED DOSAGE, FORMULATION OR DURATION

Tools and Trials

Prior to issuing prescriptions that are outliers to the dosage, formulation and duration guidelines described above (for chronic, non-cancer pain), prescribers should determine whether the patient improves functionally on opioids, which could include an opioid trial, and whether the pain relief improves his/her ability to comply with the overall pain management program.

Monitoring

The prescribing and dispensing of opioids for chronic pain must be monitored on an ongoing basis, such as:

- assessing for improved function
- rechecking the PDMP, and
- random drug screening according to the prescriber's clinical assessment.

These monitoring tools and others should be documented in a treatment agreement signed by the patient, described more below. Prescribers should not increase an initial opioid dosage without rechecking the PDMP.

Treatment Agreements

Prescribers should utilize treatment agreements (also commonly referred to as a plan or contract) and should ensure the patient understands the terms of the agreement. This may be accomplished by having the patient review and sign the

treatment agreement.

A treatment agreement often includes information about proper:

- Goals of treatment
- Patient education (proper use, risks of addiction, alternatives)
- Controls (single prescriber, single pharmacy for refills)
- Random drug testing and restrictions on alcohol use
- Storage, disposal, and diversion precautions (including detailed precautions related to adolescents and/or children and visitors to the home).
- Process and reasons for changing/discontinuing the treatment plan; communicating reduction or increase of symptoms; and referring to a specialist.

See the Appendix for resources on sample agreements.

Patient Education

Prescribers should educate patients regardless of the dosage, formulation and duration of opioid therapy on proper use, risks of addiction, alternatives, storage, and disposal of opioids and the potential for diversion (see the Appendix for resources on disposal). Risks may include but are not limited to: overdose, misuse, diversion, addiction, physical dependence and tolerance, interactions with other medications or substances, and death.

Pharmacists should offer to review information with the patient about risks, disposal, and other applicable topics.

Providers should educate patients about the risks and benefits of medications that exceed the dosage, formulation and duration guidelines indicated above which may place them at increased risk for long-term dependence and unintended adverse drug effects. Patients who have a previous history of substance use disorder (including alcohol) are at elevated risk.

When alerted to these risk factors, patients can make more informed decisions about their healthcare treatment. For example, some patients have reduced or forgone opioids when alerted to the risk factors. If a decision is made to continue with opioid therapy, a satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function and/or improved quality of life. The use of an interdisciplinary team and family members may be considered as a part of the treatment plan and ongoing monitoring.

Discontinuing Opioid Therapy

The prescriber should consider discontinuing opioid therapy when:

- The underlying painful condition is resolved;

- Intolerable side effects emerge;
- The analgesic effect is inadequate;
- The patient's quality of life fails to improve;
- Functioning deteriorates; or
- There is aberrant medication use.

The prescriber discontinuing opioid therapy should employ a safe, structured tapering regimen through the prescriber or an addiction or pain specialist. There is a risk of patients turning to street drugs or alcohol abuse if tapering is not done with appropriate supports. Prescribers of opioids should be familiar with treatment options for opioid addiction. See the Appendix for tips on tapering.

APPENDIX

PDMP

Colorado Prescription Drug Monitoring Program (PDMP):
http://www.hidinc.com/copdmp

Preventing diversion through appropriate disposal

In order to prevent diversion, providers should provide information regarding appropriate disposal, including the following:

- Secure unused prescription opioids until such time they can be safely disposed. Specifically, ensure that prescription opioids are not readily accessible to other family members (including adolescents and/or children) or visitors to the home.
- **Take-back events are preferable to flushing prescriptions down the toilet or throwing them in the trash.** Only some medications may be flushed down the toilet. See the FDA's guidelines for a list of medications that may be flushed: www.fda.gov
- **Utilize take-back events and permanent drop box locations**
- Utilize DEA disposal guidelines if take-back or drop boxes are unavailable. Those guidelines include:
    - **Take the drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter; then put them in a sealable bag, empty can, or other container to prevent the medication from leaking out of a garbage bag;**
    - Before throwing out a medicine container, tell the patient to scratch out all identifying information on the prescription label to protect their identity and personal health information; and
    - Educate patients that prescriptions are patient specific. Patients may not share prescription opioids with friends, family or others and may pose serious health risks, including death.
- Use activated charcoal absorption technologies to inactivate unused medications or used fentanyl patches.

Record keeping

Prescribers who treat patients with opioids should maintain accurate and complete medical records according to the requirements set forth by their licensing board.

Discontinuing/tapering opioid therapy

Weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account several factors related to risk, symptom, and alternatives.

Opioid Taper Plan and Calculator:
"Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain" State of Washington Agency Medical Directors Group. 2010 Online: www.agencymeddirectors.wa.gov

Withdrawal Symptoms Assessment:
"Clinical Opiate Withdrawal Scale" The National Alliance for Advocates for Buprenorphine Treatment. Online at: www.naabt.org

Aberrant drug-related behavior

Prescribers and dispensers should use clinical judgment when aberrant drug-related behaviors are observed. Such behavior should be reported to the proper authorities and/or healthcare team as appropriate.

Aberrant drug-related behaviors broadly range from mildly problematic (such as hoarding medications to have an extra dose during times of more severe pain) to felonious acts (such as selling medication). These are any medication-related behaviors that depart from strict adherence to a prescribed therapeutic plan of care.

Prescribers and dispensers should observe, monitor and take precautionary measures when a patient presents aberrant drug-related behaviors such as:

- Requesting early and/or repeated refills
- Presents at or from an emergency department seeking high quantities of a prescription
- Denied by other prescribers or dispensers
- Presents what is suspected to be a forged, altered or counterfeit prescription.
- Forging prescriptions
- Stealing or borrowing drugs
- Frequently losing prescriptions
- Aggressive demand for opioids
- Injecting oral/topical opioids
- Unsanctioned use of opioids
- Unsanctioned dose escalation
- Concurrent use of illicit drugs
- Failing a drug screen
- Getting opioids from multiple prescribers
- Recurring emergency department visits for chronic pain management*

Prescribers and dispensers should be alert for subjective behaviors such as being nervous, overly talkative, agitated, emotionally volatile, and evasive, as these may be signs of a psychological condition that may be considered in a treatment plan

or could suggest drug misuse.**

"Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain" State of Washington Agency Medical Directors Group. 2010 Online: http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf

***Webster LR, Dove B. Avoiding Opioid Abuse While Managing Pain. Sunrise River Press, North Branch, MN 2007.*

Practitioner Considerations

Healthcare team:
Consider that the patient may be receiving opioids from another prescriber. Contact the patient's healthcare team when appropriate which may include the following:

- Physician
- Specialist (pain, addiction, etc.)
- Dentist
- Advanced Practice Nurse (APN)
- Physician assistant
- Pharmacists
- Area emergency rooms
- Surrounding (within 5 miles) or historical pharmacies

Authorities:

- If the prescriber or dispenser suspects illegal activity, the matter should be referred to the Drug Enforcement Agency (DEA) and local law enforcement.
- If a prescriber or dispenser suspect illegal activity on behalf of another prescriber or dispenser, at a minimum, the matter should be reported to the appropriate licensing board.

Prescribers and dispensers should be aware that:

- There is no legal obligation to prescribe or dispense a prescription; and,
- Colorado law strongly encourages prescribers and dispensers of opiate antagonists "to educate persons receiving the opiate antagonist on the use of an opiate antagonist for overdose, including but not limited to instructions concerning risk factors for overdose, recognition of overdose, calling emergency medical services, rescue breathing and administration of an opiate antagonist." (Section 18-1-712(3)(b), C.R.S.)

Additional Resources and Tools

Establishing and maintaining competence:
Tenney, Lili and Lee Newman. "The Opioid Crisis: Guidelines and Tools for Improving Pain Management" Center for Worker Health and Environment, Colorado School of Public Health.

Functional and pain assessment:
"Functional Assessment" Colorado Division of Workers Compensation

Patient agreements:
"Screener and Opioid Assessment for Patients with Pain - Revised (SOAPP - R)" PainEDU.org Online at: www.painedu.org

Pain tool kit:
Various resources for assessing and managing pain including risk assessments, patient agreements, dose and conversion calculators among others.

Center for Worker Health and Environment, Colorado School of Public Health. Online at:
http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Pages/Pain-Management-CME.aspx

Substance use screening and brief counseling:
SBIRT Colorado
www.ImprovingHealthColorado.org

Drug abuse resources:
Substance Abuse and Mental Health Services Administration: www.samhsa.gov

NIH National Institute on Drug Abuse: www.drugabuse.gov or www.nida.nih.gov

Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain

Utah Department of Health
2009

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February, 2009

I am pleased to provide a copy of "Utah Clinical Guidelines on Prescribing Opioids for Pain." This document represents the results of many months of work on the part of many people, all of whom contributed considerable time, effort, experience, and expertise. This effort is an attempt to address what I consider one of the most pressing and challenging public health problems—premature deaths, dependency and disability associated with misuse and/or abuse of prescription drugs, especially, narcotic medications.

Utah's Medical Examiner, Dr. Todd Grey, brought to my attention soon after I assumed my position as Executive Director of the Utah Department of Health in 2005, the alarming increase in deaths in our state related to misuse of prescription drugs. In recent years, prescription medications used alone, in combination, or mixed with illicit drugs, has resulted in the death of hundreds of our fellow citizens. For the past 17 years, prescription drug-related deaths have increased and now exceed deaths resulting from automobile crashes in our state. In fact, it is now the **number one cause of unintentional death.**

These guidelines are meant to be just that—suggestions on how to properly use and prescribe opioid medication. As with any effort to achieve consensus, there were members who participated in the preparation of this document who disagree at both ends of the spectrum, i.e., some believe that the guidelines are too lax, others believe they impose barriers to access of much needed narcotic medications for the control of pain. It is our hope that the guidance in this document will educate both the public and clinicians about appropriate use of these medications which will, if followed, significantly reduce deaths from misuse and abuse, but at the same time allow for the control of chronic pain with proper use of opioid medications.

I want to thank the many individuals and organizations that contributed to the preparation of this document. Thousands of hours were spent in meetings and in reviewing related literature. I particularly want to acknowledge the outstanding work of Dr. Robert Rolfs, Utah State Epidemiologist and Erin Johnson, Prescription Pain Medication Program Manager. I would also like to acknowledge that the Utah State Legislature directed the Department of Health by law to produce this report on, "Medical Treatment and Quality Care Guidelines that are Scientifically Based; and Peer Reviewed," and provided the necessary funds. Additional encouragement and strong support was provided along with matching funds from the Labor Commission Workplace Safety Fund.

I'm hopeful that these guidelines will prove to be a "living document" that will be updated over time to reflect new knowledge and science and thereby improve the public's health in our state.

Sincerely,

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Table of Contents

Acknowledgements i

Disclosure of Funding ii

Background and Introduction 1

Summary of Recommendations 3
- Opioid Treatment for Acute Pain
- Opioid Treatment for Chronic Pain

Methods 4
- Purpose and Target Audience
- Guideline Evidence Review
- Grading of the Evidence and Recommendations
- Panel Composition
- Recommendation Development Process
- Tools Development Process

Recommendations 6
- Opioid Treatment for Acute Pain
- Opioid Treatment for Chronic Pain

Glossary 21

Tools 24

Bibliography 80

Appendix 82

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Disclosure of Funding

These Guidelines are based on research conducted at the Utah Department of Health with funding from the Utah State Legislature. Additional funds were contributed to the program by the Utah Labor Commission (from the Utah Workplace Safety Account) and by the Worker's Compensation Fund of Utah.

Statutory Authority

These Guidelines were authorized by the Utah Legislature which directed the Utah Department of Health to produce "medical treatment and quality care guidelines that are scientifically based; and peer reviewed" (§26-1-36 Utah Code Annotated).

Disclosure of Conflicts

Alan L. Colledge, MD, is the Medical Director of the Labor Commission of Utah which oversees the care of approximately 60,000 injured individuals a year provided by over 250 different insurance and payer sources.

Edward B. Holmes, MD, MPH, is an appointed member of the Utah Labor Commission Workers Compensation Advisory Council. He is also Chief Medical Consultant for Disability Determination Services for Social Security.

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Background and Introduction

Unintentional fatalities due to prescription medications are an increasing problem in the United States and Utah. In the year 2000, the Utah Medical Examiner noted an increase in the number of deaths occurring due to an overdose of prescription opioid medications that are typically used for pain management. Epidemiologic studies conducted in Utah using death certificate data, Office of the Medical Examiner data, emergency department encounter data, and data from the Utah Controlled Substances Database confirmed the increases and uncovered an alarming problem.

During the years 1999–2007 deaths attributed to poisoning by prescription pain medications increased by over 500%, from 39 to 261. Deaths of Utah residents from non-illicit drug poisoning (unintentional or intent not determined) have increased from about 50 deaths per year in 1999 to over 300 in 2007. The increase was mostly due to increased numbers of deaths from prescription opioid pain medications, including methadone, oxycodone, hydrocodone, and fentanyl (CDC, 2005).

Prescribing of opioid medications has substantially increased over the past 10-15 years, including greater use for treating acute and chronic pain. Distribution to Utah of opioids such as hydrocodone, oxycodone, and methadone increased 6-fold from 1997-2002. In addition, national data document an increase in non-medical use of prescription opioids during the past several years (Substance Abuse and Mental Health Services Administration [SAMHSA], 2004; SAMHSA, 2007). From 1990 to 2002, the number of people in the U.S. who reported using prescription pain medications non-medically for the first time that year increased from 600,000 to over 2 million people (SAMHSA, 2004).

In 2007, recognizing the need for intervention, the Utah State Legislature passed House Bill 137 appropriating funding to the Utah Department of Health (UDOH) to establish a program aimed at reducing deaths and other harm from prescription opiates. Additionally, the program's charge was to develop medical treatment and quality care guidelines for the state of Utah. The resulting Prescription Pain Medication Program is being led by the Utah Department of Health in collaboration with the Utah Attorney General, the Labor Commission, the Division of Occupational and Professional Licensure, Department of Commerce, and Division of Substance Abuse and Mental Health, Department of Human Services.

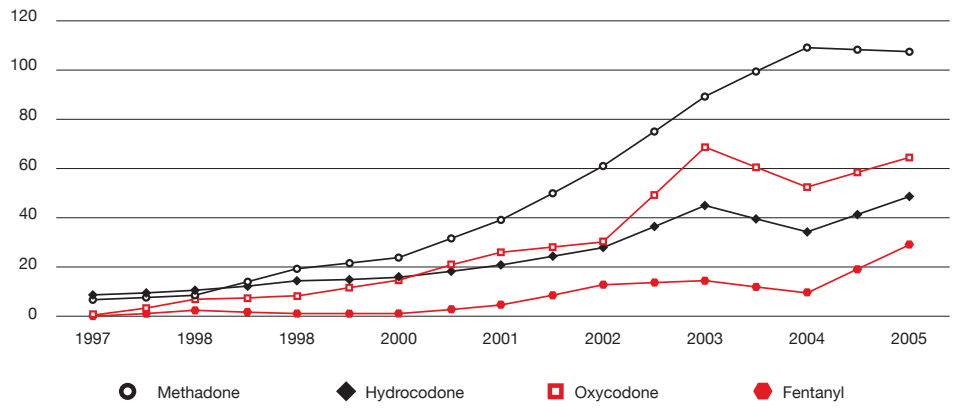
A key goal of this Guideline is to seek a balance between appropriate treatment of pain and safety in the use of opioids for that purpose. The Model Policy for the Use of Controlled Substances for the Treatment of Pain[1] (Federation of State Medical Boards, 2004) acknowledged that "undertreatment of pain is…a serious public health problem," but also sought to establish the importance of balance in treating pain as stated in the following sentence:

"…the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments."

As of the time these Utah Guidelines were produced, **adequate evidence was not available to determine the benefits of long-term treatment with opioids for persons with chronic pain due to musculoskeletal and other non-cancer causes on patient function and quality of life** (Von Korff & Deyo, 2004). Despite that lack of evidence, the use of these medications for treatment of these conditions has increased substantially in recent years. In the absence of adequate evidence to determine the true benefits and best practices in use of these medications,

[1] The Model Policy for the Use of Controlled Substances for the Treatment of Pain was developed by the Federation of State Medical Boards and endorsed by the Division of Occupational and Professional Licensing on recommendation of the Physicians Licensing Board.

Figure 1. *Number of Utah Deaths by Year and Drug: Accidental and Undetermined Cause*



these Guidelines were developed to assist physicians who choose to use opioids to treat patients with pain to manage that treatment as safely as possible.

The principal focus of these Guidelines is on the use of opioids in the long term treatment of chronic pain, especially chronic, non-cancer pain[2]. These guidelines were not developed to guide treatment of patients with malignant cancer or for patients in hospice or palliative care settings and should not limit treatment for patients for whom pain relief is the primary goal and improved function is not expected.

The diversion of opioid medications to non-medical uses also has contributed to the increased numbers of deaths. Therefore, these guidelines also include several recommendations on the use of opioids to treat acute pain to help address that public health problem. For purposes of these guidelines, acute pain is considered to be an episode of pain lasting six weeks or less and chronic pain to be pain lasting more than three months. Episodes of pain lasting from one to three months are sometimes referred to as subacute pain and were not explicitly addressed by these guidelines, however many of the recommendations are applicable to subacute pain.

The Utah Department of Health and its advisors recognized that clinicians have many demands on their time and have attempted to make these guidelines as practical and concise as possible. However, long-term use of opioid medications to treat chronic pain carries substantial risks and the benefits of this treatment approach have not been adequately established by appropriate studies. The time commitment required to safely manage patients on these medications should be considered when they are prescribed. The Utah Department of Health agrees with Von Korff and Deyo (2004) that,

"Long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up and close supervision are ensured."

Medicine is practiced one patient at a time and each patient is unique with individual needs and vulnerabilities. The Guidelines have attempted to guide clinicians but not to inappropriately constrain practice. The art of medicine is recognized. However, these Guidelines were based on evidence or consensus recommendations by experts. They are intended to improve outcomes of patient care and in particular to prevent deaths due to opioid use. Departures from these recommendations will be appropriate for some patients, but should be justified and documented.

[2] This Guideline uses the term chronic non-cancer pain to refer to chronic pain that is not associated with active cancer or occurs at the end of life (Chou et al., 2009). Some of the tools and references included in this Guideline use the term, "chronic non-malignant pain" to describe a similar or identical set of conditions.

Summary of Recommendations

Opioid Treatment for Acute Pain

1) Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.

2) When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, to not share with others, and to dispose of medications properly when the pain has resolved in order to prevent non-medical use of the medications.

4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.

5) The use of opioids should be reevaluated carefully, including assessing the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

Opioid Treatment for Chronic Pain

1) A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain.

2) Alternatives to opioid treatment should be tried (or adequate trial of such treatment by a previous provider documented), before initiating opioid treatment.

3) The provider should screen for risk of abuse or addiction before initiating opioid treatment.

4) When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.[3]

5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement.

6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.

7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).

8) Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored.

9) Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult may be useful in making that decision

10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated.

11) Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.

12) Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment.

13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use, and who are prepared to conduct the necessary careful monitoring.

[3] "Function" as used here is defined broadly to include physical, emotional, cognitive, psychological and social function.

Methods

Purpose and Target Audience

These Guidelines provide recommendations for the use of opioids for management of pain that are intended to balance the benefits of use against the risks to the individual and society, and to be useful to practitioners. The target audience for these Guidelines includes all clinicians who prescribe opioids in their practice.[4]

Guideline Evidence Review

The steering committee of the Utah Department of Health's Prescription Pain Medication Program developed the key questions, scope, and inclusion criteria used to guide the evidence review process. The process began with a literature review to identify existing guidelines on pain, chronic pain, opioids, pain management, and related topics. Guidelines were identified through electronic databases, reference lists from evaluated guidelines, and recommendations from experts. Electronic databases that were searched include: PubMed, Medline, CINAHL, and the National Guideline Clearinghouse. Investigators identified and evaluated 40 individual guidelines.

Grading of the Evidence and Recommendations

As guidelines were identified they were reviewed for key information. They were evaluated based on the following categories:

- Title
- Year Published: Guidelines were included only if they were published after the year 1999. Articles published before 2000 were merely noted in the grid by their title and date with no additional information.
- Sponsorship and funding
- Medical Perspective
- Target Audience
- The Process: This describes how the guidelines were created. Most guidelines fell into two categories: "evidence-based" and/or "consensus"
- The Rating Scale: This was based on the quality of research that went into the development of the guidelines. Explicit evidence-based guidelines received higher ratings and less explicit, consensus-based guidelines received lower ratings

The complete evaluation matrix of the 40 guidelines is available from the Utah Department of Health, Bureau of Epidemiology upon request.

In total, 40 guidelines for pain management were reviewed and evaluated. As each guideline was reviewed, it received a rating from 1-10 (for a breakdown of the rating scale, see Appendix A). Guidelines that received scores of seven (7) or lower were excluded. Four (4) sets of guidelines received scores of eight (8) or above. Three (3) public health professionals reviewed the ratings to ensure that the scores were consistent with the rating scale.

Panel Composition

The Utah Department of Health convened two multidisciplinary panels (see page 4 for complete list of panel members). The Guideline Recommendation Panel convened on four (4) occasions between May and July 2008. Their purpose was to review the evidence and formulate recommendations based on the evidence in the selected guidelines. Each member signed a Conflict of Interest disclosure. Conflicts were reported as described below (See Disclosure of Conflicts on page ii). The Guideline Implementation and Tool Panel convened twice (2) between July and August 2008 to review the recommendations to ensure that they were implementable as well as to identify tools needed in order to put the recommendations into use. The first panel consisted of twelve (12) experts and the second consisted of nine (9) experts from throughout the state of Utah.

Recommendation Development Process

The Guideline Recommendation Panel met in person on four occasions between May and July 2008. The purpose of the first meeting was to provide panel members with copies of the selected, high-scoring guidelines and to present the purpose and plan for developing the guidelines. Prior to the second meeting, panel members were asked to review the four guidelines for commonalities. The recommendations that were supported by multiple guidelines created the basis of the first draft of the recommendations used by the Guideline Recommendation Panel. Consideration was given to adopting one of the existing evidence-based guidelines outright, but the panel

[4] In Utah as of January 2009 (R156-37), clinicians who can be licensed to prescribe controlled substances as part of practice (human) includes physicians and surgeons, osteopathic physicians and surgeons, podiatrists, dentists, physician assistants, advanced practice registered nurses, certified nurse midwives, certified nurse anesthetists, and optometrists.

felt that no single guideline represented sufficiently what was desired of the Utah guidelines. The panel voted to include two (2) additional sets of guidelines that had not met the inclusion criteria for consideration while drafting the recommendations. In total, content for the Utah guidelines was drawn from six (6) guidelines. The key topics to be developed into specific recommendations were posted on a website where the Guideline Recommendation Panel members posted comments and edited the text. The panelists' postings were the basis on which content was selected from the chosen guidelines. This content was then used to create a draft of actual recommendation statements and supporting paragraphs. At the third meeting, a straw poll was taken on the recommendation draft. Through discussion and rewording, consensus on content was achieved for all of the recommendations discussed over the course of the two meetings. Outside the meetings, non-content editing of the recommendations and supporting statements was performed, based on the panel's discussions, to create the final draft of the recommendations and supporting paragraphs.

Tool Development Process

The Guideline Implementation and Tools Panel met in person on two occasions between July and August 2008. Prior to the first meeting, a book was compiled that included all tools that were identified in the forty (40) guidelines. Sample tools were solicited from panel members as well. In total, the workbook contained forty-seven (47) tools. At the first meeting, the panel reviewed the draft recommendations and discussed whether any specific recommendations were impossible or burdensome to implement. Panel members were each given a book containing all the tools. In between the first and second meeting, panel members reviewed and graded each tool according to usefulness and whether or not it should be included in the guidelines. Votes and rating were tallied prior to the second meeting. Tools that received an average rating of below two (2) were eliminated. At the second meeting, the remaining tools were discussed and it was determined which of the remaining tools should be included, modified, or eliminated.

Following the final panel meetings, Utah Department of Health staff formally drafted the complete guidelines document. Drafts of the complete guidelines were then distributed to all panel members and several Utah Department of Health internal staff for feedback and revisions. External peer reviewers were solicited for additional comments. The final draft recommendations were posted for public comment during November–December 2008 and revisions were made based on consideration of those comments (copies of comments are available online at **health.utah.gov/prescription**). Prior to publication, the Guideline was submitted to the Utah Department of Health Executive Director for approval.

Recommendations

Previously published evidence-based or consensus-based guidelines have been used as the foundation for many of the Utah recommendations. Each guideline has been assigned a number. After each recommendation, the numbers of the guidelines with similar or supporting recommendations are listed.

Reference Guidelines:

1. Department of Veterans Affairs, Department of Defense. (2003). *VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain*
2. College of Physicians and Surgeons of Ontario. (2000). *Evidence-based recommendations for medical management of chronic non-malignant pain*
3. American College of Occupational and Environmental Medicine's Occupation Medicine Practice Guidelines. (2008).
4. *Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines.* (2008).
5. Washington State Agency Medical Directors' Group. (2007). *Interagency guideline on opioid dosing for chronic non-cancer pain: An educational pilot to improve care and safety with opioid treatment*
6. Federation of State Medical Boards of the United States, Inc. (2004). *Model policy for the use of controlled substances for the treatment of pain*

Opioid treatment recommendations for acute pain:

Acute Pain Recommendation 1:
Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief. *Reference Guidelines: 3*

Most acute pain is better treated with non-opioid medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAID), or therapies such as exercise, or specific stretching) than opioid medications which have less desirable adverse effect profiles in acute pain patients. Care should be taken to assure that use of opioid pain treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. The developing brain may be more susceptible to addiction when exposed to opioid medications and nonmedical use is more common among younger people. Those risks should be considered when prescribing to an adolescent.

Acute Pain Recommendation 2:
When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain severe enough to require opioids for that condition.

Prescribing more medications than the amount likely to be needed leads to unused medications being available for non-medical use or abuse. Use of opioid pain medications should be stopped when pain severity no longer requires opioid medications.

Acute Pain Recommendation 3:
When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved in order to prevent non-medical use of the medications.

It is important that patients understand the need to store medications securely. Encourage patients to keep medications in a locked environment rather than in typical locations, such as the bathroom or kitchen cabinet, where they are accessible to unsuspecting children, curious teenagers, and can be a target for theft. Tell the patient that if they have leftover medication after they have recovered, they should dispose of their medication immediately to help protect them from being a target for theft as well as protect others from getting into the medications. The Federal Guidelines on Proper Disposal of Prescription Drugs are included in the Tool Section.

Acute Pain Recommendation 4:
Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.

Acute Pain Recommendation 5:
The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

Patients with acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course for their diagnosis should be carefully evaluated. The continuation of opioid treatment in this setting may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such at the time. The diagnosis and appropriateness of interventions should be reevaluated and the patient's medical history should be reviewed for comorbidities that could interact with opioid treatment and for risk factors for problems during opioid treatment, including substance abuse or history of substance abuse. It is recommended that the provider check the Utah Controlled Substances Database at this time as well.

Opioid treatment recommendations for chronic pain:

Before prescribing opioid treatment for chronic pain:

1. Comprehensive initial evaluation/assessment of patient

1.1 Recommendation:
A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. *Reference Guidelines: 1, 2, 4, 6*

There are many reasons for using caution when initiating opioid therapy, therefore the recommended comprehensive initial evaluation is very important. A major goal when prescribing opioids should be to provide greater benefit than harm to patients. Potential for serious harm exists, up to and including death, due either to overdose or to dangerous behaviors that occur while under the influence of these medications. The patient may be harmed, but others may also be harmed through diversion or because of an act performed by the patient on opioids. The most frequent harms are diversion, misuse, abuse, addiction, and overdose and predicting which patients will be affected by these harms is difficult. Initiating opioid treatment often results in short term relief, but that relief might not be maintained. Long-term use of opioid medications to treat chronic pain safely requires the commitment of adequate resources to regularly monitor and evaluate outcomes and identify occurrence of adverse consequences.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, evaluate how the pain is affecting the patients function and quality of life, identify other conditions or circumstances that could affect the choice of treatment or the approach to managing that treatment, assess and evaluate prior approaches to pain management, and serve as a basis for establishing a plan for treatment and evaluation of treatment outcomes.

The evaluation should specifically address these issues:

1) Assess pain and prior treatment of pain.
- Determine the cause of the pain and whether the pain is acute or chronic.
- Assess previous treatment approaches and trials for appropriateness, adequacy, and outcome.

2) Assess presence of social factors, and medical or mental health conditions that might influence treatment especially those that might interfere with appropriate and safe use of opioid therapy (Department of Veterans Affairs & Department of Defense [VA/DOD], 2003):
- Obtain history of substance use, addiction or dependence (if present, refer to Recommendations 12.2 and 12.3).
- Identify psychiatric conditions that may affect pain or treatment of pain (if present, refer to Recommendation 12.4).
- Identify use of other medications that might interact with medications used to treat the pain. Particular attention should be given to benzodiazepines and other sedative medications.
- Assess social history, including employment, social network, marital history, and any history of legal problems especially illegal use or diversion of controlled substances.
- Assess for presence of medical conditions that might complicate treatment of the pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea.
- Central sleep apnea is common among persons treated with methadone and other opioid medications, especially at higher dosages. Some clinicians recommend that all patients who are considered for long-term opioid treatment receive a sleep study prior to therapy or when higher dosages are considered.

3) Assess the effects of pain on the person's life and function.
- Assess the severity of pain, functional status of the patient, and the patient's quality of life using a method/instrument that can be used later to evaluate treatment effectiveness.

Tools to accompany Recommendation 1:
- Sheehan Disability Tool
- Pain Management Evaluation Tool

2. Consider alternative treatment options

2.1 Recommendation:
Alternatives to opioid treatment should be tried (or an adequate trial of such treatments by a previous provider documented) before initiating opioid treatment. *Reference Guidelines: 1, 2, 3, 4, 5*

Opioid medications are not the appropriate first line of treatment for most patients with chronic pain. Other measures, such as non-opioid analgesics, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., physical therapy), should be tried and the outcomes of those therapies documented first. Opioid therapy should be considered only when other potentially safer and more effective therapies have proven inadequate. This approach is consistent with the World Health Organization's Pain Relief Ladder (WHO).

2.2 Recommendation:
Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany Recommendation 2:

- Non-opioid Pain Management Tool

3. Screening for risk of addiction or abuse

3.1 Recommendation:
Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication long-term for chronic pain. *Reference Guidelines: 3*

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. Several of these are included in the Tool Section. The screening tool results are intended to assist the clinician in determining whether opioid therapy is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

3.2 Recommendation:
Consider performing drug screening before initiating long term opioid treatment for chronic pain.

Research and experience have shown that drug testing can identify problems, such as use of undisclosed medications, non-use of reported medications (i.e., diversion), undisclosed use of alcohol, or use of illicit substances, that are not identified without that testing. Several experts involved in the development of these guidelines recommended that drug screening be done on all patients before initiating opioid treatment for chronic pain. However, drug testing can damage a provider-patient relationship, the results of testing can be difficult to interpret, and that recommendation attracted a substantial number of negative comments during the public comment period. It is recommended that drug testing be strongly considered and conducted especially when other factors suggest caution.

The drug screening should be either a urine drug screen or another laboratory test that can screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use. It is recommended that this testing be considered for all patients. When screening is limited to situations when there is suspicion of substance misuse, some misuse may be missed. In one study, testing results at first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most of these discrepancies involved finding substances not reported by the patient; a small minority reported taking medications that were not found on testing (Berndt, Maier, & Schutz, 1993).

The clinician may consider testing for illegal substances (See list of Urine Drug Testing Devices in the Tool Section) in addition to screening for opioids.

A positive drug screen indicates the need for caution, but does not preclude opioid use for treatment of pain. Consideration should be given to referral to substance abuse counseling and/or to a pain management specialist. If opioid medication is subsequently prescribed, the patient should be more carefully monitored and conditions

under which opioids are being prescribed should be well documented in the treatment plan (See Recommendations 5, 6, 8, 12).

Immunoassays can be done in the office. These can determine if opioids are present but do not identify specific ones, which can subsequently be determined by confirmatory laboratory testing. However, in many cases, going over the results of the initial in-office test carefully with the patient can eliminate the need for confirmation testing. It is extremely important to keep in mind that immunoassays have both false positive and false negative results. Over-the-counter medication, for example, can cause a positive result (Washington State Agency Medical Directors' Group [WSAMDG], 2007).The prescriber may want to consider confirmatory testing or consultation with a certified Medical Review Officer if drug test results are unclear (WSAMDG, 2007).

3.3 Recommendation:
The prescriber should check Utah's Controlled Substance Database before prescribing opioids for chronic pain.

Most patients who request treatment for pain are legitimately seeking relief of the pain. However, a subset of patients who present seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of controlled substance prescriptions filled by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to the potential for problems.

The State of Utah's Division of Occupational and Professional Licensing (DOPL) maintains the Controlled Substance Database Program, which is a searchable record of all prescriptions that are filled in the state for controlled substances. The Utah Controlled Substance Database Program was legislatively created and put into effect in 1995. It is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. Access to the data is provided to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and potential abuse of controlled substances throughout the state. This database is accessible to all controlled substance prescribers online at **www.csdb.utah.gov**. A "Getting Started" presentation is available to help orient users to the site and to appropriate uses of the database.

Tools to accompany Recommendation 3:

- SOAPP-R
- Opioid Risk Tool
- Prescription Drug Use Questionnaire
- List of Recommended Urine Drug Screens

Establishing Treatment Goals and a Written Treatment Plan:

4. Establish treatment goals

4.1 Recommendation:
When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.

The treatment plan should be tailored to the patient's circumstances and the characteristics and pathophysiology of the pain. The pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function and therefore should be considered when establishing treatment goals. Non-opioid treatment modalities should be included in the treatment plan whenever possible, to maximize the likelihood of achieving treatment goals.

4.2 Recommendation:
Goals for treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain. *Reference Guidelines: 1, 3, 5*

For most chronic pain conditions, complete elimination of pain is an unreasonable goal (College of Physicians and

Surgeons of Ontario, 2000). Goals for treatment of chronic pain should include improvement in the tolerability of the pain and in function (College of Physicians and Surgeons of Ontario, 2000). The clinician should counsel the patient on reasonable expectations for treatment outcomes so that together they can agree on achievable treatment goals addressing pain, function, and quality of life.

The pathophysiologic basis of the pain can help establish a prognosis for future improvement (or worsening) in function and pain and should influence the goals of treatment. Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcome (VA/DOD, 2003; Hegmann, Feinberg, Genovese, Korevaar, & Mueller, 2008). These include:

- Objective physical findings obtained by the examining clinician (e.g., improved strength, range of motion, aerobic capacity);
- Functional status at work (e.g., increase in physical output, endurance, or ability to perform job functions); and
- Functional status at home (e.g., increased ability to perform instrumental activities of daily living, and frequency and intensity of conditioning).

Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes. These may include:

- Patient rating of quality of life on a measurement scale
- Psychosocial status (e.g., increased social engagement or decreased emotional distress)
- Familial status (e.g., improved relationships with or decreased burden on family members)
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Pain intensity should be assessed at each visit using a standard instrument such as the Numerical Rating Scale. See the Pain Management Evaluation Tool, Patient Pain and Medication Tracking Chart, Sheehan Disability Scale, and Brief Pain Inventory Form in the Tool Section or page 17 of VA/DOD guidelines.

Clinicians should consider cultural differences in assessing function, quality of life, and pain intensity (See **http://prc.coh.org/culture.asp** for examples). These measures of improvement could be reported by the patient, family members, and/or the employer. Permission to discuss the patient's condition with these persons should have previously been obtained and documented (See Recommendation 5.5).

4.3 Recommendation:
Treatment goals should be developed jointly by patient and clinician. *Reference Guidelines: 2*

Engage patients in their own healthcare. Clinicians have observed that when patients assume a significant portion of the responsibility for their rehabilitation they are more likely to improve and that when they participate in goal setting they are more likely to achieve the goals. As with any other chronic illness (such as diabetes or heart disease), the clinician should focus not just on pain control, but also on treating the patient's underlying diseases and encouraging them to engage in ownership of their own health.

Tools to accompany Recommendation 4:

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking Chart
- Sheehan Disability Scale
- Brief Pain Inventory Form
- Sample Treatment Plan for Prescription Opioids
- Cultural considerations in assessing function, quality of life, and pain intensity: **http://prc.coh.org/culture.asp**

5. Informed consent and formulation of a treatment plan

5.1 Recommendation:
The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement. *Reference Guidelines: 4*

The patient should be counseled about appropriate use of the medication, possible adverse effects, and the risks of developing tolerance, physical or psychological dependence, and withdrawal symptoms (Trescot et al., 2008; WSAMDG, 2007). Adverse effects can include nausea, constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Hegmann et al., 2008), opioid-induced hyperalgesia (Hegmann et al., 2008; WSAMDG, 2007), allodynia (WSAMDG, 2007), abnormal pain sensitivity (WSAMDG, 2007), and depression (Daniell, 2007).

Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long term complete pain relief. Without careful guidance this may lead the patient to seek excessive dosing of opioids and to disappointment.

Sedation and cognitive impairment may occur when patients are taking opioid medication. Therefore, discuss with patients the need for caution in operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.[5]

Ensure the patient does not have any absolute contraindications and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent)
- Co-administration of drug capable of inducing life-limiting drug-drug interaction
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed)

More detail about absolute contraindications is contained in the Tool Section.

Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

Signs of respiratory depression:

- Snoring heavily and cannot be awakened
- Periods of ataxic (irregular) or other sleep disordered breathing
- Having trouble breathing
- Exhibiting extreme drowsiness and slow breathing
- Having slow, shallow breathing with little chest movement
- Having an increased or decreased heartbeat
- Feeling faint, very dizzy, confused or has heart palpitations

5.2 Recommendation:
The patient and, when applicable, the family or caregiver should both be involved in the educational process. *Reference Guidelines: 1*

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver (VA/DOD, 2003). Educating the family about the signs of opioid overdose may help detect problems before they lead to a serious complication.

It is crucial to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions under which information about the patient can be disclosed to others, such as family members, and under what conditions discussions about the patient with others are allowed.

[5] Health care professionals are responsible to "counsel their patients about how their condition affects safe driving. For example, if medication is prescribed for a patient which may cause changes in alertness or coordination, the health care professional shall advise the patient about how the medication can affect safe driving, and when it would be safe to operate a vehicle." R708-7-6(1)(b) Utah Administrative Code A health care professional or other person who becomes aware of a physical, mental, or emotional impairment that appears to present an imminent threat to driving safety and reports this information to the division in good faith has immunity from any damages claimed as a result of making the report. (§53-3-303(14)(c) Utah Code Annotated) Federal law prohibits driving a commercial motor vehicle while under the influence of a narcotic (CFR §391.15).

5.3 Recommendation:
The treatment plan, which defines the responsibilities of both patient and clinician, should be documented. *Reference Guidelines: 1, 2, 3, 4, 5*

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. They could also include instructions to keep a pain diary, a diary or log of daily activities and accomplishments, and/or instructions on how and when to give feedback to the prescriber (VA/DOD, 2003).
The prescribing clinician may consider requiring that the treatment plan, be documented in the form of a treatment "contract" or "agreement" that is signed by the patient. Patients should be encouraged to store opioid medication in a lock box to keep the medication out of the hands of others who should not have access to them.

5.4 Recommendation:
The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum medication level screening upon request, and reasons for possible discontinuation of drug therapy. *Reference Guidelines: 1, 2, 4, 5, 6*

The treatment plan (sometimes referred to as treatment "contracts" or "agreements") should contain the items that were developed jointly by patient and clinician, such as follow-up appointments, the pharmacy and clinician to be used, as well as any non-negotiable demands or limitations the clinician wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the agreement and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications (VA/DOD, 2003; Trescot et al., 2008) or obtaining them from multiple providers as documented by Utah's Controlled Substance Database Program.

Optional inclusions in the agreement:

- Pill counts may be required as a means to gauge proper medication use (VA/DOD, 2003; Trescot et al., 2008).
- Prohibition on use with alcohol or certain other medications (VA/DOD, 2003)
- Documentation of counseling regarding driving or operating heavy machinery (VA/DOD, 2003 Hegmann et al., 2008)
- Specific frequencies of urine testing

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only (VA/DOD, 2003; Trescot et al., 2008; Federation of State Medical Boards, 2004).

It is not necessary to include specific consequences for specific non-compliant behaviors, but it should be documented in the treatment agreement that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship and of opioid prescribing by that clinician.

A Sample Treatment Plan for Prescribing Opioids is included in the Tool Section.

5.5 Recommendation:
Discuss involvement of family members in the patient's care and request that the patient give written permission to talk with family members about the patient's care.

This is best done before starting to treat the patient because it can be more difficult to obtain consent after an issue occurs. Prior to initiating treatment with opioids, the physician may want to consider a family conference to help assess the patient's integrity (Trescot et al., 2008). Consultation with others, however, must be done within the constraints of HIPAA, as noted above (See Recommendation 5.2). Guidance about communications with family and others under HIPAA can be found at: **http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/provider_ffg.pdf**

Tools to accompany Recommendation 5:

- Absolute Contraindications to Opioid Prescribing
- Sample Treatment Plan for Prescribing Opioids

Initiating, Monitoring, and Discontinuing Opioid Treatment:

6. Initiate opioid therapy as a treatment trial

6.1 Recommendation:
Opioid medication should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life.

The clinician should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid medication treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. Criteria for cessation should be considered before treatment begins. Refer to Recommendation 9 for more information on discontinuation of treatment.

6.2 Recommendation:
In most instances, the trial should begin with short-acting opioid medication.

Short-acting opioid medications are in general safer and easier to titrate to an effective dose. If the treatment trial proves successful in achieving the goals established in the treatment plan, the prescriber may consider switching the patient to a long-acting or sustained-release formulation (See the Dosing Guidelines in the Tool Section). The patient's individual situation should influence whether the patient is switched from short-acting medication. Treatment with long-acting opioid medication before a trial using a short-acting medication has been performed is an option that should be prescribed only by those with considerable expertise in chronic pain management.

6.3 Recommendation:
Parenteral[6] (intravenous, intramuscular, subcutaneous) administration of opioids for chronic pain is, in general, discouraged. *Reference Guidelines: 2*

Daily IM or SC injections should be avoided except under a highly supervised environment such as during an admission to the hospital or hospice.

Tools to accompany Recommendation 6:

- Dosing Guidelines
- COMM

7. Titration phase

7.1 Recommendation:
Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). Reference Guidelines: 1

Follow-up face-to-face visits should occur at least every 2-4 weeks during the titration phase. More frequent follow-up visits may be advisable and caution should be used when prescribing opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician's judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused) (College of Physicians and Surgeons of Ontario, 2000).

7.2 Recommendation:
When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered. *Reference Guidelines: 1, 2*

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than

[6] These guidelines did not consider intrathecal administration and this recommendation was not intended to discourage trained and qualified physicians from using intrathecal opioid medications.

necessary by going too slowly with the risk of causing harm, including fatal overdose, by going too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient (VA/DOD, 2003). Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of opioid measured in morphine equivalents. It is likely that the risk-benefit ratio is less favorable at higher doses. Clinical vigilance is needed at all dosage levels of opioids but is even more important at higher doses. Clinicians who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages. No clear threshold for high dose has been established based on evidence. The Washington State guideline (WSAMDG, 2007) suggested a threshold of 120 mg of morphine equivalent per day, but has been criticized for that decision. It seems reasonable to increase clinical vigilance at daily doses that exceed 120-200 mg of morphine equivalent per day.

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to Use Only as Directed, that is, not to change doses or frequency of administration without specific instructions from the clinician.

7.3 Recommendation:
During the titration phase, until the patient is clinically stable and is judged to be compliant with therapy, it is recommended that the clinician check the Controlled Substances Database at least quarterly.

For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Tools to accompany Recommendation 7:

- Dosing Guidelines

8. Maintenance – Periodic monitoring and dose adjustments:

8.1 Recommendation:
Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. *Reference Guidelines: 2, 4*

Assess each of the following four areas of concern at each visit: Analgesia, activity, adverse effects, and aberrant behavior. These assessments can be remembered as the "four A's" (Passik & Weinreb, 2000):

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess both the patient's function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior

A sample checklist for signs of aberrant behavior is included in the Tool Section.

8.2 Recommendation:
Providers should consider performing drug screening on randomly selected visits and any time aberrant behavior is suspected.

As discussed in recommendation 3, drug testing has been shown to identify problems that might otherwise go undetected. It may not be appropriate or necessary for all patients, but should be strongly considered by providers and may provide an opportunity to discuss the risks and problems that can occur with opioid treatment. Base the frequency of random drug screening on the assessed degree of risk of aberrant behavior for the individual patient. Pill counts may also be useful in some circumstances.

8.2 Recommendation:
During maintenance phase, Controlled Substances Database should be checked at least annually.

After the titration phase is complete and the maintenance phase is underway, the frequency of checks of the Controlled Substances Database can be based on clinical judgment, but should be done no less than annually. The Controlled Substances Database should be checked more often for high risk patients and patients exhibiting aberrant behavior. For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Consider evaluating for possible drug abuse-related behavior at each visit. A sample checklist is included in the Tool Section.

Provide reinforcement for previous counseling and additional education for patients at follow-up visits (Trescot et al., 2008).

Review the pathophysiologic hypothesis (to see if the diagnosis is still valid) at each visit (Trescot et al., 2008).

8.3 Recommendation:
Continuation or modification of therapy should depend on the clinician's evaluation of progress towards stated treatment goals. *Reference Guidelines: 4*

These include reduction in a patient's pain scores and improved physical, psychological and social function. If treatment goals, including patient compliance with agreed-upon activity levels, are not being achieved despite medication adjustments, the clinician should reevaluate the appropriateness of continued treatment with the current medications (WSAMDG, 2007; Federation of State Medical Boards, 2004).

A frequent need for dose adjustments after a reasonable time interval of titration is an indication to reevaluate the underlying condition and consider the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

8.4 Recommendation:
Adjustments to previously stable maintenance therapy may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant. *Reference Guidelines: 1*

Options for adjustment include reducing medication or rotating opioid medication. If it is documented that the patient is compliant with agreed-upon recommendations such as exercise, working, etc., addition of supplemental short-acting medications for control of break-through pain exacerbation (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success (Quang-Cantagrel, Wallace, & Magnuson; 2000).

Only if the patient's situation has changed permanently and consideration has been given to increased risk of adverse events, is it reasonable to consider an ongoing increase in maintenance dosing (VA/DOD, 2003).

If rotating among different opioid medications, refer to a standard dosing equivalence table taking into account the current drug's half-life. (See the Dosing Guidelines in the Tool Section)

In general, if the patient's underlying medical condition is chronic and unchanging and if opioid-associated problems (hyperalgesia, substantial tolerance, important adverse effects) have not developed, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level (VA/DOD, 2003).

8.5 Recommendation:
Dosing changes should generally be made during a clinic visit. *Reference Guidelines: 1*

If the patient's underlying pain-producing chronic medical condition improves, it is expected that the clinician will begin tapering the patient off the opioid medication (See Recommendation 10 for guidelines on discontinuation.)

Tapering opioid medication with or without the goal of discontinuation may be performed as described below (Recommendation 10) or as described in Strategies for Tapering and Weaning in the Tool Section.

Tools to accompany Recommendation 8:

- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse
- Pain Management Evaluation Tool
- Dosing Guidelines
- Strategies for Tapering and Weaning

9. Evaluate the treatment trial

9.1 Recommendation:
Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient.

9.2 Recommendation:
A second opinion or consult may be useful in making the decision to continue or discontinue the opioid treatment trial.

10. Discontinuing opioid treatment

10.1 Recommendation:
An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated. *Reference Guidelines: 5*

10.2 Recommendation:
Discontinuation of opioid therapy is recommended if any of the following occurs:

- Dangerous or illegal behaviors are identified
- Patient claims or exhibits a lack of effectiveness
- Pain problem resolves
- Patient expresses a desire to discontinue therapy
- Opioid therapy appears to be causing harm to the patient, particularly if harm exceeds benefit

Reference Guidelines: 1

The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver (Federation of State Medical Boards, 2004). This decision should include careful consideration of the outcomes of ongoing monitoring.

10.3 Recommendation:
When possible, offer to assist patients in safely discontinuing medications even if they have withdrawn from treatment or been discharged for agreement violations.

Reference Guidelines: 1

The goal is to taper all patients off opioid medication safely. "Strategies for Tapering and Weaning" in the Tool Section contains advice on tapering opioid medications (WSAMDG, 2007). If the patient is discharged, the clinician is obliged to offer continued monitoring for 30 days post-discharge.

Tools to accompany Recommendation 10:

- Strategies for Tapering and Weaning

Other Issues:

11. Documentation and Medical Records

11.1 Recommendation:
Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed. *Reference Guidelines: 1, 2, 4, 5, 6*

11.2 Recommendation:
A written treatment plan should document objectives that will be used to evaluate treatment success. *Reference Guidelines: 1, 2, 4, 5, 6*

The objectives should address pain relief, improved physical and psychosocial function, including work and exercise compliance, and should indicate if additional diagnostic tests, consultations, or treatments are planned (Trescot et al., 2008). Use of validated instruments to measure pain and function is preferred. Details on establishing treatment goals and formulation of a treatment plan are covered elsewhere in these guidelines (Recommendations 4 and 5.)

11.3 Recommendation:
The prescription for opioid therapy should be written on tamper-resistant prescription paper in a manner to help reduce the likelihood of prescription fraud or misuse. *Reference Guidelines: 2*

The written prescription for opioid therapy should contain the name of the drug, the strength, the number of dosage units, (written numerically and in text), how the drug is to be taken, the full name, address, and age of the patient, the name, address, and DEA registration number of the practitioner, and the signature of the physician or other authorized practitioner. It shall be dated and signed on the day when issued. After a stable maintenance therapy dosage has been established and therapy goals have been achieved, schedule II opioid medications may be prescribed for three months by providing the patient with prescriptions for each of the three months. Each prescription for a one month supply of medication should include the date the prescription is written and the date when that prescription is to be filled.

To reduce the chance of tampering with the prescription, write legibly, and keep a copy (College of Physicians and Surgeons of Ontario, 2000). (See the Tamper Resistant Requirements in the Tool Section.)

11.4 Recommendation:
Assessment of treatment effectiveness should be documented in the medical record. *Reference Guidelines: 2, 4, 5*

Document the patient's progress toward treatment goals, including functional status, at every visit, rather than merely reporting the patient's subjective report of decreased pain. Ideally, this progress would be evaluated using validated tools (Trescot et al., 2008).

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may affect the efficacy of treatment or risks of adverse events should be evaluated and documented at every visit.

11.5 Recommendation:
Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record. *Reference Guidelines: 1*

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics
- Follow-up referrals, tests, and other therapies

Clinicians are encouraged to make use of resources provided by the state of Utah that are designed to assist them in managing patients with aberrant behavior (See Checklist for Adverse Effects, Function, and Opioid Dependence and Signs of Substance Misuse in Tool Section). Referral to law enforcement/legal agencies may be appropriate if actions by patients are occurring that could be criminal in nature (VA/DOD, 2003). Clinicians

should consider consulting with legal counsel before contacting law enforcement (VA/DOD, 2003). Serious non-adherence issues (illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid therapy. See Recommendation 10.

Tools to accompany Recommendation 11:

- Tamper Resistant Requirements
- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse

12. Consultation and management of complex patients

12.1 Recommendation:
Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment. *Reference Guidelines: 4, 5*

Prescribers may wish to consider referring patients if any of the following conditions or situations is present or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis;
- The patient has significant co-morbidities (including psychiatric illness);
- The patient is high-risk for aberrant behavior or addiction; or
- The clinician suspects development of significant tolerance, particularly at higher doses.

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

12.2 Recommendation:
Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment.
Reference Guidelines: 1, 4, 5

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Utah where there is a shortage of readily available addiction specialists. The Directory of Resources in the Tool Section includes information on available resources for these patients.

12.3 Recommendation:
Pain patients who are addicted to medications/drugs should be referred to a pain management, mental health or substance use disorder specialist if available, for recommendations on the treatment plan and possibly for assistance in management.

The clinician may consider prescribing opioid medication for pain even if the patient has a self-reported or documented previous problem with opioids, as long as monitoring is performed during titration and maintenance phase.

12.4 Recommendation:
Patients with coexisting psychiatric disorder should receive ongoing mental health support and treatment while receiving opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation (Trescot et al., 2008; Federation of State Medical Boards, 2004). Unless the clinician treating the patient is qualified to provide the appropriate care and evaluation of the coexisting psychiatric disorder, consultation should be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric conditions.

Tools to accompany Recommendation 12:

- Strategies for Tapering and Weaning
- Directory of Resources

13. Methadone

13.1 Recommendation:
Methadone should only be prescribed by clinicians familiar with its risks and use, and who are prepared to conduct the necessary careful monitoring.

Methadone-related death rates have been increasing in Utah and the U.S. In 2006, methadone was implicated in 30% of non-illicit drug-related deaths in Utah. Methadone was the most common drug identified by the Utah Medical Examiner as causing or contributing to accidental deaths, accounting for a disproportionate number of deaths compared to its frequency of use. Methadone was the single drug most often associated with overdose death and had the highest prescription adjusted mortality rate (PAMR) with an average of 150 deaths for every 100,000 prescriptions during 1998-2004. From 1997–2004, population-adjusted methadone prescriptions increased 727%. The increase in the methadone prescription rate was for treatment of pain and not addiction therapy.

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect.

Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone metabolism is complicated and varies among individuals. Methadone interacts with several other medications that can alter its metabolism changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in a patient taking other medications and before starting any medication in a patient taking methadone.

Methadone can prolong the rate-corrected QT interval (QTc) and increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QTc interval, including those with structural cardiac disease, cardiac arrhythmias or cardiac conduction abnormalities and in patients taking another medication associated with QTc interval prolongation (Arizona Center for Education and Research on Therapeutics 2008). A useful on-line reference of such medications is available at: **http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm**

Clinicians should consider obtaining an electrocardiogram (ECG) to evaluate the QTc interval in patients treated with methadone, especially at higher doses. A recently published consensus guideline (Krantz 2009) recommended that an ECG be performed before prescribing methadone, within the first 30 days, and annually. Additional ECG examinations were recommended if the methadone dose exceeds 100 mg per day or if a patient on methadone has unexplained syncope or seizure. Guidance was provided for actions to be taken at two levels of QTc prolongation (450-500 ms and greater than 500 ms).

Methadone and other opioids have been associated with worsening obstructive sleep apnea and new onset of central sleep apnea. Clinicians should question patients about symptoms and signs of sleep apnea and consider obtaining a sleep study in patients treated with opioids if they develop any signs of sleep-disordered breathing or respiratory depression. This is particularly important for patients receiving higher doses of opioid medications. In one recent study, 92% of patients on opioid doses at or above 200 mg morphine equivalents had developed ataxic or irregular breathing (Walker, 2007).

Some clinicians recommend that all patients for whom higher doses of opioid medications are considered should be tested with a sleep study.

Tools to accompany Recommendation 13:

- Dosing Guidelines
- The Role of Methadone in the Management of Chronic Non-Malignant Pain

GLOSSARY

Term	Definition
Aberrant drug-related behavior	A behavior associated with drug abuse, addiction, and diversion.
Abuse	Maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Often with the intent of seeking a psychotropic/euphoric effect.
Acute pain	An episode of pain lasting six weeks or less
Addiction	A primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
Breakthrough pain	An acute worsening of pain in a person with chronic pain.
Chronic pain	An episode of pain lasting more than three months
Chronic non-cancer pain	Chronic pain that is not associated with active cancer or occurs at the end of life
Diversion	The intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution.
Hyperalgesia	Increased or heightened sensation to pain or pain stimulation.
IADL	Instrumental activities of daily living are activities related to independent living and include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, and using a telephone
Misuse	Use of a drug in ways other than prescribed by a health professional. Misuse usually does not include use for euphoric or psychotropic effects—that would be classified as “abuse”

Term	Definition
Physical Dependence	A state of adaptation manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
Pseudo addiction	The development of abuse-like behaviors due to unrelieved pain, and that should be eliminated by measures that relieve the pain.
Trial Period	A period of time during which the effectiveness of using opioids is tested to see if goals of functionality and decreased pain are met. A trial should occur prior to treating someone with long-acting opioids and should include goals. If trial goals are not met, the trial should be discontinued and an alternative approach taken to treating the pain.
Tolerance	A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more opioid effects over time.

Tools

Tools to Use in Evaluating & Monitoring 25

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking Chart
- Sheehan Disability Scale
- Brief Pain Inventory Form
- Sample Treatment Plan for Prescribing Opioids
- SF-12

Tools to Screen for Risk of Complications 37

- COMM
- SOAPP-R
- Opioid Risk Tool
- Urine Drug Testing Devices
- Signs of Substance Misuse
- Checklist for Adverse Effects, Function, and Opioid Dependence

Informational Tools 57

- Federal Guidelines on Proper Disposal of Prescriptions
- Non-Opioid Pain Management Tool
- Absolute Contraindications to Opioid Prescribing
- Strategies for Tapering & Weaning
- Information for Patients—Opioid Analgesics for Non-Cancer Pain
- The Role of Methadone in the Management of Chronic Non-Malignant Pain
- Dosing Guidelines

Utah-Specific Tools 75

- Directory of Resources
- Utah's Tamper Resistant Requirements

For more tools and information visit:

http://prc.coh.org/culture.asp

http://www.PainEdu.org

The tools found in this publication can be downloaded from:

www.health.utah.gov/prescription

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TOOLS

Pain Management and Evaluation Tool

Pain Management Work up and Risk Assessment

Name			ID#		Date
Pain Dxs:					DOB
					Gender M/F

Opiod Risk Tool[1]	**Mark all that apply**	**Score if Female**	**Score if Male**	**Additional Risk Assessments**		**Comments**
				Drug Screen	Y/N	
Family Hx of Substance Abuse				DOPL Screen	Y/N	
Alcohol	[ ]	1	3	Risk of Obstructive Sleep Disorder	Y/N	
Illeg Drugs	[ ]	2	3			
Prescrp	[ ]	4	4			
Personal Hx of Substance Abuse				Obesity Y/N	BMI =	
Alcohol	[ ]	3	3	Hx of Sleep Apnea	Y/N	
Illeg Drugs	[ ]	4	4			
Prescrp	[ ]	5	5			
Hx of Preadolescent Sexual abuse	[ ]	3	0	**Baseline Measures**		**Comments**
				Analgesia[2] (Pain 0-10)		
Age 16-45 yrs	[ ]	1	1	Activity[3] (Function 0-10)		
Depression	[ ]	1	1	Adverse Events	Y/N	
Psychiatric Disease				Aberrant Behavior	Identify	
ADD	[ ]	2	2			
OCD	[ ]	2	2			
Bipolar	[ ]	2	2			
Skiz	[ ]	2	2			
Total	**[ ]**					

Consultation/Referral:				**Comments**
If receiving Morphine equivalent ≥ 120 mg/day				
or Methadone ≥ 50 mg/day	**then**	Sleep Apnea Test	Y/N	
If receiving Methadone ≥ 50 mg	**then**	EKG (Qt)	Y/N	

Treatment agreement discussed and signed by patient **Date**

Patient Goals			Identify aberrant behavior which indicates discontinuation
Analgesia Pain[2] (0-10)	Activity - Function[3] (0-10)	Adverse Events - #	

[1] Opioid Risk Tool (Webster & Dove, 2007 - low risk (routine care), moderate risk (increased monitoring frequency) high risk (consider referral to Substance Abuse and/or Pain Management specialists)

[2] Pain Intensity 0 = no pain, 5 = moderate pain, 10 = worst pain imaginable

[3] Activity Function 0= no limitations, 5 = limitations (difficulty working, lifting,exercising, or conducting daily living activities) 10 = severe limitations (unable to work, conduct daily living activities, lift, or exercise)

Produced by Utah Department of Health, Prescription Pain Medication Program, 2008

Pain Management and Evaluation Tool

Pain Management Follow-Up

Name	ID#	Date
Pain Dxs:		DOB
		Gender M/F

Initation of Trial **Start Date** **Review Date**

Visit Frequency [1] Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation
							Change (Date)

Titration - Visit = 2 - 4 weeks

Visit Frequency [1] Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation
							Change (Date)

Maintenance - Visit = Quarterly

Visit Frequency [1] Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation
							Change (Date)

[1] Webster 2008 Monitoring Frequencies
Low Risk (0-3) Routine
Mod Risk 4-7 Bi-Weekly
High Risk ≥ 8 Weekly

TOOLS

Patient Pain and Medication Tracking Chart

Patient Pain and Medication Tracking Chart

Name	ID#	Date
Pain Dxs:		DOB
		Gender M/F

Directions: At the end of each day use this log to record your function, pain, sleep and alcohol/drug use. This will be used by your provider to properly adjust your medications to obtain optimal benefit and to minimize risk to your health and safety.

Date	Medications	# Pills/day	Pain [1] (0-10)	Function [2] (0-10)	# Hours Slept	Alcohol or Drugs used

[1] Pain Scale: 0 = no pain, 5 = moderate pain, 10 = worst pain imaginable
[2] Function Scale: 0 = no limitations, 5 = limitations (difficulty working, lifting, exercising, or conducting daily living activities, 10 = severe limitations (unable to work, conduct daily living activities, lift or exercise)

Produced by Utah Department of Health, Prescription Pain Medication Program, 2008

Sheehan Disability Scale

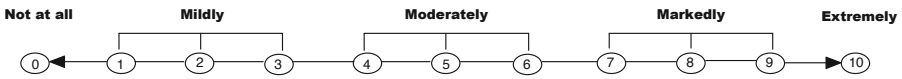
SHEEHAN DISABILITY SCALE

A BRIEF, PATIENT RATED, MEASURE OF DISABILITY AND IMPAIRMENT

Please mark ONE circle for each scale.

WORK* / SCHOOL

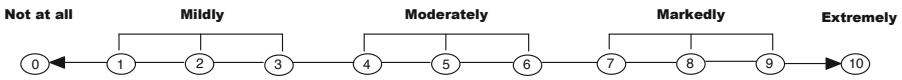
The symptoms have disrupted your work / school work:



☐ I have not worked /studied at all during the past week for reasons unrelated to the disorder.
* Work includes paid, unpaid volunteer work or training

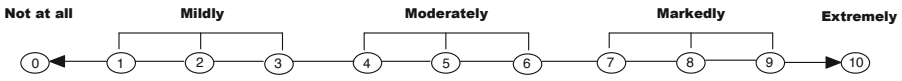
SOCIAL LIFE

The symptoms have disrupted your social life / leisure activities:



FAMILY LIFE / HOME RESPONSIBILITIES

The symptoms have disrupted your family life / home responsibilities:



DAYS LOST

On how many days in the last week did your symptoms cause you to miss school or work or leave you unable to carry out your normal daily responsibilities? _____

DAYS UNDERPRODUCTIVE

On how many days in the last week did you feel so impaired by your symptoms, that even though you went to school or work, your productivity was reduced? _____

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TOOLS

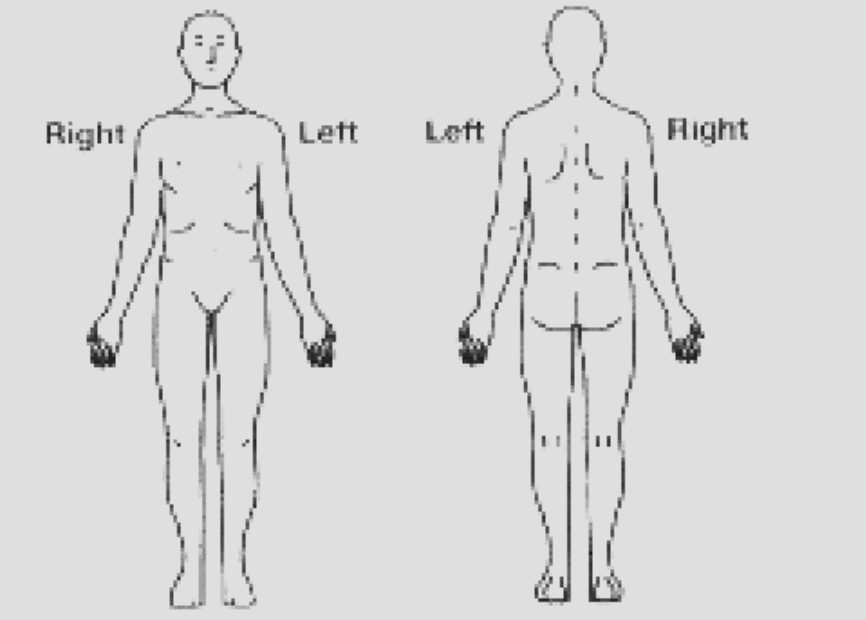
Brief Pain Inventory Form

Brief Pain Inventory (Short Form)©

Study ID#_____ Hospital#_____
Do not write above this line
Date:____/____/____
Time:_____
Name:_____
Last First Middle Initial

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?
1. yes 2. no

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its **WORST** in the past 24 hours.

0 1 2 3 4 5 6 7 8 9 10
No pain — Pain as bad as you can imagine

Brief Pain Inventory Form

4) Please rate your pain by circling the one number that best describes your pain at its **LEAST** in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

5) Please rate your pain by circling the one number that best describes your pain on the **AVERAGE.**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

6) Please rate your pain by circling the one number that tells how much pain you have **RIGHT NOW.**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

7) What treatments or medications are you receiving for your pain?

8) In the past 24 hours, how much **RELIEF** have pain treatments or medications provided? Please circle the one percentage that most shows how much.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No relief										Complete relief

9) Circle the one number that describes how, during the past 24 hours, **PAIN HAS INTERFERED** with your:

A. General Activity:

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Brief Pain Inventory Form

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Used with permission. May be duplicated and used in clinical practice. Source: Dr. Charles Cleeland, Anderson Cancer Center, Pain Research Group, 1100 Holcombe, Houston, TX 77030.

Sample Treatment Plan for Prescribing Opioids

Treatment Plan Using Prescription Opioids

Patient name: _____

Prescriber name: _____

THE PURPOSE OF THIS AGREEMENT IS TO STRUCTURE OUR PLAN TO WORK TOGETHER TO TREAT YOUR CHRONIC PAIN. THIS WILL PROTECT YOUR ACCESS TO CONTROLLED SUBSTANCES AND OUR ABILITY TO PRESCRIBE THEM TO YOU.

I (patient) understand the following (initial each):

_____ Opioids have been prescribed to me on a trial basis. One of the goals of this treatment is to improve my ability to perform various functions, including return to work. If significant demonstrable improvement in my functional capabilities does not result from this trial of treatment, my prescriber may determine to end the trial.

Goal for improved function: _____

_____ Opioids are being prescribed to make my pain tolerable but may not cause it to disappear entirely. If that goal is not reached, my physician may end the trial.

Goal for reduction of pain: _____

_____ Drowsiness and slowed reflexes can be a temporary side effect of opioids, especially during dosage adjustments. If I am experiencing drowsiness while taking opioids, I agree not to drive a vehicle nor perform other tasks that could involve danger to myself or others.

_____ Using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. These symptoms can include: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches and flu-like symptoms. I understand that opioid withdrawal is uncomfortable but not physically life threatening.

_____ There is a risk that opioid addiction can occur. Almost always, this occurs in patients with a personal or family history of other drug or alcohol abuse. If it appears that I may be developing addiction, my physician may determine to end the trial.

Continued on other side.

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Sample Treatment Plan for Prescribing Opioids

I agree to the following (initial each):

_____ I agree not to take more medication than prescribed and not to take doses more frequently than prescribed.

_____ I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged, or stolen medication will not be replaced.

_____ I agree not to share, sell, or in any way provide my medication to any other person.

_____ I agree to obtain prescription medication from one designated licensed pharmacist. I understand that my doctor may check the Utah Controlled Substance Database at any time to check my compliance.

_____ I agree not to seek or obtain **ANY** mood-modifying medication, including pain relievers or tranquilizers from **ANY** other prescriber without first discussing this with my prescriber. If a situation arises in which I have no alternative but to obtain my necessary prescription from another prescriber, I will advise that prescriber of this agreement. I will then immediately advise my prescriber that I obtained a prescription from another prescriber.

_____ I agree to refrain from the use of **ALL** other mood-modifying drugs, including alcohol, unless agreed to by my prescriber. The moderate use of nicotine and caffeine are an exception to this restriction.

_____ I agree to submit to random urine, blood or saliva testing, at my prescriber's request, to verify compliance with this, and to be seen by an addiction specialist if requested.

_____ I agree to attend and participate fully in any other assessments of pain treatment programs which may be recommended by the prescriber at any time.

I understand that ANY deviation from the above agreement may be grounds for the prescriber to stop prescribing opioid therapy at any time.

_____ _____

Patient Signature Date

_____ _____

Prescriber Signature Date

Produced by Utah Department of Health, Prescription Pain Medication Program, 2008

SF-12

Your Health and Well-Being

SAMPLE

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

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(SF12v2 Standard, US Version 2.0)

TOOLS

SF-12

3. During the past 4 weeks, how much of the time have you had any of the result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

SAMPLE

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SF-12

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

SAMPLE

Thank you for completing these questions!

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COMM

The Current Opioid Misuse Measure (COMM)® is a brief paper and pencil self-administered patient questionnaire to help monitor chronic pain patients who are on chronic opioid therapy. The COMM helps clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with the misuse or abuse of opioid medications. Validated in 2006 and unlike other available predictive measures, the objective was to provide clinicians with an assessment tool to periodically monitor misuse of medication for patients who have been prescribed opioids for an extended period of time over the course of treatment. Additionally, the COMM serves as an ideal way to help document risk assessment over the continuum of care with opioid treatment.

The COMM tool, instructions for administration, and scoring information guide are available for download for individual clinician use at http://www.painedu.org/registration.asp?target=terms.

COMM

Current Opioid Misuse Measure (COMM)®

The Current Opioid Misuse Measure (COMM)® is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM is for clinician use only. The tool is not meant for commercial distribution.
- The COMM is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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COMM

Current Opioid Misuse Measure (COMM)®

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

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COMM

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O

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COMM

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

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COMM

Scoring Instructions for the Current Opioid Misuse Measure (COMM)®

To score the COMM, simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
> or = 9	+
< 9	-

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM is at different cutoff values. These values suggest that the COMM is a sensitive test. This confirms that the COMM is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM score (at a cutoff of 9) is over 2 times (2.26 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM score suggests the patient is really at low-risk, while a high COMM score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 9 or above	.77	.66	.66	.95	2.26	.35

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TOOLS

SOAPP-R

The *Screener and Opioid Assessment for Patients with Pain- Revised Version (SOAPP®-R)* is a brief paper and pencil self-administered patient questionnaire that was developed for clinicians to help them better assess and determine how much monitoring a patient on long-term opioid therapy might require prior to prescription. The SOAPP®-R was validated in 2008, and is an updated and revised version of SOAPP V.1 originally released in 2003. The use of opioid medications sometimes includes concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Since long-term opioid therapy may carry significant risk in certain patients, the SOAPP®-R is intended to play a role as a quick and easy-to-use tool that can help clinicians identify and mitigate that risk, document risk assessment prior to opioid prescription.

The SOAPP®-R tool, instructions for administration, and scoring information guide are available for download for individual clinician use at http://www.painedu.org/registration.asp?target=terms.
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SOAPP-R

2007 Release

Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is **NOT** intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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TOOLS

SOAPP-R

SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	○	○	○	○	○
2. How often have you felt a need for higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impatient with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often have you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

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SOAPP-R

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	○	○	○	○	○
14. How often have others told you that you had a bad temper?	○	○	○	○	○
15. How often have you felt consumed by the need to get pain medication?	○	○	○	○	○
16. How often have you run out of pain medication early?	○	○	○	○	○
17. How often have others kept you from getting what you deserve?	○	○	○	○	○
18. How often, in your lifetime, have you had legal problems or been arrested?	○	○	○	○	○
19. How often have you attended an AA or NA meeting?	○	○	○	○	○
20. How often have you been in an argument that was so out of control that someone got hurt?	○	○	○	○	○
21. How often have you been sexually abused?	○	○	○	○	○
22. How often have others suggested that you have a drug or alcohol problem?	○	○	○	○	○
23. How often have you had to borrow pain medications from your family or friends?	○	○	○	○	○
24. How often have you been treated for an alcohol or drug problem?	○	○	○	○	○

Please include any additional information you wish about the above answers.
Thank you.

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SOAPP-R

TOOLS

Scoring Instructions for the SOAPP®-R®

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is nearly 4 times (3.80 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

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SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	3.80	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

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SOAPP-R

How does the SOAPP-R help determine appropriate treatment?
The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater*)

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician' care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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SOAPP-R

Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21*)

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Who is at a low risk for opioid misuse? (SOAPP-R score < 9*)

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

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SOAPP-R

Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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Opioid Risk Tool

Date _____

Patient Name _____

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder Obsessive Compulsive Disorder Bipolar Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
TOTAL		**[ ]**		

Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk $\geq$ 8

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Opioid Risk Tool

Low-risk patients should be monitored at a level that could be described as routing. This does not mean these individuals are not monitored with vigilance and care, only that no extraordinary measures are required.

- Explain the standard treatment agreement; both provider and patient should sign it.
- Schedule regular follow-up visits (monthly at first).
- Set the frequency of medication refills (monthly for the first 6 months).
- Perform initial urine (or other) drug screening.
- Communicate with pharmacies or obtain initial reports from prescription-monitoring programs (where available) and prior medical providers.
- Document every patient and clinician interaction.
- Continually review the Four A's during return visits.
- Consultations with specialists are not required.
- Medication type: adequate analgesia, no restrictions.

Moderate risk for drug abuse calls for another layer of vigilance in addition to the routine monitoring established for low-risk patients:

- Regular follow-up visits and prescriptions refills should occur every 2 weeks initially.
- Observe patients for signs of complicating co morbid diagnoses, such as anxiety, depression, or a sleep disorder.
- Consider referring the patient for evaluation by pain management and psychiatric specialists.
- Conduct regular checks (every 6-12 months) of your state's prescription monitoring database, if available, or consult with the patient's pharmacist.
- Visit with the patient's family members or other third parties to verify the patient's accounts and for evidence of environmental influences.
- Institute random urinalysis (or another screening method) to confirm compliance with medication levels.
- Consider checking leftover medications to verify their quantity.
- Consider limiting the use of rapid-onset analgesics.

High-risk patients require the following measures of intense monitoring in addition to those required by the low-risk and moderate-risk groups:

- Schedule regular follow-up visits more frequently than usual. If problems develop, shorten the treatment interval to weekly.
- Prescribe just enough medication to last until the next appointment and ensure that prescription refills are contingent upon attendance.
- Typically, psychiatric and addiction-medicine consultations are required. Consider consultation with a pain management specialist. Coordinate treatment.
- Conduct regular urine (or other) drug screenings in addition to some unexpected screenings.
- Consider using blood screenings.
- During every visit, count the patient's leftover medication.
- Consult a prescription database (if available) more frequently.
- Strongly enforce the treatment agreement.
- Avoid prescribing rapid-onset analgesics and consider limiting short-acting analgesics.

Webster & Dove, 2007

Opioid Risk Tool

The 3 risk categories help make treatment decisions easier but should not be used to label patients. Remember that the need to monitor for aberrant behavior is ongoing, and patients can move from 1 risk group to another throughout the course of treatment. For example, a patient initially assessed as low risk may later display multiple aberrant behaviors in response to a deteriorating physical condition or life stresses.

In general, exhibiting more than 3 mildly aberrant behaviors during 1 year or exhibiting 1 egregious behavior should cause a patient to move to a higher risk category and to be monitored more closely. If patients remain in the low-risk category for 6 months, the interval between visits and refills of medication can be increased. Eventually, when patients have remained in the low-risk category for 1 year, refills that last for 3 months are common.

Webster & Dove, 2007

Urine Drug Testing Devices

Urine Drug Testing Devices

To the best of our knowledge, this is a comprehensive list of CLIA waived office drug testing devices that test for specific prescription drugs and are under $10.

Test Name	Analytes that are Tested	Approx. Price
Alfa Scientific Designs, Inc. Instant Verdict Multi-Drug of Abuse Urine Test	Methadone, Morphine-Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	$8.50
American Bio Medica Rapid TOX	Buprenorphine, Methadone, Opiates, Oxycodone, Propoxyphene- Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	$4.15
BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)	Methadone, Morphine-Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	$6.80

Search for CLIA approved tests
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm
CLIA waived tests
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm
CLIA waived analytes
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Signs of Substance Misuse

Features of presentation that may alert practitioner to the possibility of substance misuse

- Cutaneous signs of drug abuse - skin tracks and related scars on the neck, axilla, groin, neck, forearm, wrist, foot and ankle. Such marks are usually multiple, hyper-pigmented and linear. New lesions may be inflamed. Shows signs of “pop” scars from subcutaneous injections.
- Being assertive, aggressive or emotionally labile
- Current intoxication/withdrawal
- May show unusual knowledge of controlled substances.
- Gives medical history with textbook symptoms or gives evasive or vague answers to questions regarding medical history.
- Reluctant or unwilling to provide reference information. May have no General Practitioner.
- Will often request a specific controlled drug and is reluctant to try a different drug.
- Generally has no interest in diagnosis - fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation.

British Pain Society, 2007

Checklist for Adverse Effects, Function, and Opioid Dependence

Checklist for adverse effects

- Constipation, sweating, nausea
- Exacerbation of sleep apnea, COPD
- Opioid bowel syndrome
- Rebound headaches
- Fatigue and confusion (particularly in the elderly)
- Reproductive effects (impotence in men and menstrual irregularities in women)
- Sensitization to pain (higher opioid doses may be required in acute pain compared to stable chronic pain)
- Neurotoxicity, seizures and hallucinations (for example with repeated administration of Demerol)

Checklist for function that should be assessed

- Sleep
- Mood
- Libido
- Time out of bed, ability to sit, ability to stand
- Activities within the house and outside (e.g., household chores, shopping, etc.)
- Activities at work (return to work, modified duties, trial employment, etc.)

Checklist for signs of opioid dependence

- On high and escalating doses of opioids
- Frequently runs out of medicine early observed to be intoxicated or in withdrawal
- Alters, borrows, steals, or sells prescriptions
- Accesses multiple sources of opioids, including from ERs, other prescribers, friends, acquaintances, or on the street *
- Injects oral medications
- Threatens or harasses staff to get immediate appointment
- Reluctant to try alternatives
- Angry, demanding, or tearful if not given drug of choice
- Deterioration of functional status while in receipt of opioid
- Concurrent abuse of alcohol or other illicit drugs
- Multiple dose escalations or other noncompliance with therapy despite warnings
- Multiple episodes of prescription loss

College of Physicians and Surgeons of Ontario, 2000

Federal Guidelines on Proper Disposal of Prescriptions

Proper Disposal of Prescription Drugs

Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper **disposal**. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:
Actiq (fentanyl citrate)
Daytrana Transdermal Patch (methylphenidate)
Duragesic Transdermal System (fentanyl)
OxyContin Tablets (oxycodone)
Avinza Capsules (morphine sulfate)
Baraclude Tablets (entecavir)
Reyataz Capsules (atazanavir sulfate)
Tequin Tablets (gatifloxacin)
Zerit for Oral Solution (stavudine)
Meperidine HCl TabletsPercocet (Oxycodone and Acetaminophen)
Xyrem (Sodium Oxybate)
Fentora (fentanyl buccal tablet)
Note: Patients should always refer to printed material accompanying their medication for specific instructions.

Office of National Drug Control Policy
ONDCP, Washington, D.C. 20503p (202) 395-6618 f (202) 395-6730

www.WhiteHouseDrugPolicy.gov

TOOLS

Non-Opioid Pain Management Tool

Area/Type of Pain	Treatment Options (Strongest Recommendations listed first)	When to Initiate	Population	Duration/Indication of Treatment	Cautions/MISC
Back Pain <4 weeks	Directed Exercise Program (1, 2, 3, 4, 5, 6)	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss (2)	Immediately	All ages	Life long	Consider co morbidities
	Ice/Heat (2, 4, 6, 7)	During the first 1-4 days	All ages	Most effective in first 1-3 days	Consider co morbidities
	Acetaminophen up to 4 g/day (1, 2, 4, 6, 8, 9)	Immediately	Adults	Can be long term	Consider co morbidities
	Physical therapy (4, 6, 10, 11)	After 3 weeks of conservative therapy	Adults	1-2 visits	Consider co morbidities
	NSAIDs (2, 4, 6, 9, 12)	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers (4, 9, 13)	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing
	Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Back School (14, 15)	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain.
	Tramadol/acetaminophen (2)	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol (2)	After initial acetaminophen trail	Adults	Can be long term	Consider co morbidities
	Manipulation (1, 4, 6, 16, 17, 18, 19)	Most effective when used for pain <6 weeks of duration without radiculopathy	Adults	3-4 weeks of treatment has been studied. Up to 8 treatments.	Consider co morbidities, not shown to be better than other therapies. Not to be used with herniated disks
Back Pain >4 weeks	Directed Exercise Program (1, 2, 3, 4, 5, 8, 18, 19)	Immediately	Adults	Life Long	Consider co morbidities
	Yoga exercises (viniyoga) (20)	Immediately	Adults	Life Long, studies for 12 weekly sessions	Has been shown to be as or more beneficial than exercise in some studies.
	Controlled Weight Loss (2)	Immediately	Adults	Life Long	Consider co morbidities
	Acetaminophen up to 4 g/day (1, 2, 4, 8)	Immediately	Adults	Can be long term	Consider co morbidities

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Non-Opioid Pain Management Tool

	NSAIDs (2, 4, 12)	Immediately, recommend acetaminophen trial first. Some evidence that NSAIDs are equal with acetaminophen in chronic low back pain (21) Some evidence that it is superior at pain control. (22)	Adults with no CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers (4, 13)	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing, some studies did not show any benefit after 3-4 weeks of injury
	Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and no CV risk factors	Adults with no CV risk factors	Short term	Consider co morbidities, no CV risk factors
	Back School (14, 15, 18)	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain. Swedish Back School program was studied.
	Tricyclic antidepressants (9, 23)	After 3-4 weeks and failing conservative therapy, acetaminophen	Adults	As long as deemed beneficial	Have significant side effects profile, consider co morbidities
	Tramadol/acetaminophen (2)	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol (2)	After failing acetaminophen trial, co administration with acetaminophen has been shown to have more favorable results	Adults	Can be long term	Consider co morbidities
	Injections, epidural/facet joints (24, 25)	After failing conservative treatment	Adults	As long as beneficial, if effective often last 1-4 months in duration, can be used to help diagnosis and evaluate for additional treatment options	Choose population according to guidelines. There are conflicting opinions on efficacy
	Physical Therapy (10, 11)	Recommend starting immediately	Adults	1-2 visits	Consider co morbidities
	Message Therapy (26, 27, 28)	Recommended in conjunction exercise and education	Adults	As long as beneficial has been shown to effective for up to one year, >5 visits shows better results, most studies showed results in 6-10 treatments	Some disagreement in literature, but done by licensed therapist found to be more effective
	Neuroreflexotherapy (29)	Only in Chronic LBP	Adults	Undetermined	Preliminarily this has shown some effect.

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Non-Opioid Pain Management Tool

Non-Opioid Pain Management Tool

Neck Pain	Directed Exercise Program (1, 2, 3, 6, 30)	Within 7-10 days of injury	All ages	Life long	Requires lengthy training of practitioner to be considered effective
	Acetaminophen 4g/day maximum (2, 6, 31)	Immediately	Adults	Can be long term	Consider co morbidities, can add mechanical manipulation to an exercise program
	NSAIDs (6, 12, 31)	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities
	Physical Therapy (6)	After 2 weeks of conservative treatment	Adults	1-2 visits for education, counseling of home exercise	Consider co morbidities, no CV, renal or GI risk factors
	Manipulation (6)	Once more conservative measures fail	Adults	Best when combined with exercise	Consider co morbidities
	IV methylprednisolone (31)	Within 8 hours of injury for acute whiplash	Adults	One time treatment	Consider co morbidities, rare instances of CVA
	IM Lidocaine (31)	Chronic neck pain with arm symptoms	Adults	Only a few treatments indicated	Any contraindications to IV steroids.
	Muscle Relaxers (31)	Immediately	Adults	Short term	Consider co morbidities
	Acupuncture (32)	After failing exercise and/or acetaminophen/NSAIDs	Adults	Ideally 6 or more treatments, effects have been shown for short-term pain relief	Consider co morbidities
Headache	Directed exercise program (33)	Immediately	Adults	When the HA is a result of a mechanical neck disorder	Consider co morbidities
	Acetaminophen 4g/day maximum (34)	Immediately	Adults	Long term, has not been shown to be effective in migraines	Consider co morbidities
	NSAIDS (12, 35, 36)	Immediately	Adults	Short term, shown to be effective in both migraine and non-migraine HAs	Consider co morbidities, not to be used with CV, renal or GI risk factors
	Triptans (36, 37)	Use if unable to control HA with NSAIDs and or acetaminophen	Adults	Beneficial for migraine headaches. IM has been shown to be more effective than oral, but both are superior to placebo. Sumatriptan most studied	Consider co morbidities
	Excedrin (36)	Immediately	Adults	Shown to be beneficial in Acute migraines	Consider co morbidities
	Amitriptyline (35)	Immediately	Adults	Best for migraine headaches, can be started immediately	Monitor for side effects and complications of medication, can cause drowsiness
	Antidepressants (other TCAs, SNRIs,	After failing conservative	Adults	Migraine, tension, and mixed.	Independent of depression,

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Non-Opioid Pain Management Tool

	SSRIs) (38, 39)	therapy		Studies lasted 4-27 weeks	SSRI least effective
	Antiemetics (36)	With migraine associated nausea	Adults	Has been shown to help with pain and nausea with migraines	Consider co morbidities
	Anticonvulsants (40)	After failing other therapies, for prevention	Adults	For prevention of migraine headache	Sodium valproate/divalproex sodium and topiramate are the best studied
	NSAIDS combined with metoclopromide (41)	After failing acetaminophen	Adults	Migraine	Consider co morbidities, metoclopromide can cause dystonia. NNT 3.5
	DHE IM/SC/IV (36)	After failing more conservative therapies	Adults	Have shown to help migraines, more effective in combination with antiemetics	Consider co morbidities
	Isometheptene (36)	After failing more conservative therapies	Adults	Found effective for mild-moderate migraine	Consider co morbidities
	Normal barometric oxygen therapy (42)	Immediately	Adults	For use in Cluster Headaches	Unknown
	TENS (35)	Immediately	Adults	Best for cervical tension headaches, mildly affective in some migraine headaches	Do not use in patients with pacemakers, cardiac conduction abnormalities, or over the carotid body or sinus
	Manipulation (35)	Immediately	Adults	Best for tension, post-traumatic headache. Can be helpful in some migraine headaches	Choose population according to literature
	Acupuncture (43)	As adjuvant treatment	Adults	Shown to be effective for both tension and migraine	Choose population according to literature, not effective for all
Osteoarthritis	Directed Exercise Program (1, 2, 3, 6, 44)	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss (2)	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen 4g/day maximum (2, 8)	Immediately first line	Adults	Can be long term	Consider co morbidities
	NSAIDs (2, 12)	Immediately	Younger adults, without any CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
	Non-acetylated salicylates (2)	Immediately	Adults	Short term	Consider co morbidities, watch for ototoxicity
	Topical capsaicin (2)	Immediately	Adults	Short term	Consider co morbidities
	Intra-articular steroid injection (2, 45)	Immediately	Adults	Can be long term, but if too long can consider joint replacement.	This should be considered first-line therapeutic intervention if OA is confined to a single joint.
	Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and failed Acetaminophen	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors

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Non-Opioid Pain Management Tool

Non-Opioid Pain Management Tool

		therapy			
	Diacerein (46, 47)	After failing other therapies	Adults	Studies lasted 2 months to 3 years	Consider co morbidities, shown to have minimal pain relief
Acute Sports Injury	Ice/Heat (2)	Immediately for first 1-4 days	All ages	For first 1-4 days	Instruct on timing to not cause tissue damage
	Acetaminophen 4g/day maximum (2)	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs (2, 12)	Immediately, recommended to try acetaminophen first	Adults	Short term	Consider co morbidities
Neuropathic Pain	Acetaminophen 4g/day maximum (48)	Immediately	Adults	Can be long term	Consider co morbidities
	Anticonvulsants (49, 50)	After failing acetaminophen	Adults	Can be long term	Have a side effect profile that must be monitored. Carbamezapine and gabapentin found to most effective, some showing crabamezapine to be more effective with lower NNT and higher NNH
	Systemic administration of local anesthetics (51)	After failing acetaminophen	Adults	Undetermined	Can be as effective as anticonvulsants. Monitor for side effects
	Antidepressants (34, 52)	After failing acetaminophen.	Adults	Can be long term, TCAs (amitriptyline) and Venlafaxine shown to be most effective. Not shown to be effective in HIV neuropathies	Monitor for side effects, follow black box warnings. Newer SSRIs have less evidence supporting their use in neuropathic pain
Post-Herpetic Pain	Anticonvulsants (49)	Immediately	Adults	While symptoms last	Can cause drowsiness
Fibromyalgia	Supervised Aerobic/Strength training exercise (53, 54, 55)	Immediately, for at least 20 minutes a day 3 times a week	All ages	Life long, most studies were conducted on average for 12 weeks, 3-24 weeks.	Consider co morbidities
	Cognitive Behavioral Therapy (54, 56)	Immediately	Adults	Data showed results from 6-30 months	Works best as a multidisciplinary approach
	Amitriptyline (54, 57, 58)	Immediately	Adults	While beneficial	Does have side effect profile, tolerance to effect can occur
	Cyclobenzaprine (54, 57)	Typically is after exercise, acetaminophen and amitriptyline	Adults	While beneficial	Significant side effects
	Acupuncture (54, 59, 60)	After exercise and	Adults	While beneficial	Mild/weak evidence

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Non-Opioid Pain Management Tool

		amitriptyline			
	Deep tissue message (54)	Immediately	Adults	While beneficial	Mild/weak evidence
	Fluoxetine (54)	Typically start with exercise, acetaminophen, and amitriptyline first	Adults	While beneficial	Secondary to amitriptyline, can be used in conjunction with tricyclics
	Dual-reuptake inhibitors (SNRIs): (54)	Immediately	Adults	While beneficial	Weaker evidence than previous medications
	Gabapentin (61)	Immediately	Adults	While beneficial, studied over a 12 week period	Consider co morbidities
	Pregabalin (54, 62, 63)	Immediately	Adults	While beneficial	Still under investigation, one study showing positive results
Dental Pain	Acetaminophen (64, 65)	Immediately	All ages	As needed	Consider co morbidities
	NSAIDs (65)	Immediately	Adults	As needed	Consider co morbidities
	Acupuncture (57, 66)	Immediately post-op	Adults	1-4 sessions	
Pelvic Pain (dysmenorrheal)	Directed exercise program (67)	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen (68)	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	NSAIDs (68, 69)	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	Oral contraceptives (70)	Immediately	Adults/Adolescents	While beneficial	Consider co morbidities, can be traditional or extended continuous cycle
	Acupuncture (71)	Immediately	Adults	10 visits over 3 months	Consider co morbidities
	Chinese herbal medication (72)	After other interventions	Adults	While beneficial	Not all interactions known with other medications
Pelvic Pain (chronic pelvic pain)	Directed exercise program (73)	Immediately	All ages	Life long	Consider co morbidities
	Medroxyprogesterone acetate (73)	Immediately	Adults	Not found to be effected after 9 months	Consider co morbidities
	Goserelin (73)	After failing more conservative therapies	Adults	As long as beneficial, cannot be taken longer than six months	Consider co morbidities, extensive side effects
Pelvic Pain (Endometriosis)	Danazol (74)	After failing conservative therapy	Adults	For up to 6 months	Consider co morbidities, extensive side effects
	OCPs (75)	Immediately	Adults	While beneficial	Consider co morbidities
	Goserelin (75)	After failing more conservative therapies	Adults	While beneficial, cannot be taken for longer than six months	Consider co morbidities, extensive side effects

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Absolute Contraindications to Opioid Prescribing

Absolute Contraindications to Opioid Prescribing: Discussion

1. Allergy to opioid agents
Morphine causes the release of histamine, frequently resulting in itching, but this is not an allergic reaction. True allergy to opioid agents (e.g. anaphylaxis) is not common but does occur. Generally, allergy to one opioid agent does not mean the patient is allergic to other opioids; also switching to an agent in another opioid drug class may be effective. For example, if a patient has a hypersensitivity to a phenanthrene, then a diphenylheptane drug may be tried. (See table below.) When patients report an "allergy" to all but one agent (such as meperidine), the presence of a substance use disorder should be considered. Consultation with an allergist may be helpful to resolve these issues.

Classes of Opioid Medications

Phenanthrenes	Diphenyleptanes	Phenylpiperidine
Codeine	Methadone	Fentanyl
Hydrocodone	Propoxyphene	Meperidine
Hydromorphone		
Levorphanol		
Morphine		**Other**
Oxycodone		Tramadol

[a] Meperidine is not recommended for chronic pain because of the potential for accumulation of the neurotoxic metabolite, normeperidine, and a potentially fatal drug interaction with monoamine oxidase inhibitors (MAOIs).

2. Co-administration of a drug capable of inducing life limiting drug-drug interaction
Providers should carefully evaluate potential drug interactions prior to initiating opioid therapy, (such as MAOI with concurrent meperidine use, or propoxyphene and alcohol and other CNS depressants). (Note: meperidine is not recommended for chronic pain because of this potentially fatal drug interaction and the potential for accumulation of the neurotoxic metabolite, normeperidine, with regular dosing.)

3. Active diversion of controlled substances
Diversion should be suspected when there are frequent requests for early refills, atypically large quantities are required, when purposeful misrepresentation of the pain disorder is suspected, or when a urine drug screen (UDS) is negative for the substance being prescribed, in the absence of withdrawal symptoms. Routine UDS often does not detect synthetic and semi-synthetic opioids (methadone, oxycodone, fentanyl, hydrocodone, meperidine or hydromorphone). Verified diversion is a crime and constitutes a strong contraindication to prescribing additional medications, and consultation with a pain specialist, psychiatrist, or addiction specialist may be warranted.

Strategies for Tapering & Weaning

Strategies for tapering:

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

Recognizing and managing behavioral issues during opioid weaning:

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation (“You are indifferent to my suffering”)
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary.

TOOLS

Washington State Agency Medical Directors’ Group, 2007

Information for Patients—Opioid Analgesics for Non-Cancer Pain

Photocopy for use by clinician

Information for Patients - Opioid (Narcotic) Analgesics for Non-Cancer Pain

FOR:

FROM: **Dr.**

DATE:

Making Pain Tolerable

The main reason for using an opioid (narcotic) analgesic for chronic non-cancer pain is to make the pain tolerable - not to eliminate it. This treatment is usually only considered after more standard treatments such as anti-inflammatory drugs have failed. If you are agreeable, your physician will prescribe an opioid analgesic for you in gradually increasing doses to minimize side effects. It is extremely important that you follow the directions exactly. Your physician will be the only one prescribing this medication to you. If you increase the dose without your physician's permission, give the medication to another person or obtain this medication from another physician without the consent of your primary physician, the physician may stop prescribing the opioid analgesic for you.

Pain medication is only part of your chronic pain treatment program. Equally important is a gradual exercise program that will increase your activity level despite ongoing pain. You and your physician should agree on specific ongoing treatment goals.

What is My Risk of Addiction?

There is increasing scientific evidence that strong painkillers can relieve some pain in selected patients without causing addiction. It is important to be careful, however, when defining what "addiction" is. Addiction, or psychological dependence, is a pattern of drug use in which the patient craves a drug for its ability to produce a "high" rather than for its pain-relieving properties. This can lead to the selling and injection of drugs and attempts to obtain drugs from multiple physicians - activities generally referred to as "drug abuse". Studies have shown that if a person has no past history of drug abuse and the pain is physical in origin, the risk of addiction is extremely low. If you are placed on an opioid analgesic for a period of weeks, however, and then are suddenly taken off the medication, it is possible to experience a short withdrawal reaction. Although this can be prevented by withdrawing the drug slowly, it does not mean that you have developed a craving for the drug or developed a drug addiction.

Information for Patients—Opioid Analgesics for Non-Cancer Pain

What are the Side Effects?

Although opioid analgesics can produce side effects (drowsiness, confusion, nausea, constipation), these can be minimized by slowly increasing the dose of the drug and by using anti-nausea drugs and bowel stimulants. Pain medication as prescribed will not depress your respiration or prevent you from breathing normally.

Remember Your Follow-up

If you seem to benefit from the pain medications, your physician will see you about every 4 to 6 weeks for the first few months and about every two to three months thereafter. During each visit, you and your physician will assess pain relief, any side effects from the pain medication and your ability to meet your established activity goals.

Other Instructions:

_____

_____

_____

The Role of Methadone in the Management of Chronic Non-Malignant Pain

The Role of Methadone in the Management of Chronic Non-Malignant Pain: Specific Considerations

Overview

Although the literature on methadone for non-malignant pain is scanty and based on case studies, the increasing use of methadone for this purpose requires recommendations to guide practice. There is extensive literature on the use of methadone as a potent analgesic agent for cancer pain and therefore recommendations for the use of methadone in the management of chronic non-malignant pain must be extrapolated from the cancer pain literature.

Methadone is a synthetic opioid analgesic with excellent oral bioavailability, a side effect profile similar to other opioid analgesics and a duration of action of at least eight hours with repetitive dosing. These qualities make it an attractive drug for outpatient pain management. Methadone also has an opioid receptor profile different from that of morphine and has N-methyl-D-aspartate (NMDA) antagonist activity that may confer advantages over morphine. However, experience in the use of methadone for cancer pain has revealed that methadone is far more potent as an analgesic agent than has been suggested by equianalgesic tables derived from single dose studies. With repetitive dosing, methadone is approximately ten times more potent than indicated in these standard tables. The main reason for this is probably the long elimination half-life of methadone (24-36 hours) which allows for much higher drug levels to be reached than could be predicted from single dose studies. This has obvious clinical implications since methadone takes 5-7 days to reach steady state at any particular dose. Therefore, the use of methadone as an analgesic agent requires the same pain assessment skills as for any other opioid drug, but even greater scrutiny in patient monitoring of analgesic and side effects.

Methadone use in the Management of Chronic Non-Malignant Pain

In Canada, methadone is available at low cost as an elixir which is usually made up at a concentration of 1 mg/ml. In opioid-naive patients or patients taking codeine preparations, methadone 2.5 mg q8h is safe and usually well-tolerated. For patients already on a major opioid analgesic like oxycodone or morphine, a reasonable starting dose of methadone is 5 mg q8h with dose increments of 5 mg q8h every 5-7 days. A general rule is to provide careful dose titration until adequate pain relief is achieved or side effects limit further dose escalation. However, one should look for a graded analgesic response to incremental dosing. The absence of a graded analgesic response may mean that the patient is not

The Role of Methadone in the Management of Chronic Non-Malignant Pain

'opioid-responsive. Patients should be seen weekly during the titration phase and every month or two during the maintenance phase.

For patients being switched from relatively large doses of an opioid analgesic (> 200 mg oral morphine or morphine equivalents daily), the table below should be used to calculate equianalgesic doses. For patients taking more than 500 mg oral morphine or morphine equivalents daily, the conversion to methadone should be staged with a third of the anticipated methadone dose being introduced every five days so that the entire conversion takes fifteen days. The dose of the previous opioid is decreased by a third every five days in inverse fashion.

Equianalgesic Doses of Common Opioid Analgesics Relative to Oral Methadone with Repetitive Dosing

Drug	Per Os (PO)	Intramuscular/Subcutaneous
Methadone	2 mg	
Morphine	30 mg	10 mg
Hydromorphone	8 mg	2 mg
Oxycodone	15 mg	

Patients and co-habitants should be warned about potential side effects (especially drowsiness and respiratory depression) and the possibility that side effects can continue to evolve for five to seven days after each dose adjustment. The spouse or significant other should be available at least twice daily to monitor for toxicity. Since drowsiness commonly precedes respiratory depression, they should be instructed to call the prescribing physician if drowsiness develops to obtain advice about further dosing. This obviously requires physician availability 24 hours a day during the titration phase. Elderly patients (over the age of 65), patients with severe lung disease and patients who cannot be adequately monitored at home should be considered for inpatient initiation of methadone treatment.

Note: *The CPSO involvement in the opioid dependence program mentioned is unrelated to the use of Methadone for analgesic purposes. If a physician wishes to obtain a permit to prescribe Methadone for analgesic purposes, he or she needs to apply to the* ***Office of Controlled Substances in Ottawa (613) 946-5139***

Dosing Guidelines

Starting Methadone Dose

Morphine Equivalent	Healthy adult <70 yrs	Adult w/ chronic illness or >70 yrs
Opioid naïve	5mg tid	2.5 mg bid
60 mg - 100 mg	5 mg tid	5 mg bid
>100mg	5 mg qid	5 mg bid

*Webster, 2005

MED for Selected Opioids

Opioid	Approximate Equianalgesic Dose (oral & transdermal)*
Morphine (reference)	30mg
Codeine	200mg
Fentanyl transdermal	12.5mcg/hr
Hydrocodone	30mg
Hydromorphone	7.5mg
Oxycodone	20mg
Oxymorphone	10mg

*Adapted from Washington 2007 Guidelines

Dosing Threshold for Selected Opioids*

Opioid	Recommended dose threshold for pain consult (not Equianalgesic)	Recommended starting dose for opioid-naïve patients	Considerations
Codeine	800mg per 24 hours	30mg q 4-6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Fentanyl Transdermal	50mcg/hour (q 72 hr)		Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer
Hydrocodone	30mg per 24 hours	5-10mg q 4-6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Hydromorphone	30mg per 24 hours	2mg q 4-6 hours	

*the Utah guidelines do not specifically recommend a pain consult

Dosing Guidelines

Opioid	Recommended dose threshold for pain consult (not Equianalgesic)	Recommended starting dose for opioid-naïve patients	Considerations
Methadone**	*See table above*		Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids.
Morphine	120mg per 24 hours	Immediate- release: 10mg q 4 hours Sustained-release: 15mg q 12 hours	Adjust dose for renal impairment.
Oxycodone	80mg per 24 hours	Immediate-release: 5 mg q 4-6 hours Sustained-release: 10mg q 12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Oxymorphone	40mg per 24 hours	Immediate-release: 5-10mg q 4-6 hours	Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol

*the Utah guidelines do not specifically recommend a pain consult

Acetaminophen warning with combination products

Hepatotoxicity can result from prolonged use or doses in excess of recommended maximum total daily dose of acetaminophen including over-the-counter products.

- Short-term use (<10 days) – 4000 mg/day
- Long-term use – 2500mg/day

Key considerations in dosing long acting opioids

- Monitoring for adequate analgesia and use of "rescue" medications (at least until the long-acting opioid dose is stabilized). All new dosage calculations should include consideration for concurrent utilization of short-acting opioids.
- If the patient is more debilitated, frail and/or has significant metabolic impairments (e.g. renal or hepatic dysfunction), consider starting at the lower end of the conversion dose range.
- Always monitor for adverse effects (nausea, constipation, over-sedation, itching, etc.)

Equianalgesic dose table for converting opioid doses

All conversions between opioids are estimates generally based on "equianalgesic dosing" or ED. Patient variability in response to these EDs can be large, due primarily to genetic factors and incomplete cross-tolerance. **It is recommended that, after calculating the appropriate conversion dose, it be reduced by 25–50% to assure patient safety.**

Directory of Resources

Utah Directory of Resources

Consultation and Referral

Identifying Pain Management, Mental Health, and Substance Abuse Providers

1) The 211 Information and Referral Bank
http://www.informationandreferral.org
The 211 Info Bank strives to ease the process of locating available and appropriate resources.

2) Utah Cares: State Online Services
https://utahcares.utah.gov/erepucpub/en/ServiceSupplier_searchPage.do?__o3rpu=ScreenReferralHomePage.do
This site allows you to do a search on providers by type and county.

3) Utah Resources Hotline: 2-1-1
Dial 2-1-1 and someone can direct you to providers by specialty in any county in Utah.

4) Utah Medicaid Pain Management Providers
http://health.utah.gov/medicaid/pharmacy/documents/chronic.php

5) Utah Mental health providers
http://mentalhealth.samhsa.gov/databases/facility-search.aspx?state=UT&fullname=Utah

6) Substance Abuse Providers
http://www.dsamh.utah.gov/locationsmap.htm
This link allows you to seek providers by location using an interactive map.

Referral Services

8) Substance Abuse Hotline: 1-866-633-HOPE (4673)

5) Utah Medicaid Restriction Program
http://health.utah.gov/medicaid/pharmacy/Restriction/restriction.php

9) University of Utah Assessment & Referral Services
Assessment & Referral Services is a University of Utah Clinic within the Department of Psychiatry that provides high-quality, objective substance abuse assessments and referrals for individuals with possible substance abuse problems.

Laws Governing Use of Controlled Substances

Federal/DEA laws – www.dea.gov

1) Practitioner Manual
http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf
This manual has been prepared by the Drug Enforcement Administration to assist practitioners and other registrants authorized to prescribe, dispense, and

Directory of Resources

administer controlled substances. A summary of the act can be found below in Appendix C.

2) Schedules of Controlled Substances
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr1308_01.html
Schedules of controlled substances can be found in Title 21, Chapter II.

3) Prescriptions
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr1306_01.html
Contains the rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829)

4) Administering and Dispensing of Controlled Substances
http://edocket.access.gpo.gov/cfr_2001/aprqtr/pdf/21cfr1306.07.pdf
Persons who are entitled to fill prescriptions are described in this document found at the link above.

State of Utah Laws – State legislation and regulations

1) Utah Medical Practice Act Rules
http://www.dopl.utah.gov/laws/R156-67.pdf

2) Utah Controlled Substance Act 58-37
http://www.dopl.utah.gov/laws/58-37.pdf

3) Utah Controlled Substance Rules R156-37
http://www.dopl.utah.gov/laws/R156-37.pdf

4) Reporting Prescription Fraud and/or Prescription Related Crime
http://www.urxnet.org/ or http://www.urxnet.org/tip/addtip.asp

5) Division of Occupational and Professional Licensure
http://dopl.utah.gov/

6) Utah Controlled Substance Database
https://csdb.utah.gov/

7) Model Policy for the Use of Controlled Substances for the Treatment of Pain—Federation of State Medical Boards
http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf
The Model Policy, which was adopted by the Utah Medical Board of Examiners, is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision making.

*If there are legal or workplace concerns, it is recommended that patients go to the industrial clinic

Utah's Tamper Resistant Requirements

Tamper Resistant Prescription Pad/Paper Mandate
Effective April 1, 2008

Effective April 1, 2008, all non-electronic prescriptions must be written on tamper-resistant pads/paper in order to be eligible for reimbursement by Medicaid. The tamper resistant prescription pads/paper requirement applies to all outpatient drugs, including over-the-counter drugs. It also applies whether DOM is the primary or secondary payer of the prescription being filled. This new provision impacts all DOM prescribers: physicians, dentists, optometrists, nurse practitioners and other providers who prescribe outpatient drugs.

The Centers for Medicare & Medicaid Services (CMS) has issued guidance to the States in implementing the new federal requirement. This guidance allows for compliance with the tamper-resistant prescription pad/paper requirement to occur in two phases. For the first phase, a prescription must contain at least one of the three features outlined below by April 1, 2008, in order to be considered "tamper-resistant." All three features are required on the prescription pads by October 1, 2008.

DOM encourages providers to implement all security features by April 1, 2008 to be in compliance with all program requirements. Note that computer generated prescriptions are not exempt from the CMS mandate.

The features listed below are recommended as best practice tamper resistant features by a national taskforce including representatives from CMS, State Medicaid agencies, and national medical and pharmacy organizations. Features listed in bold tend to be less costly and easier for prescribers to implement.

Category 1 – One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.	
Feature	**Description**
"Void" or "Illegal" Pantograph	**The word "Void" appears when the prescription is photocopied. Due to the word "Void" on faxed prescriptions, this feature requires the pharmacy to document if the prescription was faxed.**
Reverse "RX" or White Area on prescription	"Rx" symbol or white area disappears when photocopied at light setting. This feature is normally paired with the "Void" pantograph to prohibit copying on a light setting.
Coin-reactive ink	Ink that changes color when rubbed by a coin – Can be expensive and is not recommended.
Security Back print	Printed on the back of prescription form. The most popular wording for the security back print is "Security Prescription" or the security back print can include the states name.
Watermarking (forderiner)	Special paper containing "watermarking".
Diagonal lines (patented "Void")	Diagonal lines with the word "void" or "copy". Can be distracting or expensive.
Micro printing	Very small font writing, perhaps acting as a signature line. This is difficult to photocopy and difficult to implement if using computer printer. It is also difficult for a pharmacist to see.

Utah's Tamper Resistant Requirements

Category 2 - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.	
Feature	**Description**
Uniform non-white background color	**Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase or copy, the consistent background color will look altered and show the color of the underlying paper.**
Quantity check off boxes	**In addition to the written quantity on the prescription, Quantities are indicated in ranges. It is recommended that ranges be 25's with the highest being "151 and over". The range box corresponding to the quantity prescribed MUST be checked for the prescription to be valid. See illustration in Appendix 1.**
Refill Indicator (circle or check number of refills or "NR")	**Indicates the number of refills on the prescription. Refill number must be used to be a valid prescription.**
Pre-print "Rx is void if more than___ Rx's on paper" on prescription paper	**Reduces the ability to add medications to the prescription. - Line must be completed for this feature to be valid. Computer printer paper can accommodate this feature by printing "This space intentionally left blank" in an empty space or quadrant.**
Quantity Border and Fill (for computer generated prescriptions on paper only)	**Quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional)**
Refill Border and Fill (for computer generated prescriptions on paper only)	**Refill quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **5** Value may also be expressed as text, e.g. (FIVE), (optional)**
Chemically reactive paper	**If exposed to chemical solvents, oxidants, acids, or alkalis to alter, the prescription paper will react and leave a mark visible to the pharmacist.**
Paper toner fuser	Special printer toner that establishes strong bond to prescription paper and is difficult to tamper.
Safety or security paper with colored pattern	White (or some other color) mark appears when erased. This is expensive paper.

Category 3 – One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.	
Feature	**Description**
Security features and descriptions listed on prescriptions	**Complete list of the security features on the prescription paper for compliance purposes. This is strongly recommended to aid pharmacists in identification of features implemented on prescription.**
Encoding techniques (bar codes)	Bar codes on prescription. Serial number or Batch number is encoded in a bar code.
Logos	Sometimes used as part of the background color or pantograph.
Metal stripe security	Metal stripe on paper, difficult to counterfeit.
Heat sensing imprint	By touching the imprint or design, the imprint will disappear.
Invisible fluorescent fibers/ink	*Visible only under black light.*
Thermo chromic ink	*Ink changes color with temperature change. This is expensive paper and problematic for storage in areas not climate controlled.*
Holograms that interfere with photocopying	*May interfere with photocopying or scanning.*

Utah's Tamper Resistant Requirements

Per CMS guidance, pharmacies that are presented with a prescription on a non-tamper-resistant prescription pad/paper may satisfy the federal requirement by calling the provider's office and verbally confirming the prescription with the physician or prescriber. The pharmacy shall document through placement on the original non-compliant prescription form that such communication and confirmation has taken place.

Prescriptions that the federal requirement does not apply to:

- E-prescriptions transmitted to the pharmacy;
- Prescriptions faxed to the pharmacy;
- Prescriptions communicated to the pharmacy by telephone by a prescriber;
- Transfer of a prescription between two pharmacies, provided that the receiving pharmacy is able to confirm by facsimile or phone call the authenticity of the tamper-resistant prescription with the original pharmacy;
- Written orders prepared in an institutional setting (which include Intermediate Care Facilities and Nursing Facilities), provided that the beneficiary never has the opportunity to handle the written order and the order is given by licensed staff directly to the dispensing pharmacy;
- Drugs dispensed or administered directly to the beneficiary in the physician's office or clinic;
- Written prescriptions dispensed to MS Medicaid beneficiaries s who become retroactively eligible after April 1, 2008, provided the prescription was filled on or after April 1, 2008, and before the beneficiary became retroactively eligible for MS Medicaid;
- Emergency fills, provided that the prescriber provides a verbal, faxed, electronic or compliant written prescription within 72 hours;
- Refills of written prescriptions presented at a pharmacy before April 1, 2008;
- Written prescriptions paid for by Medicare, a Medicare Part D plan or Medicare Advantage Plan, unless MS Medicaid fee-for-service is a secondary payer. Part D excluded drugs paid for by Medicaid must be executed on tamper-resistant pad/paper[1].

[1] Prescriber may not know when Medicaid is the primary or secondary payer for MS Medicaid beneficiaries; therefore, the Division of Medicaid (DOM) recommends that prescribers use tamper-resistant prescription pads/paper for all DOM beneficiaries.

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1. Department of Veterans Affairs, Department of Defense. (2003). *VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain.*

2. College of Physicians and Surgeons of Ontario. (2000). *Evidence-based recommendations for medical management of chronic non-malignant pain.*

3. American College of Occupational and Environmental Medicine's Occupation Medicine Practice Guidelines. (2008).

4. *Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines.* (2008).

5. Washington State Agency Medical Directors' Group. (2007). *Interagency guideline on opioid dosing for chronic non-cancer pain: An educational pilot to improve care and safety with opioid treatment.*

6. Federation of State Medical Boards of the United States, Inc. (2004). *Model policy for the use of controlled substances for the treatment of pain.*

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Appendix A: Guideline Rating Scale

10/10	• Extremely explicit evidence-based guidelines The "gold standard" • Evidence has been analyzed thoroughly through an explicit rating system • Recommendations are based on the evidence with the highest rating of quality • Expert consensus creates the recommendations, • Recommendations verified through a peer review
9/10	• Very explicit evidence-based guidelines • Evidence has been analyzed thoroughly through an explicit rating system • Recommendations are based on the evidence with the highest rating of quality • Expert consensus creates the recommendations
8/1	• Explicit evidence-based guidelines • Evidence has been analyzed thoroughly through an explicit rating system • Expert consensus
7/10	• Evidence-based guidelines • No record of the evidence from which the guidelines have been created is present • No rating system of the evidence is present either
6/10	• Evidence-based guidelines • Limited details to how they were created • No record of the evidence from which the guidelines have been created is present • No rating system of the evidence is present either
5/10	• Expert consensus statement only • Very detailed explanation of how the consensus was formed • Reviewed thoroughly by pain experts
4/10	• Expert consensus statement only • Detailed explanation of how the consensus was formed
3/10	• Expert consensus statement only • Little explanation of how the consensus was reached
2/10	• Expert consensus statement only • No explanation of how the consensus was reached
1/10	• No explanation of how guidelines were created

Utah Department of Health
PO Box 142104
Salt Lake City, Utah 84114
(801) 538-6191

To order, email requests to:
useonlyasdirected@utah.gov

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2017 Proposed Delegated Authorities

Proposed Authorities Delegated to the Monitoring Liaison

1. Accept Respondent's written request to surrender credential. If accepted by the Liaison, Monitor will consult with Board Counsel to determine if a stipulation is necessary. If a stipulation is not necessary, Monitor will draft an order and sign on behalf of the Liaison. If denied by the Liaison, the request to surrender credential will go to the full Board for review.

2. Grant Respondent's petition for a reduction in drug screens per the standard schedule, below. If approved, Monitor will draft an order and sign on behalf of the Liaison.

    a. Year 1: 49 screens (including 1 hair test, if required by original order)
    b. Year 2: 36 screens (plus 1 hair test, if required by original order)
    c. Year 3: 28 screens plus 1 hair test
    d. Year 4: 28 screens plus 1 hair test
    e. Year 5: 14 screens plus 1 hair test

Proposed Authorities Delegated to the Department Monitor

1. Suspend the license (or remove stay of suspension) if Respondent fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if Respondent ceases participation in the Approved Program without Board approval. *This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.*

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:	2) Date When Request Submitted:
Association of Regulatory Boards of Optometry	1/12/2017
	Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Optometry Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
2/16/2017	☒ Yes ☐ No	Advocacy Talking Points from the Federations of Associations of Regulatory Boards (FARB)

7) Place Item in:	8) Is an appearance before the Board being scheduled?	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	N/A

10) Describe the issue and action that should be addressed:

Review of Federations of Associations of Regulatory Boards talking points with Board review for comment.

11) Authorization

Signature of person making this request — Date

Supervisor (if required) — Date

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — Date

Directions for including supporting documents:

1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Dear FARB Governing Members:

On behalf of the Federation of Associations of Regulatory Boards (FARB), attached please find the newly created FARB Talking Points, a document originating with the FARB Advocacy Committee. The FARB Talking Points are a series of summarizations that address important aspects of the state-based regulatory structures and systems. They are categorized under four (4) topics as follows:

Effective State Regulation
Board Composition
Deregulation of Professions
Active State Supervision

The FARB Talking Points are a resource to FARB Governing Members and their state licensing boards when engaging in discussions and debates with legislators and other stakeholders about the regulatory community. FARB will continue its efforts to address questions and issues as they surface but, more importantly, FARB looks to be a proactive voice for common sense regulation. We welcome any comments or feedback on these Talking Points and any other initiatives that proactively address regulatory issues and the public served.

As a FARB Governing Member, we ask that you consider disseminating this email and attachment to your member state licensing boards and their board members and administrative staff as a means to identify, outline, and support state-based, common sense regulation of the occupations and professions. Recipients are encouraged to review the attachment and anticipate additional scrutiny on the regulatory structures and systems. The FARB Talking Points can assist in a clear, uniform message to relevant stakeholders and decision makers.

Dale Atkinson
Executive Director
General Counsel

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Advocacy Talking Points

The Federation of Associations of Regulatory Boards (FARB) has developed a series of resource documents regarding the regulation of licensed professionals. These documents address common sense regulation and promote efficient and effective state licensing boards. These talking points will assist state licensing boards in their discussions with legislators and other stakeholders and are categorized as follows:

1. **Effective State Regulation** – Statements supporting the regulation of licensed professionals through a state Board responsible for administering the practice/title act and associated state laws.

2. **Board Composition** – Statements that identify the issues surrounding the composition of state licensing boards and the important role played by all volunteer board members, including active licensees and public representatives.

3. **Deregulation of Professions** – Statements outlining many of the issues that can arise when a profession is deregulated or monitored by a voluntary, private sector certification program.

4. **Active State Supervision** – Statements that identify some of the issues surrounding various proposed options to implement additional oversight over decisions made by state licensing boards.

The Federation of Associations of Regulatory Boards (FARB) promotes common sense regulation through efficient and effective state-based licensure of professions. FARB supports state licensing boards which provide essential health, safety, and welfare protections of the public through the enforcement of applicable statutes and regulations.

Effective State Regulation

- The constitutional rights of the states to regulate the professions in the interest of the protection of the health, safety, and welfare of the public should be recognized and respected.
- Common sense state regulation of the professions through legislatively enacted statutes that create and delegate authority to the state licensing board should be recognized and respected.
- State statutes should establish the standards and criteria necessary for licensure and enforcement.
- The state licensing board appointment process should include reasoned policies and procedures regarding the nomination, evaluation, appointment, and oversight of board members to ensure an understanding of their regulatory obligations.
- Recognition of the need for professional expertise on the licensing boards is essential to effectively and efficiently fulfill their mandate to protect the public.
- Comprehensive training ensures that board appointees clearly understand and adhere to their public protection roles and responsibilities in regulating the profession.

The Federation of Associations of Regulatory Boards (FARB) promotes common sense regulation through efficient and effective state-based licensure of professions. FARB supports state licensing boards which provide essential health, safety, and welfare protections of the public through the enforcement of applicable statutes and regulations.

Board Composition

- A well-structured state licensing board is comprised of active licensed practitioners, public members, experienced administrative staff, and legal counsel.
- Volunteer active licensed practitioners provide the board with subject matter expertise that contributes to the effectiveness and efficiencies in fulfilling the legislative mandates.
- Public members provide the balance of perspectives that contribute to the effectiveness and efficiencies in fulfilling the legislative mandates.
- This balance of representation provides much needed expertise and consumer perspectives and allows for informed decisions in the interest of the health, safety and welfare of the public.
- Informed, efficient decisions involve board operations and meetings, legislative interpretation, rulemaking, assessment of complaints and investigations, administrative proceedings, and defense of decisions.
- A well-structured state licensing board provides fiscal accountability and operational benefits by diminishing the need for paid subject matter experts necessary to conduct investigations, provide opinions, and assist in resolving practice-related questions.
- A well-structured state licensing board ensures that board decisions are consistent, fair, comply with applicable due process requirements, and promote deference to the board decisions by the judiciary when challenges and appeals are filed.

The Federation of Associations of Regulatory Boards (FARB) promotes common sense regulation through efficient and effective state-based licensure of professions. FARB supports state licensing boards which provide essential health, safety, and welfare protections of the public through the enforcement of applicable statutes and regulations.

Deregulation of Professions

- Regulation of the professions provides inherent fairness through a regulatory process for the benefit of consumers, applicants for licensure, licensees, and complainants by promulgation of and adherence to administrative procedures and due process principles.
- Regulation of the professions provides a mechanism for protection of the public as a whole, a benefit not realized by a “buyer beware” approach to consumer protection.
- A “buyer beware” approach to regulation only affects the parties to the dispute to the detriment of the public as a whole and does not deter future misconduct on the part of the licensee.
- Deregulation of the professions eliminates the abilities of government to act on behalf of the public and places enforcement and protection burdens on the consumers.
- Deregulation disadvantages consumers otherwise unable to protect themselves from unqualified practitioners based upon economic factors and lack of knowledge regarding the profession.
- Deregulation in deference to private sector certification programs displaces government involvement at the expense of due process and administrative procedures not mandated upon the private sector.
- Deregulation in deference to private sector certification may unlawfully empower a private sector organization to act on behalf of the state.
- Deregulation in deference to voluntary regulation of a profession creates a tiered licensure structure that may be applied inconsistently and will be confusing to the public.

The Federation of Associations of Regulatory Boards (FARB) promotes common sense regulation through efficient and effective state-based licensure of professions. FARB supports state licensing boards which provide essential health, safety, and welfare protections of the public through the enforcement of applicable statutes and regulations.

Active State Supervision

- To rely on the state action immunity doctrine defense as a shield to antitrust allegations, state boards comprised of active licensed practitioners must operate under active state supervision.
- Relatively few board activities, such as individual disciplinary actions, implicate the antitrust laws.
- Boards are represented by attorneys, usually from the attorney general's office, which consider and advise the board regarding activities and decision making.
- Active state supervision is a fact-specific determination and supervision can exist in numerous forms, such as attorney general representation, executive branch appointment, training of board members, and legislative mandates in statutes.
- Active state supervision through the creation of additional agencies removes the expertise necessary to assess and determine factual findings specific to the profession and may also result in decisions that are more likely susceptible to legal challenge on appeal.
- Active state supervision through the creation of additional agencies adds redundancy, slows the decision making process, and contributes to the inefficient use of government resources.
- Alternative options exist whereby the board can request legislative changes, promulgate regulations, and/or seek declaratory rulings from the judicial branch.

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Laura Smith		2) Date When Request Submitted: 01/20/2017 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting
3) Name of Board, Committee, Council, Sections: Optometry Examining Board		
4) Meeting Date: 02/16/2017	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Association of Regulatory Boards of Optometry Annual Meeting – June 18-20, 2017 in Washington, D.C. – Board Consideration of Attendance and Scholarship Offer
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? ☐ Yes (Fill out Board Appearance Request) ☒ No	9) Name of Case Advisor(s), if required: N/A
10) Describe the issue and action that should be addressed: Nomination of one Board member or staff to receive scholarship to Annual meeting, accommodations and travel. Designate a member to submit a letter of nomination to the Association of Regulatory Boards of Optometry.		
11) Authorization Signature of person making this request — Date Supervisor (if required) — Date Executive Director signature (indicates approval to add post agenda deadline item to agenda) — Date		
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.		

Revised 12/2016

ARBO
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Association of Regulatory Boards of Optometry

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John D. Robinson Founder's Scholarship

ARBO has established the Founder's Scholarship in honor of Dr. John D. Robinson, former member of the Board of Directors, long-time Secretary, and ARBO Life Member. The scholarship will be given to one person each year from an active ARBO member board who demonstrates the same passion and vision for the regulation of optometry that Dr. Robinson exemplified.

Founder's Scholarship Details:

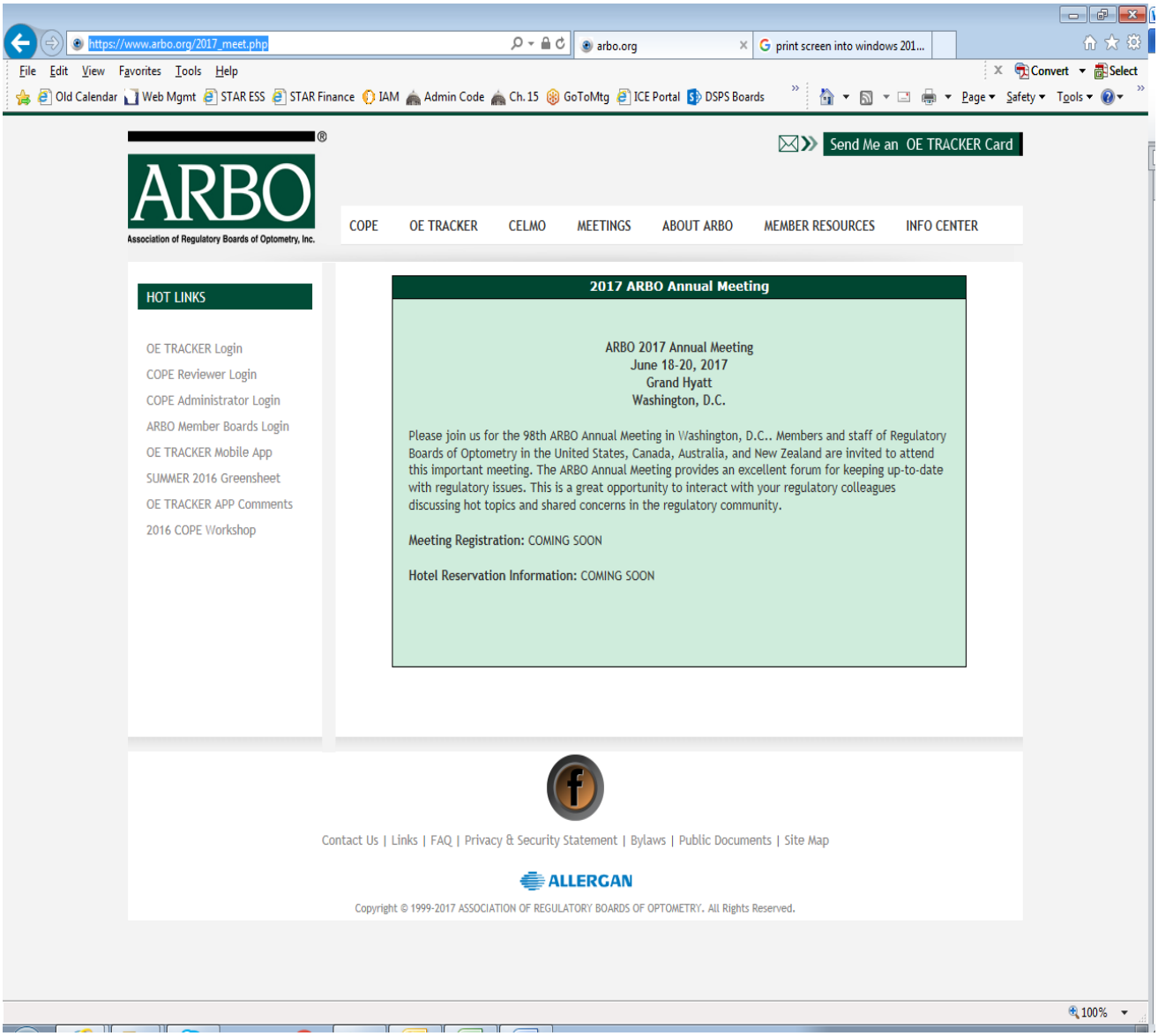
ARBO Member Boards may nominate one of their Board members or staff for the scholarship. The recipient of the award will receive the following:

- Complimentary registration for the Annual Meeting
- Accommodations for up to three nights at the meeting hotel
- Airfare to the meeting city (coach class, reservation must be made at least 2 weeks in advance of the meeting)

Founder's Scholarship Criteria:

- Must be a Board member or staff person of an ARBO Member Board in good standing for at least 3 years.
- Candidate must be nominated by the leadership of an ARBO Member Board.
- Nominations must be submitted by March 1st.
- Submit a letter on your Board letterhead stating why you feel the candidate should be given the scholarship.
- Include the following in your letter:
    - Background information on your candidate— length of time on your Board, positions held, involvement in ARBO activities, etc.
    - Regulatory Board program support— Briefly explain any programs/projects for which your candidate has made significant contributions to your regulatory Board.
    - Community/Civic Involvement— List any community and/or civic activities your candidate is involved with.
    - Provide any additional information that you would like the committee to know about your candidate.
- The ARBO Annual Meeting Planning Committee will review applications and recommend a recipient to the ARBO Board of Directors for their final approval.
- The recipient will be notified by April 15th.

To be considered for the scholarship for the 2017 ARBO Annual Meeting, please submit your nominations to Lisa Fennell, ARBO Executive Director, by email: lfennell@arbo.org or fax: 888-703-4848 no later than March 1, 2017.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2017 ARBO Annual Meeting
ARBO 2017 Annual Meeting
June 18-20, 2017
Grand Hyatt
Washington, D.C.
Please join us for the 98th ARBO Annual Meeting in Washington, D.C.. Members and staff of Regulatory Boards of Optometry in the United States, Canada, Australia, and New Zealand are invited to attend this important meeting. The ARBO Annual Meeting provides an excellent forum for keeping up-to-date with regulatory issues. This is a great opportunity to interact with your regulatory colleagues discussing hot topics and shared concerns in the regulatory community.
Meeting Registration: COMING SOON
Hotel Reservation Information: COMING SOON
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