
**Report of the
Special Committee on
Reentry to Practice**

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ON REENTRY TO PRACTICE**

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EXECUTIVE SUMMARY

In 2010, the Federation of State Medical Boards (FSMB) formed a Special Committee on Reentry to Practice and charged it with issuing recommendations to the FSMB Board of Directors concerning physician and physician assistant reentry to the clinical practice of medicine. It is reported that a growing number of physicians have or will take a temporary leave from the practice of medicine. Physicians may take a temporary leave from practice for multiple reasons, including personal lifestyle decisions, or to pursue research, administrative or other professional interests not involving the clinical practice of medicine.

Regardless of the reasons for an interruption in clinical practice, it is critical for state medical and osteopathic boards (hereafter referred to as state member boards or SMBs), to address physician and physician assistant reentry as part of their mission to insure patient safety. As part of this mission, state member boards should provide a standardized process for physicians and physician assistants, who may take a temporary leave from practice, to demonstrate their competence prior to reentering practice. State member boards should also be aware that physician reentry may offer an additional means of addressing the anticipated national physician shortage.

The Special Committee recognizes that physician reentry can be a normal aspect of a physician's career. The Special Committee believes that concepts and standards for physician reentry should be consistent with lifelong learning expectations for all physicians, which include reflective self-assessment, assessment of knowledge and skills, and performance in practice.

In formulating this report, the Special Committee reviewed existing reentry activities and programs of state member boards, sought guidance from published literature, and consulted with other advisors. The Special Committee identified key reentry issues, and has developed 12 Reentry Guidelines.

The goal of the Special Committee's Report and 12 Reentry Guidelines are to provide to the FSMB and its state member boards a framework of common standards and conceptual processes for physician and physician assistant reentry. The Special Committee has purposefully linked its recommendations to discussions and activities regarding Maintenance of Licensure (MOL), the American Board of Medical Specialties (ABMS) Maintenance of Certification (MOC), and the American Osteopathic Association and Bureau of Osteopathic Specialists' (AOA BOS) Osteopathic Continuous Certification (OCC).

The Special Committee recommends 12 Reentry Guidelines to the FSMB. These guidelines are organized as follows:

- Education and Communications Issues
- Determining Fitness to Reenter Practice
- Mentoring Practitioners Who Want to Reenter the Workforce
- Improving Regulation of Licensed Practitioners Who Are Clinically Inactive
- The Relationship between Licensure and Specialty Certification

For state member boards, implementation of the Special Committee's Reentry Guidelines may require review and revision of existing medical and osteopathic practice acts, consideration of staffing, costs and resource issues, modification of license application and renewal forms, integration of reentry with MOL activities, and initiation of proactive communications with prospective and current licensees and applicants.

INTRODUCTION AND CHARGE

Freda Bush, MD, Immediate Past Chair of the FSMB Board of Directors, recently stated: "The question of how physicians reenter the practice of medicine after an extended absence for a significant period of time has always been important – and challenging – to SMBs. Ensuring physicians are qualified to reenter practice after a period of clinical inactivity is a complex process, which involves close coordination of education, testing, monitoring and regulation."¹

The Federation of State Medical Boards (FSMB) Special Committee on Reentry to Practice was convened in the late summer of 2010. The Committee was charged with issuing recommendations to the FSMB Board of Directors concerning physician and physician assistant reentry to the practice of medicine as outlined below.

1. Review and evaluate the recommendations relative to reentry in the Special Committee on Maintenance of Licensure as contained in its 2008 draft report;²
2. Review and evaluate the policies, procedures and other mechanisms currently used by state member boards to oversee physicians and physician assistants in reentering the active practice of medicine;
3. Review and evaluate the work to date on issues related to reentry to practice from medical professional organizations and other entities, including the AMA, AOA, AAP, et al;
4. Review and evaluate the FSMB's recommendations related to Maintenance of Licensure (MOL) and its implementation and develop recommendations as to how MOL requirements can be aligned with reentry to practice requirements;
5. Establish and recommend guidelines that state member boards can utilize to determine the competence of physicians who have been out of clinical practice for a significant period of time for non-disciplinary reasons;
6. Provide guidance about the potential application of guidelines developed as part of #5, to disciplinary, impairment or retraining issues that may be associated with reentry.

Recognizing that physician reentry is becoming a common career trajectory and a normal part of a physician's continuing practice of medicine, the goal of the Special Committee's Report is to provide to the FSMB and its state member boards a framework of common standards and conceptual processes for physician and physician assistant reentry.

Reentry programs are consistent with lifelong learning expectations for physicians and there is some evidence that physicians who participated in a supportive, structured educational program were generally successful in achieving their goal of restoring licensure and returning to practice.³

Although reentry affects a broad spectrum of health care providers, the Special Committee's intent is to make its recommendations useable for physicians and physician assistants. Implementation of the Special Committee's recommendations should result in a reentry process that is appropriately comprehensive, but practical and flexible enough to address a variety of situations and specialties. The Special Committee also specified that its report should provide common standards and conceptual processes for state member boards to implement the recommendations, and not necessarily be a specific "tool box" at this point. They agreed that important outcomes would be to fulfill SMBs' mission of ensuring public safety, an increase in public confidence in physicians and their licensing boards,

enhanced communications between SMBs and physicians about the implications of what taking a leave from practice means and increased awareness of how physicians should prepare for such an event.

The Special Committee developed a description of desired outcomes for this project and the audience, scope and organization of the report. This information is contained in Attachment A. A glossary is included in Attachment B. Attachment C provides a listing of barriers to reentry as developed by The Physician Reentry into the Workforce Project of the American Academy of Pediatrics. Attachment D is a summary of the FSMB policy on Maintenance of Licensure, which is referred to frequently in this report. Attachment E provides a number of resources from state member boards that are intended to provide practical assistance on reentry. Attachment F provides references for additional literature on reentry.

NEED FOR REENTRY GUIDELINES FOR STATE MEMBER BOARDS

It is reported that a growing number of physicians are making the decision to take leave from the clinical practice of medicine, with many seeking to return at some future point⁴. Physicians may take a break from practice due to family responsibilities or they may decide to temporarily focus on research or administrative careers not involving the everyday practice of medicine. Other reasons physicians take time off from clinical practice include birth of a child, child care, caring for an ill family member, personal health, military service, humanitarian leave, and change in career path and career dissatisfaction.⁵

Regardless of the reasons for an interruption in practice, it is critical for SMBs to address reentry for the following reasons:

- To advance patient safety and quality of care;
- For SMBs to provide a standardized process for physicians and physician assistants, who may take a temporary leave from practice, to demonstrate their competence prior to reentering practice;
- For physicians who leave practice and do not reenter, there is:
 - A loss of physician contributions to the health care delivery system;
 - A worsening of the current access problems, especially in underserved areas;
 - The forfeiture of the investment in medical education and specialty/subspecialty training;
- Reentry to practice may offer an additional and more cost-effective means of addressing the anticipated national physician shortage and/or responding to national or local emergencies, such as natural disasters.

Several SMBs have already addressed reentry in response to the above points in order to assure citizens of their respective states that physicians who leave clinical practice are qualified to return. There is research that indicates that physicians who have been out of practice a certain number of years lose their skills.⁶ With the emphasis on outcomes measurement in health care reform, it is anticipated that there will be increased demand for programs of quality assessment for those in practice as well as those reentering it.

SMBs are also concerned that Maintenance of Licensure (MOL) requirements^{7, 8} and the ongoing rollout of American Board of Medical Specialties Maintenance of Certification (ABMS MOC) and the American Osteopathic Association Bureau of Osteopathic Specialists (AOA BOS) Osteopathic Continuous Certification (OCC) requirements may uncover a significant number of physicians who are not in active

clinical practice. The same activities that physicians may need to meet MOL and specialty board certification requirements should also be used as part of a reentry process. SMBs are anticipating that there will be a link between MOL/MOC/OCC and Performance in Practice requirements, and reentry guidelines are needed to avoid unnecessary duplication.

Finally, there are a host of barriers for physicians who want to reenter practice (see Attachment C for a listing developed by the American Academy of Pediatrics Physician Reentry Project). The FSMB, working with its state member boards, can develop a more unified system to help address and reduce those barriers to reentry.

There are concerns that Maintenance of Licensure and certification requirements will identify a significant number of physicians who will need reentry activities. There is also anecdotal evidence that the problem is increasing in part because of economic and demographic changes among physicians. It appears that there are increasing numbers of retired physicians who desire to return to practice to augment their incomes during the current economic recession.⁹ With women comprising a larger percentage of the physician workforce, they often, although not exclusively, may take on responsibilities of childbirth, childcare, and caring for an ill or elderly family member.¹⁰

KEY REENTRY ISSUES

Physician reentry into clinical practice can be defined as returning to professional activity/clinical practice for which one has been trained, certified or licensed after an extended period.¹¹ Reentry is an issue that cuts across genders and specialties. However, anecdotal evidence indicates that reentry into the workforce affects women more often than men.¹² Although there is paucity of data on this complex topic, many agree that it is an issue that is gaining prominence,¹³ and is crucial to continuing public safety.

The Special Committee identified several key issues to be addressed during its work. The following list is neither exhaustive nor in an order of priority.

- **Timeframe:** More than two years away from practice is commonly accepted as the timeframe for when physicians should go through a reentry process. The two-year timeframe is based on a 15-year-old FSMB policy, but further information is needed. In the absence of data, the Committee recognizes the need for flexibility when applying the two-years-away-from-practice timeframe to an individual practitioner, as there is great variability in specialty, type of practice, etc.
- **Data Needs:** More data are needed to know how many physicians are impacted by reentry issues. Information about how many physicians are clinically inactive but maintain an active license to practice is needed. The number of physicians who have been out of practice and have sought or are currently seeking reentry is needed. Although data are lacking, the Committee believes that anecdotal evidence speaks to the need for reentry interventions and that a growing number of physicians will need reentry tools and programs.
- **SMB Data Collection:** There is an urgent need for SMBs to add questions to their license renewal applications in order to help determine the status of physicians and the magnitude of the reentry problem.

- **Congruence with Maintenance of Licensure and Maintenance of Certification:** SMBs need to ensure that licensees and applicants are ready to reenter after a period of inactivity. However, as SMBs design or redesign their reentry programs, they should allow activities that physicians may need to meet MOL and specialty board certification requirements to satisfy the reentry process.
- **Barriers to Reentry:** There are difficulties associated with identifying entities that provide reentry services to physicians. Cost, geographic considerations, eligibility requirements, licensure, malpractice issues and lack of uniformity among alternatives available to physicians seeking reentry are problematic.
- **Mentors of Reentry Physicians:** The availability of physician mentors and the processes of vetting their skills, paying them for their work, and defining the types of tools they should use in assisting those physicians who are on a reentry path are considerations that need to be addressed.
- **Role of Academic Medical Centers (AMCs) and Community Hospital Training Centers:** Because they already have the facilities and resources, AMCs could play multiple roles in the reentry process. They could provide a complete reentry package from initial assessment of the reentry physician to his or her final evaluation of competence and performance in practice. Academic Medical Centers could provide selected services on an as-needed basis such as assessment testing, focused practiced based learning, procedure labs and providing and vetting mentors. Potential incentives to stimulate AMC involvement in reentry include research opportunities and generation of revenue.
- **Resources for Funding:** There is a need for funding to help cover the costs of physician reentry. Federal, state and local funding driven by physician shortages may become a funding source. Potential employers, including community hospitals and large group practices, may be willing to offset individual physician reentry costs in exchange for later service. There is a challenge to creatively find new funding, both nationally and locally, and promote its availability.
- **Medical Liability Insurance:** Better understanding is needed about how malpractice coverage works when physicians leave and when they reenter practice. It would also be helpful to know how coverage for mentoring physicians is handled.
- **Maintaining Licensure if Not in Active Clinical Practice:** SMBs are facing the question of whether physicians who are not in active clinical practice should be allowed to maintain an active license. Some states consider the work done and decisions made by medical directors of health care programs to be the practice of medicine and therefore they are required to have an active license. Other states recognize administrative medicine as a distinct area of practice and issue full and unrestricted licenses to administrative physicians with the expectation that administrative physicians, like all other licensees/applicants, appropriately limit their practice to areas where they are competent.
- **Retraining When Practice Differs or is Modified from Area of Primary Training:** Some physicians who seek reentry want to practice in a specialty or area that differs from their area of primary training. For example, an obstetrician/gynecologist may wish to practice family medicine. Another example is when a physician seeks to modify his or her primary area of practice, such as when an

obstetrician/gynecologist seeks to only practice gynecology. It is uncertain how much, if any, additional training might be needed for these types of physicians.

- **Simulation:** Simulations will play an important role in the future because they replicate cognitive and procedural skills and simulate team interaction. How can reentry activities take advantage of simulation centers and also pay for the services these centers might provide?

INPUT FROM ADVISORS

As part of its work, the Committee invited several professionals experienced in reentry to help inform its opinions and recommendations via two webinars. These presenters, which included representatives from previously or currently active reentry programs, had firsthand experience with physician reentry programs and were willing to discuss their experiences. The Committee would like to thank: Robin Wooton, Executive Director, Society for Simulation in Health Care (SSH); Barry Manuel, MD, Associate Dean, Professor of Surgery, Boston University School of Medicine; Elizabeth J. Korinek, MPH, Board Member, Coalition for Physician Enhancement (CPE); and Joann Baumer, MD, John Peter Smith Hospital in Ft. Worth, Texas.

The participants discussed several issues including costs, effectiveness and need for reentry programs. Some specific considerations involved:

Costs: It appears that, depending on design, costs for participating in and completing a formal reentry program can range from \$5,000-\$20,000 per individual participant. For those who have been ill, taken family medical leave, or for those in primary care specialties, limited funds can make program costs especially prohibitive.

Need for Programs: It appears that currently the number of participants is relatively small. For example, approximately 30 physicians are participating in a three-year period at one program and approximately 60 are completing another six-month university program.

Program Completion: It appears that most physicians who begin the programs complete them successfully, although one program found through prescreening that 20-30% were judged not to have the capacity to complete the program.

Programs Tailored to Individuals: All of the presenters agreed that it was desirable to have flexible programs that addressed the tremendous variety of individual needs.

Two-Year Minimum: It was agreed that there is a need for a commonly accepted "out of practice" timeframe for physician reentry.

ROLE OF STATE MEMBER BOARDS IN REENTRY

The Special Committee recognizes that several state member boards have strong policy and significant experience with the reentry process. The North Carolina Medical Board, for example, has supervised the reentry of approximately 60 physicians and 40 physician assistants. The Special Committee noted that Oregon, Massachusetts, and others have reentry rules (see Attachment E for examples). Based on

this experience, there appear to be a number of roles that state member boards can play in the process. For example, state member boards may:

- Develop a policy and provide advice to those desiring to reenter.
- Proactively identify those who are not complying with MOC or MOL requirements and inquire about their practice status and advise them of how to reenter.
- Notify all applicants/licensees about what they should do in advance of taking a leave from the practice of medicine in order to avoid future reentry problems.
- Directly supervise the reentry process using Board staff, while others will rely on programs in place for this purpose or academic medical centers
- Cooperate, perhaps on a regional basis, to best serve licensees/applicants and make best use of limited resources.
- Facilitate or support programs at academic medical centers in their state or region.

Recently, Nebraska enacted a law to provide for reentry licenses under its Medicine and Surgery Practice Act. Upon recommendation of the state board, a physician who has not been actively practicing medicine for the two-year period immediately preceding, or who has not otherwise maintained continued competency during such period as determined by the board, may qualify for a reentry license, which can then convert to a regular license after completion of assessment and supervised practice.

SUGGESTED REENTRY GUIDELINES*

The following 12 guidelines are intended to help SMBs facilitate a physician's reentry to practice while simultaneously ensuring the public is protected. Building on the FSMB's work in Maintenance of Licensure (MOL), the Special Committee believes that for individual physicians the reentry process should segue into MOL. Whenever possible, the three MOL components (Reflective Self-assessment, Assessment of Knowledge and Skills, and Performance in Practice) have been included as part of the reentry process.

While some of the guidelines contained herein may be appropriate for physicians whose absence is due to disciplinary or impairment reasons, the guidelines are primarily intended to address situations where a physician has taken a voluntary leave of absence. For purposes of this report, the recommendations apply to both physicians and physician assistants.

The Special Committee discussed the issue of impaired physicians and how the following guidelines might affect them and their SMBs. After a review of the FSMB Policy on Physician Impairment, which was adopted by the FSMB as policy in 2011, it was decided that these guidelines do not conflict with the FSMB policy and, in fact, enhance it.¹⁴ It is suggested that SMBs use these guidelines on Physician Reentry to augment their programs and to convey the importance of a reentry plan to the physicians participating in an Impaired Physician Program.

**This section is adapted from the draft final report of the Special Committee on Maintenance of Licensure (2008).*

Education and Communication Issues

Guideline 1: Proactive Communications

To help prepare licensees/applicants who either are thinking about taking a leave of absence or are considering returning to clinical practice, SMBs should proactively educate licensees/applicants about the issues associated with reentering clinical practice (e.g., continued participation in CME activities while out of practice, unintended consequences of taking a leave of absence such as impact on malpractice costs and future employment).¹⁵ For example, SMBs could develop written guidance on issues like the importance of engaging in clinical practice, if even on a limited, part-time basis, or seeking counsel from their insurance carriers prior to withdrawal from practice and when they are ready to reenter practice. They might also suggest that the licensee/applicant consult the Inventory created by the Physician Reentry to the Workforce Project (www.physicianreentry.org).¹⁶ State member boards could include such information with the initial license, with the license renewal application, in the board's newsletter and on the board's website.

Guideline 2: Flexibility

The medical community will have to determine how to make the system flexible enough to accommodate reentering practitioners whose personal lives or professional goals interfere with the ability to remain clinically active. All entities that depend on physicians to provide clinical care should be encouraged to accommodate individuals who are interested in returning to clinical practice but who may need flexible or part-time scheduling. A recent study concluded that the lack of opportunities for part-time work and flexible scheduling may preclude some who otherwise would reenter practice from returning to practice.¹⁷ This systemic issue is difficult for SMBs to address, but it remains a significant issue.

Determining Fitness to Reenter Practice

It is the responsibility of SMBs to determine whether a licensee/applicant who has had an interruption in practice should demonstrate whether he or she is competent to return to practice. Of the 30 boards that have a reentry policy, a majority use a two-year continuous interruption in practice as an indicator for the need for a reentry activity, although requirements range from one to five years.¹⁸ The FSMB recommends that for licensure by endorsement, SMBs should adopt a flexible approach based on an applicant's individual needs, and guidelines established by the licensee/applicant specialty society or specialty board. SMBs may be guided by the concept that those who have not been in active practice for the previous 24-month period may be required to demonstrate their continued competence. Despite SMB requirements and FSMB recommendations, little research is available to inform discussions about how time away from clinical practice impacts competence.

Guideline 3: Case-by-Case Basis

Because competence is maintained in part through continuous engagement in patient care activities, licensees/applicants seeking to return to clinical work after an extended leave should be considered on a case-by-case basis. Decisions about whether the licensee/applicant should demonstrate readiness to reenter practice should be based on a global review of the licensee/applicant's situation, including

length of time out of practice, what the practitioner has done while away from practice, the licensee/applicant's prior and current or intended area of specialization, prior disciplinary history, hospital privilege reports, and the licensee/applicant's participation in continuing medical education and/or volunteer activities during the time out of practice. Licensees/applicants who wish to take some time away from clinical practice should be encouraged to remain clinically active in some, even if limited, capacity, and urged to participate in continuing medical education and MOC, OCC, National Commission on Certification of Physician Assistants (NCCPA) certification maintenance processes and MOL activities if available.

Guideline 4: Documentation

All licensees/applicants returning to clinical practice after a period of inactivity should be required to provide a detailed description of their future scope of practice plans. The degree of documentation required may vary depending on the length of time away from clinical practice and whether the licensee/applicant's scope of practice is consistent with his or her medical education and training. For example, documented evidence might include CME certificates and verification of volunteer activities.

The Special Committee distinguishes between the need for reentry and the need for retraining. A physician returning to a scope or area of practice in which he/ she is previously trained or certified, or in which he/ she previously had an extensive work history may need reentry. A physician returning to clinical work in an area or scope of practice in which he or she has NOT previously trained or certified or in which he/ she has NOT had an extensive work history needs retraining and, for the purposes of this report, is not considered a reentry physician. Because the licensee/applicant's intended scope of practice may not be the same as the specialty in which he/ she is trained or board certified, the reentering licensee/applicant should also be required to provide information regarding the environment within which they will be practicing, the types of patients they anticipate seeing, and the types of clinical activities in which they will be engaged.

Guideline 5: Reentry Plan

Licensees/applicants who have been clinically inactive should become involved in a reentry plan approved by the state member board before reentering the workforce. The reentry plan should include three fundamental components: reflective self-assessment by the licensee/applicant, assessment of the licensee/applicant's knowledge and skills, and the licensee/applicant's performance in practice as defined by the FSMB requirements for Maintenance of Licensure.¹⁹

State member boards should approve the elements and scope of the reentry plan prior to its initiation. Subsequently, the licensee/applicant should be required to present the outcomes of the reentry plan to the state member board.

If the licensee/applicant has not previously implemented a reentry plan, then SMBs may be authorized as needed to use non-punitive, time-limited license mechanisms to return a practitioner's license to active, unrestricted status. Such a mechanism permits the licensee/applicant to participate in activities necessary to regain the knowledge and skills needed to provide safe patient care, such as participation in a mini-residency.

5a: Reflective Self-assessment

Reentry documentation should reflect the licensee/applicant's participation in assessment and/or self-reflection activities with subsequent successful completion of educational activities tailored to address weaknesses or deficiencies identified through the assessment. These activities should be congruent with Component One of the FSMB MOL Framework. (See Attachment D) Continuing medical education activities presented by the licensee/applicant in support of his/ her competence should be relevant to the area of practice in which the licensee/applicant intends to engage and should be certified by an agency acceptable to the state member board.

5b: Assessment of Knowledge and Skills

Congruent with MOL Component Two: Assessment of Knowledge and Skills, state member boards should require licensees to undertake objective knowledge and skills assessments to identify learning opportunities and guide improvement activities.

SMBs should provide guidance about the appropriate content of a reentry plan. For example, SMBs could ask licensees/applicants to provide the results of their self-assessment, the processes used to assess knowledge and skills, and the means by which performance in practice was evaluated. Other appropriate content should include the qualifications of the mentoring physician, information from the mentor about the licensee/applicant's clinical duties and responsibilities, location of the practice, approximate number of hours worked, patient volume and acuity, procedures done, results of chart audits, method of mentoring, and frequency of direct observation.

Documentation of such activities should be required. For example, mentors should be sufficiently vetted to participate with the licensees/applicants' process of assessment. There are also recognized assessment programs that are available and could be an option for meeting this requirement.

5c: Performance in Practice:

Consistent with MOL Component Three: Performance in Practice, licensees/applicants should also be required to provide documentation showing their satisfactory performance in practice as part of a reentry plan. Qualifying activities could include a variety of methods that incorporate reference data to assess physician performance in practice as a guide to improvement. Potential resources that may be used to specifically address the component include standardized testing (e.g., SPEX, COMVEX, other), practice mentors, chart audits, "mini-residencies," individualized, tailored continuing medical education and evaluation by a formal assessment program, or other equivalent activities.

Guideline 6: SMB Collaborative Relationships

State member boards should foster collaborative relationships with academic institutions, community hospital training centers and specialty societies within their jurisdictions to develop assessment, educational and other interventions and resources for the various types of practices. The National Board of Osteopathic Medical Examiners, the National Board of Medical Examiners, the American Board of Medical Specialties, and the American Osteopathic Association Bureau of Osteopathic Specialties may likewise serve in a supportive role to state member boards in this regard. These institutions and organizations may have readily adaptable programs or simulation centers that meet the individual needs of reentering physicians.

Mentoring for Practitioners Who Want to Reenter the Workforce

Guideline 7: Board-approved Practice Mentors

Practice mentors may be selected by either the state member board or the licensee/applicant, but in all cases should be approved by the state member board. At a minimum, the practice mentor should be ABMS or AOA board certified and practice in the same clinical area as the licensee/applicant seeking reentry.

The state member board should set forth in writing its expectations of the practice mentor, including what aspects of the reentering licensee/applicant's practice are to be mentored, frequency and content of reports by the mentor to the state member board and how long the practice is to be mentored. The board's expectations should be communicated both to the mentor and the licensee/applicant being mentored. For physician assistants, the role of practice mentor may be fulfilled by the supervising physician.

The practice mentor should be required to demonstrate to the board's satisfaction that he/ she has the capacity to serve as a practice mentor, for example, sufficient time for mentoring, lack of disciplinary history, proof of an active, unrestricted medical license, and/or demonstration of a prescribed number of years in clinical practice. The practice mentor may be permitted to receive financial compensation or incentives for work associated with practice mentoring. Potential sources of bias should be identified and in some cases may disqualify a potential mentor from acting in that capacity.

State member boards should work with the state medical and osteopathic societies and associations and the medical education community to identify and increase the pool of potential practice mentors. For example, to protect the pool of mentors, some SMBs have made them agents of the board.

Guideline 8: Transition to a Full Unrestricted License

Physicians and physician assistants who have gone through a reentry process and receive a full, unrestricted license should then be subject to the same rules and regulations as other licensees.

Improving Regulation of Licensed Practitioners Who Are Clinically Inactive

State member boards should implement the following mechanisms to improve regulation of licensed practitioners who are clinically inactive but may return to clinical practice in the future.

Guideline 9: Identifying Clinically Inactive Licensees

State member boards should require licensees to report information about their practice as part of the license renewal or registration process, including: type of practice, status (e.g., full-time, part-time, number of hours worked per week), whether they are actively seeing patients, specialty board certification status, and what activities they are engaged in if they are not engaged in clinical practice (e.g., research, administration, non-medical work, retired, etc.). Such information will enable SMBs to identify licensees who are not clinically active and to intervene and guide, as needed, if and when a licensee chooses to return to patient care duties. State member boards should advise licensees who are

clinically inactive of their responsibility to participate in an individualized, diagnostic reentry plan prior to resuming patient care duties.

The report of the FSMB Workgroup to Define Minimal Data Set is expected to provide additional recommendations regarding a minimal physician demographic data set that state member boards should collect as part of the licensure process. In addition, the report of the FSMB Maintenance of Licensure Workgroup on Non-Clinical Physicians is expected to provide recommendations regarding how non-clinically active physicians may participate in a state member board's MOL program and how participation in such a program should be evaluated at the time of reentry to clinical practice.

Guideline 10: Licensure Status

Licensees who are clinically inactive should be allowed to maintain their licensure status as long as they pay the required fees and complete any required continuing medical education or other requirements as set forth by the board. Upon a licensee's decision to return to clinical practice, he or she should be required to participate in a reentry process.

Guideline 11: Consistency of Reentry across Jurisdictions

State member boards should be consistent in the creation and execution of reentry processes. In recognition of the differences in resources, statutes and operations across states and acknowledging that implementation of physician reentry should be within the discretion and purview of each SMB, these guidelines are designed to be flexible to meet local considerations. At the same time, physicians may be concerned about an overly burdensome reentry process where they might have to meet varying criteria to obtain licensure in different states. For purposes of license portability, FSMB should coordinate the implementation of these guidelines so there is as much consistency as possible.

Relationship between Licensure and Specialty Certification

A physician's ability to maintain specialty board certification during a leave of absence will depend on whether the physician has voluntarily allowed his or her license to lapse. The 24 boards of the American Board of Medical Specialties (ABMS) have implemented Maintenance of Certification (MOC) programs, which require, in part, the physician's ability to demonstrate good professional standing by virtue of having a full and unrestricted license. In addition, the American Osteopathic Association Bureau of Osteopathic Specialists (AOA BOS) is implementing an Osteopathic Continuous Certification (OCC) program, which also requires, in part, demonstration of a full and unrestricted license.

Guideline 12: Maintenance of Specialty Certification

In situations where a licensed, board certified physician is returning to clinical practice, state member boards should make every effort to ensure that any conditions for the physician's reentry to practice do not hinder the physician's ability to maintain specialty certification.

IMPLICATIONS FOR STATE MEMBER BOARDS AND THE ROLE OF FSMB

The Special Committee on Reentry to Practice discussed possible implications of reentry on SMBs and the role of the FSMB in implementing the Special Committee's recommendations. For state member

boards, there will be a need to review and perhaps revise their medical practice acts, to consider staffing, costs and resource issues, to modify license application and renewal forms, to integrate reentry with MOL activities and to initiate proactive communications with prospective and current licensees/applicants.

To assist SMBs with implementing reentry requirements, FSMB should consider the following suggestions:

- FSMB should develop a uniform set of questions for SMBs to add to their license renewal application.
- Once guidelines are adopted as policy, FSMB should offer advice and consultation to their member boards.
- FSMB should commit to reviewing its reentry recommendations and policy every three to five years to ensure it remains current.
- FSMB could develop standards for language, forms and checklists to assist in implementation. For example, FSMB could provide sample guidance on issues like the importance of engaging in clinical practice, if even on a limited and part-time basis, or seeking counsel from their insurance carriers prior to withdrawal from practice.
- FSMB can help share best practices, information and resources across states through conferences, the FSMB Annual Meeting, publications and web-based reporting tools.

CONCLUSION AND NEXT STEPS

Widespread and well-defined physician reentry processes will probably not be fully realized nationwide for several years. During that time, the Special Committee recommends that FSMB launch a systematic effort to encourage states to share with each other what is working and what may need improvement in order to define best practices. Most immediately, there is a need to understand the magnitude of the problem.

As indicated in Guideline 9, state member boards should require licensees/applicants to report information about their practice as part of the license renewal or registration process. When these data are collected nationwide and reported, there will be a much stronger understanding of the opportunity to increase the physician and physician assistant workforce.

Secondarily, there is a significant need to develop an evidence base for reentry. Research is needed about the type and degree of assessment that is required to determine educational needs. Another question deserving study is the effectiveness of various types of reentry programs.

Finally, the short and long term results of reentry programs must be evaluated. Although there is evidence from the existing reentry programs that most physicians who begin a reentry program complete it successfully, more systematic research needs to be undertaken, especially regarding the two-year time frame precedent. Also, longer term follow up studies will be necessary to determine if those completing program make a successful transition to practice and what, if any, obstacles they may encounter.

SPECIAL COMMITTEE DESIRED OUTCOMES

The Special Committee agreed that its work should be focused on the following desired outcomes:

- The overall goal should be to establish physician reentry as a common career trajectory with an expectation that it is a normal part of a physician's continuing practice of medicine.
- Although reentry affects a broad spectrum of health care providers, the Special Committee's intent is to make its recommendations useable for physicians and physician assistants; implementation of the Special Committee's recommendations should result in a reentry process that is rigorous, but practical and flexible enough to address a variety of situations and specialties.
- The report should provide common standards and conceptual processes for state member boards to implement the recommendations, and not necessarily be a specific "tool box" at this point.
- Recommendations from the Special Committee should increase public confidence in physicians and their licensing boards; the ideal would be for the recommendations to be linked to the enhancement of patient outcomes.
- An important outcome will be enhanced communications between SMBs and physicians about the implications of what taking a leave from practice means and increased awareness of how physicians should prepare for such an event.
- The Special Committee believes involvement of academic medical centers in reentry activities, including focused research on this topic, is highly desirable.
- The report should explicitly link reentry with Maintenance of Licensure (MOL), ABMS Maintenance of Certification (MOC), and AOA BOS Osteopathic Continuous Certification (OCC).

THE AUDIENCE, SCOPE AND ORGANIZATION OF THE SPECIAL COMMITTEE REPORT

The Special Committee discussed the nature of the report and provided the following guidance.

- The primary audience for the report will be state member boards, with the understanding that the report could be useful and easily adapted to the following secondary audiences of individuals and groups: physicians and physician assistants, students, residents, specialty organizations, hospital credentialing groups, national and state legislators and regulators, and the public.
- It will be important to establish the rationale for the work; the audience must be able to clearly understand why guidelines-or-pathways for state member boards are needed.
- The report should be of journal quality, media-worthy and also be clear and relevant to SMBs and their licensees/applicants, perhaps including diagrams and algorithms; perhaps a 10-page document with additional appendices.
- Clear definitions of what is meant by reentry, active practice and inactive practice, for example, should be provided in the glossary.

- The tone of the report should be positive and reinforce the concept that reentry is an accessible and professionally rewarding process.
- The report will focus on undifferentiated licenses and not address administrative licenses, which should be deferred until the FSMB Maintenance of Licensure Initiative progresses.
- The Committee also discussed whether its recommendations should address non-physician clinicians beyond physician assistants and decided that the recommendations will be available to other groups that could chose what to adopt for their use.

GLOSSARY

The following definitions were adapted from the AAP Physician Reentry into the Workforce Project, the AMA, the AOA, the American Board of Medical Specialties, and the FSMB Special Committee report on Maintenance of Licensure.

AMA Definition of Physician Reentry: A return to clinical practice in the discipline in which one has been trained or certified following an extended period of clinical inactivity not resulting from discipline or impairment; distinct from remediation or retraining.

AAP Definition of Physician Reentry: Returning to professional activity/clinical practice, for which one has been trained, certified or licensed after an extended period.

Clinically Active Practice: Clinically active status is defined as any amount of direct and/or consultative patient care that has been provided in the preceding 24 months. STANDARDS FOR ABMS MOC® (PARTS 1-4) PROGRAM, Approved March 16, 2009

Clinically Inactive Practice: No direct and/or consultative patient care that has been provided in the past 24 months. STANDARDS FOR ABMS MOC® (PARTS 1-4) PROGRAM, Approved March 16, 2009

Comprehensive Osteopathic Medical Variable-Purpose Examination (COMVEX): The evaluative instrument offered by the National Board of Osteopathic Medical Examiners for osteopathic physicians who need to demonstrate application of clinical knowledge for the practice of osteopathic medicine.

Education: The process whereby deficiencies in physician performance identified through an assessment system are corrected.

Impaired Physician: A physician who is unable to fulfill personal or professional responsibility because of psychiatric illness, alcoholism, or drug dependency.

Maintenance of Certification: In 2000, the 24 member boards of the American Board of Medical Specialties (ABMS) agreed to evolve their recertification programs to one of continuous professional development – ABMS Maintenance of Certification® (ABMS MOC®). ABMS MOC assures that the physician is committed to lifelong learning and competency in a specialty and/or subspecialty by requiring ongoing measurement of six core competencies adopted by ABMS and ACGME in 1999.

Maintenance of Licensure: Maintenance of Licensure is a system of continuous professional development that requires all licensed physicians to demonstrate, as a condition of license renewal, their involvement in lifelong learning that is objective, relevant to practice and improves performance over time.

Mentoring: a dynamic, reciprocal relationship in a work environment between two individuals where, often but not always, one is an advanced career incumbent and the other is a less experienced person. The relationship is aimed at fostering the development of the less experienced person. (Baucher H. Mentoring Clinical Researchers. Archives of Diseases of Children. 2002:86; 82-84.)

Osteopathic Continuous Certification: The American Osteopathic Association's Bureau of Osteopathic Specialists (AOA BOS) has mandated that each specialty certifying board implement "Osteopathic Continuous Certification" (OCC). OCC will serve as a way for board certified DOs can maintain currency and demonstrate competency in their specialty area. The American Osteopathic Association's seven core competencies are: 1) medical knowledge, 2) patient care, 3) practice-based learning and improvement, 4) interpersonal and communication skills, 5) professionalism, 6) systems-based practice, and 7) osteopathic philosophy and osteopathic manipulative medicine.

Physician Assistant Certification Maintenance Process: The National Commission on Certification of Physician Assistants is expanding its long-standing requirements of continuing medical education and regular retesting to include new self-assessment activities and performance improvement activities.

Physician Reentry Program: Structured curriculum and clinical experience which prepared physicians to return to clinical practice following an extended period of clinical inactivity.

Physician Reentry Program System: Provides a way of organizing and planning physician reentry programs.

Physician Retraining: The process of updating one's skill or learning the necessary skills to move into a new clinical area.

State Member Boards: State medical and osteopathic licensing boards that oversee the activities of the physicians licensed in the states, District of Columbia and U.S. Territories, assuring that a high standard of practice by the physicians is maintained. (Adapted from McGraw-Hill Concise Dictionary of Modern Medicine. © 2002 by The McGraw-Hill Companies, Inc.)

REENTRY BARRIERS
(from the Physician Reentry into the Workforce Project
of the American Academy of Pediatrics)

The Physician Reentry into the Workforce Project maintains that decisions to leave and then reenter the workforce should be regarded as part of a physician's career trajectory, and not as an unusual event. Physicians who are considering leaving clinical practice, as well as those who are planning to reenter, should understand and acknowledge that there can be barriers to this process. Not all physicians will encounter all or even most of these barriers on the following list, but it is wise to be prepared.

• Physician/Practitioner Factors:

- Lack of confidence and/or psychological concerns;
- Lack of knowledge and skills, both clinical and documentation skills (i.e., EMR experience);
- Lack of experience and comfort with other technological advances (i.e., internet searches, PDA use, etc.);
- Lack of knowledge of requirements, sometimes leading to decisions that cause difficulty in returning (such as allowing a license to lapse or become inactive);
- Failure to maintain knowledge in their clinical specialty because they do not anticipate a return to medicine;
- “Unconscious incompetence” – even though the practitioner may have tried to prepare, s/he may be unaware of or unable to anticipate all areas in which s/he needs to update; inability to self-assess educational needs relative to the needs of the prospective practice setting; personal feelings of adequacy or ability to practice medicine as needed;
- Pride: difficulty admitting that one is in need of further training;
- Lack of time to address the educational needs; and inability to plan for oneself how to address the needs;
- Difficulty determining when the educational gap is sufficiently addressed.

• Licensure and Licensing Board Factors:

- Failure to educate practitioners who allow their license to lapse of these requirements and potential consequences;
- Requirements that may be vague, arbitrary, and may have changed over time (or may in the future);
- Requirements that differ in vigor from state to state;
- Limited options given by which to demonstrate competence for any given state;
- Limited means available by which to demonstrate competence;
- Lack of understanding whether the options to demonstrate competence actually do so; lack of understanding of what can be used as a proxy for “competence”;
 - Often the criteria used is hands-on patient care in the U.S. (and the only criteria accepted by boards);
 - If criteria exist (such as the “two-year rules”) they often do not

differentiate between specialties. For example, perhaps “hands-on” care is more relevant for maintaining “competence” in surgical and procedural based specialties, and the critical time out period should be different for procedural and non-procedural specialties;

- Licensing organizations do not usually risk-stratify practitioners in deciding how a physician should prove competency after a time away (based on factors such as whether the practitioner is/was ever board certified, or whether the physician has required to recertify periodically, and has done so).

- Hospital and Other Privileging Bodies:

- Discomfort with and/or lack of willingness to allow privileges to a physician who has not been in recent clinical practice;
- Significant variations in this comfort level between hospitals (even for the same specialty);
- Varying ability to provide proctoring or work with physicians in a staged re-entry process (i.e., gradually lessening levels of supervision);
- Hesitance of managed care organizations and medical insurance companies to accept a re-entering physician onto their provider panel.

- Liability Coverage Factors:

- Discomfort with and/or lack of willingness to provide liability coverage to a physician who has not been in recent clinical practice;
- Significant variations in this comfort level between insurers and from individual to individual.

- Prospective Employer Factors:

- As with all the other levels, lack of understanding of how to judge competence of a clinician who does not have recent clinical experience;
- Limited availability of flexible work options;
- Lack of support from the institution and colleagues for those integrating back into the workplace.

- Reentry Program Factors:

- Discomfort with and lack of practicality in providing a “certificate of competence”;
- Variability in what each program can offer to the practitioner and offer to the prospective board/hospital/malpractice insurer, etc.
- Limited availability of sites where re-entry programs can provide hands on clinical experiences for physicians because of the above factors;
- Cost of and distance to established programs; need for convenient and affordable programs;
- Need for flexible programs;

- Lack of standardization of how these evaluations are done and/or reentry process is conducted.
- Home and Family Barriers:
 - Ongoing needs such as childcare and needs of other family/household members;
- Multi-level Factors:
 - Multiple different layers of regulating and certifying bodies with different criteria for demonstration of aptitude and proficiency (which may or may not equate to competence), all of which the practitioner must fulfill; for example, requirements to maintain specialty board certification are not considered adequate demonstration of competence by boards and licensing authorities;
 - Unclear who is/should be the decision-maker in such matters;
 - Need for counseling to provide direction regarding the kind of learning and training needed.

For more information on The Physician Reentry into the Workforce Project visit www.physicianreentry.org

Physician Reentry into the Workforce Project. Issue Brief: Reentry Barriers. Elk Grove Village, Ill. American Academy of Pediatrics; 2010.

FSMB MAINTENANCE OF LICENSURE FRAMEWORK

As a condition of license renewal, physicians should provide evidence of participating in a program of professional development and lifelong learning that is based on the general competencies model:

- medical knowledge
- patient care
- interpersonal and communication skills
- practice based learning
- professionalism
- systems based practice

The following requirements reflect the three major components of what is known about effective lifelong learning in medicine.

1. Reflective Self Assessment (What improvements can I make?)

Physicians must participate in an ongoing process of reflective self-evaluation, self-assessment and practice assessment, with subsequent successful completion of appropriate educational or improvement activities.

2. Assessment of Knowledge and Skills (What do I need to know and be able to do?)

Physicians must demonstrate the knowledge, skills and abilities necessary to provide safe, effective patient care within the framework of the six general competencies as they apply to their individual practice.

3. Performance in Practice (How am I doing?)

Physicians must demonstrate accountability for performance in their practice using a variety of methods that incorporate reference data to assess their performance in practice and guide improvement.

STATE MEMBER BOARD RESOURCES

Oregon Administrative Rules on Reentry for Physician Assistants (p. 27)

Oregon Administrative Rules on Reentry for Physicians (p. 28)

North Carolina Rule on Reentry to Practice (p. 30)

Nebraska Reentry License (p. 33)

A detailed overview of state board requirements for reentry is also available in the *2012 State Medical Licensure Requirements and Statistics* book published by the American Medical Association. The book includes data such as number and percent of boards that currently have a reentry policy, the average length of time out of practice after which boards require a reentering physician to complete a reentry program, and a table of physician reentry regulations by board.

**OREGON MEDICAL BOARD PROPOSED RULE ON REENTRY FOR PHYSICIAN ASSISTANTS
CHAPTER 847, DIVISION 050 – OREGON MEDICAL BOARD**

PROPOSED RULES CHANGES - FIRST REVIEW – JULY 2011

Proposed rule amendment establishes requirements for re-entry to practice after ceasing practice for more than one year and contains general language and grammar housekeeping.

847-050-0043

Inactive Registration and Re-Entry to Practice

(1) Any physician assistant licensed in this state who changes location to some other state or country, or who is not in a current supervisory relationship with a licensed physician for 6 months or more, will be listed by the Board as inactive.

(2) If the physician assistant wishes to resume active status to practice in Oregon, the physician assistant must submit the Affidavit of Reactivation and processing fee, satisfactorily complete the reactivation process and be approved by the Board before beginning active practice in Oregon.

(3) The Board may deny active registration if it judges the conduct of the physician assistant during the period of inactive registration to be such that the physician assistant would have been denied a license if applying for an initial license

(4) If a physician assistant applicant has ceased practice for a period of 12 or more consecutive months immediately preceding the application for licensure or reactivation, the applicant may be required to do one or more of the following:

(a) Obtain certification or re-certification by the National Commission on the Certification of Physician Assistants (N.C.C.P.A.);

(b) Provide documentation of current N.C.C.P.A. certification;

(c) Complete 30 hours of Category I continuing medical education acceptable to the Board for every year the applicant has ceased practice;

(d) Agree to increased chart reviews upon re-entry to practice.

(5) The physician assistant applicant who has ceased practice for a period of 24 or more consecutive months may be required to complete a re-entry plan to the satisfaction of the Board. The Board must review and approve a re-entry plan prior to the applicant beginning the re-entry plan. Depending on the amount of time out of practice, the re-entry plan may contain one or more of the requirements listed in section (4) of this rule and such additional requirements as determined by the Board.

Stat. Auth.: ORS 677.265

Stats. Implemented: ORS 677.512

**OREGON PROPOSED ADMINISTRATIVE RULES FOR PHYSICIANS
CHAPTER 847, DIVISION 020 – OREGON MEDICAL BOARD**

FIRST REVIEW RULE ADOPTION – OCTOBER 2011

The amendment includes the new Osteopathic school opening in Oregon and clarifies the standards for re-entry to practice.

847-020-0183

Re-Entry to Practice – SPEX or COMVEX Examination, Re-Entry Plan and Personal Interview

If an applicant has ceased the practice of medicine for a period of 12 or more consecutive months immediately preceding the application for licensure or reactivation, the applicant may be required to demonstrate clinical competency.

(1) The applicant who has ceased the practice of medicine for a period of 12 or more consecutive months may be required to pass the Special Purpose Examination (SPEX) or Comprehensive Osteopathic Medical Variable-Purpose Examination (COMVEX). This requirement may be waived if the applicant has done one or more of the following:

(a) The applicant has received a current appointment as Professor or Associate Professor at the Oregon Health and Science University or the Western University of Health Sciences College of Osteopathic Medicine of the Pacific; or

(b) The applicant has within ten years of filing an application with the Board:

(A) Completed one year of an accredited residency, or an accredited or Board-approved clinical fellowship; or

(B) Been certified or recertified by a specialty board recognized by the American Board of Medical Specialties or the American Osteopathic Association; or

(c) The applicant has subsequently:

(A) Completed one year of an accredited residency, or

(B) Completed one year of an accredited or Board-approved clinical fellowship, or

(C) Been certified or recertified by a specialty board recognized by the American Board of Medical Specialties or the American Osteopathic Association, or

(D) Obtained continuing medical education to the Board's satisfaction.

(2) The applicant who has ceased the practice of medicine for a period of 24 or more consecutive months may be required to complete a re-entry plan to the satisfaction of the Board. The Board must

review and approve a re-entry plan prior to the applicant beginning the re-entry plan. Depending on the amount of time out-of-practice, the applicant may be required to do one or more of the following:

- (a) Pass the SPEX/COMVEX examination;
- (b) Practice for a specified period of time under a mentor/supervising physician who will provide periodic reports to the Board;
- (c) Obtain certification or re-certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association's Bureau of Osteopathic Specialists (AOA-BOS);
- (d) Complete a re-entry program as determined appropriate by the Board;
- (e) Complete one year of accredited postgraduate or clinical fellowship training, which must be pre-approved by the Board's Medical Director;
- (f) Complete at least 50 hours of Board-approved continuing medical education each year for the past three years.

(3) The applicant who fails the SPEX or COMVEX examination three times, whether in Oregon or other states, must successfully complete one year of an accredited residency or an accredited or Board-approved clinical fellowship before retaking the SPEX or COMVEX examination.

(4) The Limited License, SPEX/COMVEX may be granted for a period of up to 6 months. It permits the licensee to practice medicine only until the grade results of the SPEX or COMVEX examination are available and the applicant completes the initial registration process. If the applicant fails the SPEX or COMVEX examination, the Limited License SPEX/COMVEX becomes invalid, and the applicant must cease practice in this state as expeditiously as possible, but not to exceed two weeks after the applicant receives notice of failure of the examination.

(5) The applicant may be required to appear before the Board for a personal interview regarding information received during the processing of the application. The interview must be conducted during a regular meeting of the Board.

(6) All of the rules, regulations and statutory requirements pertaining to the medical school graduate remain in full effect.

Stat. Auth.:—ORS 677.175, 677.265

Stats. Implemented: ORS 677.010, 677.175, 677.265

NORTH CAROLINA REENTRY RULE

21 NCAC 32B .1370 REENTRY TO ACTIVE PRACTICE

(a) A physician or physician assistant applicant ("applicant" or "licensee") who has not actively practiced or who has not maintained continued competency, as determined by the Board, for the two-year period immediately preceding the filing of an application for a license from the Board shall complete a reentry agreement as a condition of licensure.

(b) The applicant shall identify a mentoring physician.

(c) The applicant shall propose a reentry plan containing the components outlined in Paragraphs (g) and (h) of this Rule to the Board. The Board shall review the proposed reentry plan and interview the applicant.

(d) Factors that may affect the length and scope of the reentry plan include:

- (1) The applicant's amount of time out of practice;
- (2) The applicant's prior intensity of practice;
- (3) The reason for the interruption in practice;
- (4) The applicant's activities during the interruption in practice, including the amount of practice-relevant continuing medical education;
- (5) The applicant's previous and intended area(s) of practice;
- (6) The skills required of the intended area(s) of practice;
- (7) The amount of change in the intended area(s) of practice over the time the applicant has been out of continuous practice;
- (8) The applicant's number of years of graduate medical education;
- (9) The number of years since completion of graduate medical education; and
- (10) As applicable, the date of the most recent ABMS, AOA or equivalent specialty board, or National Commission on Certification of Physician Assistant certification or recertification.

(e) If the Board approves an applicant's reentry plan, it shall be incorporated by reference into a reentry agreement and executed by the applicant, the Board and the mentoring physician.

(f) After the reentry agreement has been executed, and the applicant has completed all other requirements for licensure, the applicant shall receive a restricted License. The licensee may not practice outside of the scope of the reentry agreement and its referenced reentry plan during the reentry period.

(g) The first component of a reentry plan is an assessment of the applicant's current strengths and weaknesses in his or her intended area of practice. The process used to perform the assessment shall be described by the applicant and confirmed by the mentoring physician. The process may include self-reflection, self-assessment, and testing and evaluation by colleagues, educators or others. The applicant and mentoring physician shall evaluate and describe applicant's strengths and areas of needed improvement in regard to the core competencies. The assessment shall continue throughout the reentry period as the licensee and the mentoring physician practice together.

(h) The second component of the reentry plan is education. Education shall address the licensee's areas of needed improvement. Education shall consist of:

- (1) a reentry period of retraining and education under the guidance of a mentoring physician, upon terms as the Board may decide, or
- (2) a reentry period of retraining and education under the guidance of a mentoring physician consisting of the following:
 - (A) Phase I – The observation phase. During the observation phase, the licensee will not practice, but will observe the mentoring physician in practice.
 - (B) Phase II – Direct supervision phase. During the direct supervision phase, the licensee shall practice under the direct supervision of the mentoring physician. Guided by the core competencies, the mentoring physician shall reassess the licensee's progress in addressing identified areas of needed improvement.
 - (C) Phase III – Indirect supervision phase. During the indirect supervision phase, the licensee shall continue to practice with supervision of the mentoring physician. Guided by the core competencies, and using review of patient charts and regular meetings, the mentoring physician shall reassess the licensee's progress in addressing the areas of needed improvement.
 - (D) No later than 30 days after the end of phase I and II, the mentoring physician shall send a report to the Board regarding the licensee's level of achievement in each of the core competencies. At the completion of phase III the mentoring physician shall submit a summary report to the Board regarding the licensee's level of achievement in each of the core competencies and affirm the licensee's suitability to resume practice as a physician or to resume practice as a physician assistant.
 - (E) If the mentoring physician reassesses the licensee and concludes that the licensee requires an extended reentry period or if additional areas of needed improvement are identified during Phases II or III, the Board, the licensee and the mentoring physician shall amend the reentry agreement.

(i) Under the terms of either reentry periods Subparagraph (h)(1) or (h)(2) of this Rule, the mentoring physician may terminate his role as the mentoring physician upon written notice to the Board. Such written notice shall state the reasons for termination. The licensee's approval is not required for the mentoring physician to terminate his role as mentoring physician. Upon receipt of the notice of termination, the Board shall place the licensee's license on inactive status. Within six months from the effective date of the mentoring physician's termination, the licensee shall provide a substitute mentoring physician, who must be approved by the Board in writing, and resume the reentry plan upon such terms as are acceptable to the Board. In such event, an amended reentry agreement must be executed prior to resumption of the reentry plan. If licensee does not resume the reentry plan as required herein within six months from the effective date of the mentoring physician's termination, then the Board shall not return the licensee to active status unless and until licensee applies and is approved for reactivation of the license with a new reentry agreement and reentry plan, which must be in place before licensee may resume practice as a physician or physician assistant.

(j) Under the terms of either reentry periods Subparagraph (h)(1) or (h)(2) of this Rule, the licensee may terminate the relationship with the mentoring physician upon written notice to the Board. Such written notice shall state the reasons for termination. The mentoring physician's approval is not required for the licensee to terminate this relationship. Upon receipt of the notice of termination, the Board shall place the licensee's license on inactive status. Within six months from the effective date of the mentoring physician's termination, the licensee shall provide a substitute mentoring physician, who must be approved by the Board in writing, and resume the reentry plan upon such terms as are

acceptable to the Board. In such event, an amended reentry agreement must be executed prior to resumption of the reentry plan. If licensee does not resume the reentry plan as required herein within six months from the effective date of the mentoring physician's termination, then the Board shall not return the licensee to active status unless and until licensee applies and is approved for reactivation of the license with a new reentry agreement and reentry plan, which must be in place before licensee may resume practice as a physician or physician assistant.

(k) The licensee shall meet with members of the Board at such dates, times and places as directed by the Board to discuss the licensee's transition back into practice and any other practice-related matters.

(l) Unsatisfactory completion of the reentry plan or practicing outside the scope of the reentry agreement, as determined by the Board, shall result in the automatic inactivation of the licensee's license, unless the licensee requests a hearing within 30 days of receiving notice from the Board.

(m) If the Board determines the licensee has successfully completed the reentry plan, the Board shall terminate the reentry agreement and notify the licensee that the license is no longer restricted.

*History Note: Authority G.S. 90-8.1; 90-14(a)(11a);
Eff. March 1, 2011.*

NEBRASKA REENTRY LICENSE

TITLE: Provide for reentry licenses under the Medicine and Surgery Practice Act

05/12/2011 PASSED ON FINAL READING 46-0-3.

05/12/2011 PRESIDENT/SPEAKER SIGNED.

05/12/2011 PRESENTED TO GOVERNOR ON MAY 12, 2011.

(1)(a) Present proof that he or she is a graduate of an accredited school or college of medicine, (b) if a foreign medical graduate, provide a copy of a permanent certificate issued by the Educational Commission on Foreign Medical Graduates that is currently effective and relates to such applicant or provide such credentials as are necessary to certify that such foreign medical graduate has successfully passed the Visa Qualifying Examination or its successor or equivalent examination required by the United States Department of Health and Human Services and the United States Citizenship and Immigration Services, or (c) if a graduate of a foreign medical school who has successfully completed a program of American medical training designated as the Fifth Pathway and who additionally has successfully passed the Educational Commission on Foreign Medical Graduates examination but has not yet received the permanent certificate attesting to the same, provide such credentials as certify the same to the Division of Public Health of the Department of Health and Human Services;

(2) Present proof that he or she has served at least one year of graduate medical education approved by the board or, if a foreign medical graduate, present proof that he or she has served at least three years of graduate medical education approved by the board;

(3) Pass a licensing examination approved by the board covering appropriate medical subjects; and

(4) Present proof satisfactory to the department that he or she, within the three years immediately preceding the application for licensure, (a) has been in the active practice of the profession of medicine and surgery in some other state, a territory, the District of Columbia, or Canada for a period of one year, (b) has had at least one year of graduate medical education as described in subdivision (2) of this section, (c) has completed continuing education in medicine and surgery approved by the board, (d) has completed a refresher course in medicine and surgery approved by the board, or (e) has completed the special purposes examination approved by the board.

Sec. 3. (1) The department, with the recommendation of the board, may issue a reentry license to a physician who has not actively practiced medicine for the two-year period immediately preceding the filing of an application for a reentry license or who has not otherwise maintained continued competency during such period as determined by the board.

~~(2) To qualify for a reentry license, the physician shall meet the same requirements for licensure as a regular licensee and submit to evaluations, assessments, and an educational program as required by the board.~~

(3) If the board conducts an assessment and determines that the applicant requires a period of supervised practice, the department, with the recommendation of the board, may issue a reentry license allowing the applicant to practice medicine under supervision as specified by the board. After satisfactory completion of the period of supervised practice as determined by the board, the reentry licensee may apply to the department to convert the reentry license to a license issued under section 38-2026.

(4) After an assessment and the completion of any educational program that has been prescribed, if the board determines that the applicant is competent and qualified to practice medicine without supervision, the department, with the recommendation of the board, may convert the reentry license to a license issued under section 38-2026.

(5) A reentry license shall be valid for one year and may be renewed for up to two additional years if approved by the department, with the recommendation of the board.

(6) The issuance of a reentry license shall not constitute a disciplinary action.

ADDITIONAL LITERATURE ON REENTRY

The following peer-reviewed articles provide a more in-depth overview and analysis of the issues associated with reentry.

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**Model Policy on
the Use of Opioid
Analgesics in the
Treatment of
Chronic Pain**

July 2013

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MODEL POLICY ON THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

INTRODUCTION

The Federation of State Medical Boards (FSMB) is committed to assisting state Medical Boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, the use of opioid analgesics. [1]. The FSMB updated its guidelines in 2003 [2] so that its Model Policy would reflect the best available evidence on management of pain and give adequate attention to both the undertreatment and overtreatment of pain and the inappropriate use of opioid analgesics.

Through these initiatives, the FSMB has sought to provide a resource for use by state medical boards in educating their licensees about cautious and responsible prescribing of controlled substances while alleviating fears of regulatory scrutiny. The FSMB recognizes that inappropriate prescribing can contribute to adverse outcomes such as reduced function, opioid addiction, overdose, and death [3-5]. By promulgating its Model Policies, the FSMB has sought to provide a framework for the legitimate medical use of opioid analgesics for the treatment of pain while emphasizing the need to safeguard against their misuse and diversion.

Since their publication, the 1998 and 2004 Model Policies have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The policies have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted all or part of the Model Policies.¹

The updated Model Policy presented here reflects the considerable body of research and experience accrued since the 2004 revision was adopted [2]. While recognizing that adequate evidence is currently lacking as to the effectiveness and safety of long-term opioid therapy, this Model Policy is designed to promote the public health by encouraging state medical boards to adopt consistent policy regarding the treatment of pain, particularly chronic pain, and to promote patient access to appropriate pain management and, if indicated, substance abuse and addiction treatment. The Model Policy emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate. It also includes references and the definitions of key terms used in pain management.

¹ As of March 7, 2012, 57 of 70 State Medical Boards have policy, rules, regulations or statutes reflecting the Federation's 1997 or 2004 *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.

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The FSMB encourages every state medical board to work with the state attorney general to evaluate the state's policies, regulations and laws in an effort to identify any barriers to the effective and appropriate use of opioids to relieve pain, while ensuring that adequate safeguards are in place to deter and rapidly detect those who would obtain opioid analgesics for nonmedical purposes [6-7].

The FSMB acknowledges with gratitude the efforts of the state board members and directors who collaborated to prepare this updated Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The FSMB also thanks SAMHSA for its support of this important project.

ISSUES ADDRESSED IN THE NEW MODEL POLICY

There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated[8-10]. Since the 2004 revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffers from pain so intense as to interfere with the activities of daily living [4]. Pain arises from multiple causes and often is categorized as either *acute pain* (such as that from traumatic injury and surgery) or *chronic pain* (such as the pain associated with terminal conditions such as cancer or severe vascular disease or with non-terminal conditions such as arthritis or neuropathy) [4,8]. This model policy applies most directly to the treatment of chronic pain and the use of opioid analgesics but many of the strategies to improve appropriate prescribing and mitigate risks can be applied to the use of other controlled medications and to the treatment of acute pain.

Undertreatment of pain is recognized as a serious public health problem that compromises patients' functional status and quality of life [4,9]. A myriad of psychological, social, economic, political, legal and educational factors—including inconsistencies and restrictions in state pain policies—can either facilitate or impede the ability and willingness of physicians to manage patients with pain [6,10-11].

While acknowledging that undertreatment of pain exists, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment [4,8,12]. Indeed, some cases of intractable pain actually result from overtreatment in terms of procedures and medications.

Complicating the picture, adverse outcomes associated with the misuse, abuse and diversion of prescription opioids have increased dramatically since the FSMB's last review [3]. Physicians and other health care professionals have contributed—often inadvertently—to these increases.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioids by physicians may include: (1) physician uncertainty or lack of knowledge as to prevailing best clinical practices; (2) inadequate research into the sources of and treatments for pain; (3) sometimes conflicting clinical guidelines for appropriate treatment of pain; (4) physician concerns that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; (5) physician misunderstanding of causes and manifestations of opioid dependence and addiction; (6) fear on the part of physicians of causing

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addiction or being deceived by a patient who seeks drugs for purposes of misuse; (7) physicians practicing outside the bounds of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and (8) inadequate physician education about regulatory policies and processes [3-4,12,14-20]. Inappropriate treatment also can result from a mistaken belief on the part of patients and their physicians that complete eradication of pain is an attainable goal, and one that can be achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

Patients share with physicians a responsibility for appropriate use of opioid analgesics [21-22]. This responsibility encompasses providing the physician with complete and accurate information and adhering to the treatment plan. While many patients take their medication safely as prescribed and do not use opioids problematically, some patients—intentionally or unintentionally—are less than forthcoming or have unrealistic expectations regarding the need for opioid therapy or the amount of medication required. Other patients may begin to use medications as prescribed, then slowly deviate from the therapeutic regimen. Still others may not comply with the treatment plan because they misunderstood the physician's instructions. Some patients share their drugs with others without intending harm (a pattern of misuse that is seen quite often among older adults [15]). Then there are patients who deliberately misuse or are addicted to opioids, and who mislead, deceive or fail to disclose information to their physicians in order to obtain opioids to sustain their addiction and avoid withdrawal [19-23].

Patients often leave medications unsecured where they can be stolen by visitors, workers and family members, which is another important source of diversion. Thus a prescription that is quite appropriate for an elderly patient may ultimately contribute to the death of a young person who visits or lives in the patient's home. Therefore, the physician's duty includes not only appropriate prescribing of opioid analgesics, but also appropriate education of patients regarding the secure storage of medications and their appropriate disposal once the course of treatment is completed [18,23].

A more problematic individual is the criminal patient, whose primary purpose is to obtain drugs for resale. Whereas many addicted patients seek a long-term relationship with a prescriber, criminal patients sometimes move rapidly from one prescriber (or dispenser) to another. Such individuals often visit multiple practitioners (a practice sometimes characterized as "doctor shopping") and travel from one geographic area to another not for the purposes of relief of legitimate pain but in search of unsuspecting targets [19-21]. Physicians' attention to patient assessment and the routine use of state prescription drug monitoring programs (PDMPs), where available, have been cited as effective ways to identify individuals who engage in such criminal activities [20-23,45].

Conclusion: The goal of this Model Policy is to provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:

- **Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain:** Not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.

- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.
- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the physician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances or certain condition (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- **Unjustified dose escalation without adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.
- **Excessive reliance on opioids, particularly high dose opioids for chronic pain management:** Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic non-cancer pain only when safer and reasonably effective options have failed. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.
- **Not making use of available tools for risk mitigations:** When available, the state prescription drug monitoring program should be checked in advance of prescribing opioids and should be available for ongoing monitoring.

In addition, the Model Policy is designed to communicate to licensees that the state medical board views pain management as an important area of patient care that is integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that physicians will not be sanctioned solely for prescribing opioid analgesics or the dose (mg./mcg.) prescribed for legitimate medical purposes. However, prescribers must be held to a safe and best clinical practice. The federal Controlled Substances Act [25] defines a “lawful prescription” as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on physicians a responsibility to minimize the potential for misuse, abuse and diversion of opioids and all other controlled substances.

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SECTION I: PREAMBLE

The (name of Board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The (name of Board) recognizes that principles of high-quality medical practice dictate that the people of the State of (name of state) have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41, 80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

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Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

SECTION II: GUIDELINES

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For

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example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted

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to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance [21-23]. With all patients, the physician’s decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician’s own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community [21-23].

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient’s pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient’s surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a “treatment contract”) is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician’s prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician’s policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

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Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating an Opioid Trial: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29]and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial

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risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

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If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of

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treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (any relevant documents issued by the state medical board).

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SECTION III: DEFINITIONS

For the purposes of this Model Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors" [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death" [40].

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

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The CSA does *not* limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in *Schedules II or III* under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [28]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition (ICD-10)* of the World Health Organization [70], and the *Diagnostic and Statistical Manual (DSM)* of the American Psychiatric Association [71]. In the DSM-IV-TR, a diagnosis of “substance dependence” meant addiction. In the upcoming DSM V, the term *dependence* is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid” [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been “diverted” [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [17,19,74].

Misuse: The term *misuse* (also called *nonmedical use*) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [28].

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Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

Most physicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed [53,59-260].

Pain: An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic non-cancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

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Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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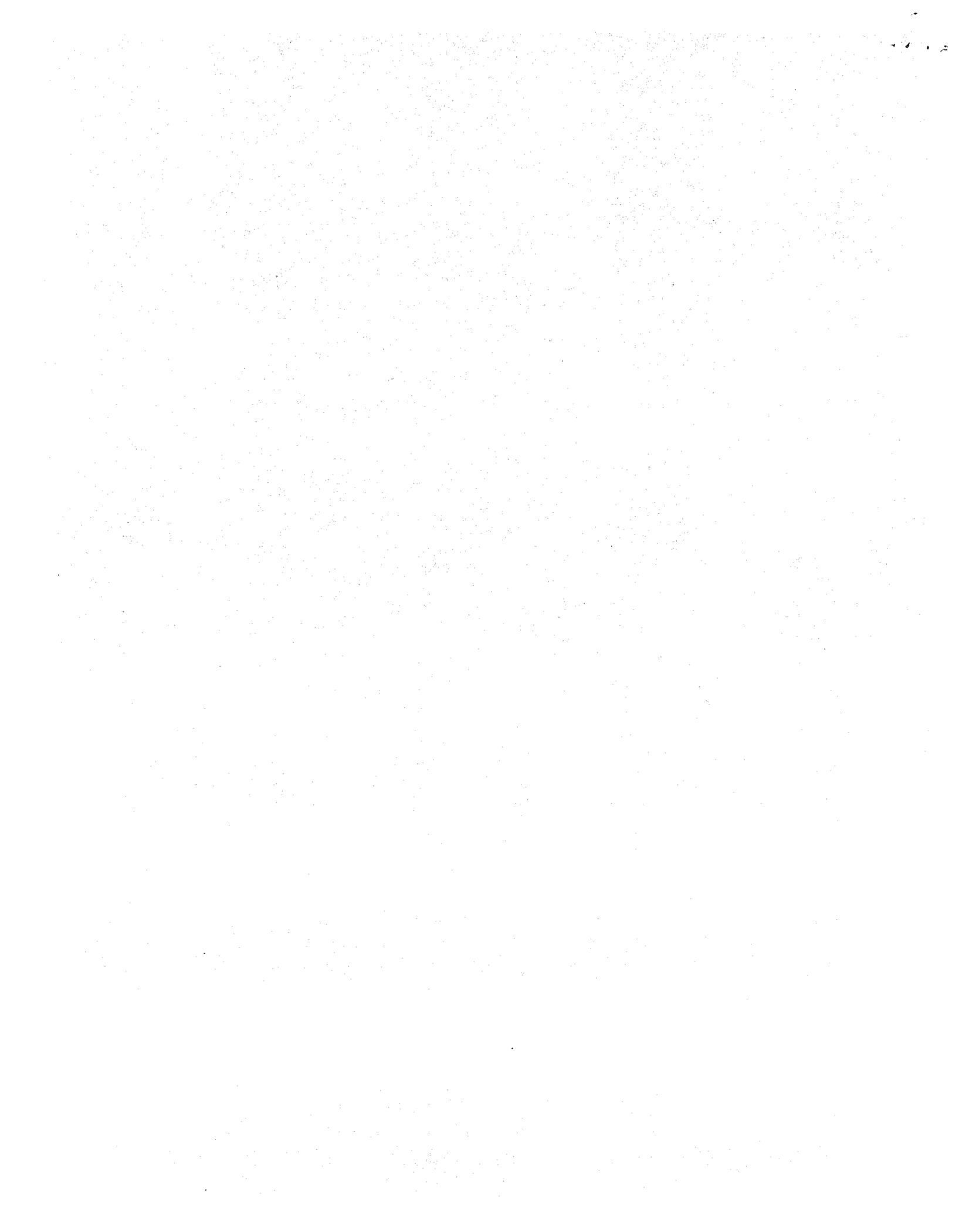
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**Model Policy on DATA
2000 and Treatment of
Opioid Addiction in the
Medical Office**

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MODEL POLICY ON DATA 2000 AND TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE

INTRODUCTION

The profile of opioid addiction in the United States is changing, in that nonmedical use of prescription opioids has become a problem as significant as the use of heroin. Recent data indicate that approximately 1.6 million persons in the U.S. misused or were addicted to prescription opioids in 2010 [1], while 323,000 persons misused or were addicted to heroin [2]. Despite the dimensions of the problem, nearly 80% of opioid-addicted persons do not receive treatment for their addiction because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care [3].

To address this need, researchers, federal health agencies, and pharmaceutical manufacturers have focused on developing medications that can be used to treat opioid addiction in medical office settings, rather than being limited to use only in specialized Opioid Treatment Programs (OTPs) [4]. As a result of those efforts, two major products are now available for use in office settings: buprenorphine (alone and in combination with naloxone) and naltrexone (in an oral formulation and an extended-release injectable formulation). These medications have been shown to be effective when used in office-based settings and thus to increase access to treatment for many patients who would not or cannot obtain care in OTPs [5-7].

Regardless of setting, the primary goals of addiction treatment are to reduce or stop opioid use, to improve the patient's overall health and social functioning, and to help the patient avoid some of the more serious consequences of opioid addiction. Treatment also can help the patient see his or her problems from a different perspective, improve self-reliance, and empower the individual to make positive changes in his or her life [8].

Buprenorphine: Buprenorphine is a partial opioid agonist that was approved by the FDA to treat opioid addiction in 2002. It is available in both tablet and film formulations for the treatment of addiction, either as buprenorphine alone (Subutex®) or in a 4:1 combination with naloxone (Suboxone®). The film formulation – which is similar to a dissolvable film strip of mouthwash – is marketed in unit-dose packaging with a serial number on each foil packet. (A transdermal formulation [BuTrans®] has been approved by the FDA, but only for the treatment of chronic pain.)

The addition of naloxone to buprenorphine does not reduce the efficacy of the medication when it is taken sublingually, yet it appears to serve as a deterrent to injection misuse [9]. For this reason, the buprenorphine/naloxone combination is the preferred formulation for most patients, with the exception of pregnant women, for whom current guidelines recommend use of the monoproduct [10]. Whenever the monoproduct is used, extra attention should be given to the risks of misuse and diversion.

Multiple studies have shown that, administered sublingually and at therapeutic doses in appropriately

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selected patients, buprenorphine is safe and effective [11-15]. The blockade of the opioid receptor imposed by buprenorphine limits the effects of subsequently administered opioid agonists or antagonists, reducing the risk of opioid overdose, and the “ceiling effect” appears to confer a higher safety profile and generally milder withdrawal symptoms (compared to full agonists) when the drug is tapered after prolonged administration [16-17].

Nevertheless, overdoses and deaths due to buprenorphine can occur and have been reported [18]. Most overdoses, especially fatal ones, involve concurrent use of another CNS depressant such as benzodiazepines, other opioids, or alcohol [19-22]. Buprenorphine also poses a significant risk to non-tolerant individuals, especially children [23].

Relatively few serious adverse events have been associated with buprenorphine. Where such events have been reported, most have involved abuse of the drug by injection, rather than sublingual administration in a clinical setting [24-28]. A national evaluation of pharmacotherapies for opioid addiction in Australia involving more than 1,200 patients found no significant difference in rates of serious adverse events between methadone, LAAM, and buprenorphine, or between different doses of buprenorphine [29].

Although early reports based on animal studies suggested that buprenorphine would have a low potential for misuse to achieve euphoria, researchers have documented a measurable level of misuse and diversion of buprenorphine [30-31]. Varying levels of misuse and diversion were predicted by early investigators [32] because buprenorphine is prescribed to high-risk individuals who are addicted to opioids. Subsequent research confirms that misuse and diversion have been reported worldwide wherever buprenorphine has been used for the treatment of addiction [33-36].

The tablet form of buprenorphine has proved more vulnerable to diversion and nonmedical use than the sublingual film, so the pharmaceutical company that held the original patent stopped manufacturing the tablet form and petitioned the Food and Drug Administration (FDA) to require that all buprenorphine products be formulated as unit-dose sublingual filmstrips, thereby eliminating tablet formulations from the market. (As of January 2013, the FDA had not acted on the petition.)

Role of Federal Legislation: The use of buprenorphine for the treatment of opioid addiction is governed by the federal Drug Addiction Treatment Act of 2000, commonly referred to as “DATA 2000” (Public Law 106-310, Title XXXV, Sections 3501 and 3502). This legislation is of particular interest to state medical boards because, for the first time in almost a century, it allows physicians to treat opioid addiction with FDA-approved controlled drugs in office-based settings. Specifically, DATA 2000 allows physicians to use buprenorphine and other controlled substances in CSA Schedules III, IV, and V, which have been approved by the FDA for the treatment of opioid dependence, to treat patients in office-based settings, provided certain conditions are met.

DATA 2000 thus has enlarged treatment capacity by lifting the requirement that patients who need opioid agonist treatment can receive such treatment only in specially licensed opioid treatment programs (OTPs), often referred to as “methadone clinics.”

Implementation of DATA 2000 required changes in the oversight systems within the Department of Health and Human Services (HHS) and the Drug Enforcement Administration (DEA). The Secretary of HHS delegated authority in this area to the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA).

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Role of State Medical Boards: The use of opioid agonist medications to treat opioid-addicted patients in the offices of individual physicians significantly increases the role of state medical boards in overseeing such treatment. For this reason, the Federation of State Medical Boards entered into an agreement with SAMHSA to develop model guidelines for use by state medical boards in regulating office-based treatment of addiction. This resulted in the Model Policy adopted by the Federation in 2002 [37].

The updated Model Policy presented here reflects the large body of research and experience accrued in the decade since buprenorphine was approved in 2002 for the treatment of opioid addiction. The Model Policy is designed to encourage state medical boards to adopt consistent standards, to promote the public health by making appropriate treatment available to opioid-addicted patients, and to educate the regulatory and physician communities about the potential of new treatment modalities for opioid addiction.

The Federation acknowledges with gratitude the efforts of the state Board members and directors who worked to update the Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The Federation also thanks SAMHSA for its support of this important project.

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SECTION I: PREAMBLE

The (*name of Board*) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the principles of high-quality medical practice dictate that the people of (name of state) have access to appropriate, safe and effective medical care, including the treatment of addiction. The application of up-to-date knowledge and evidence-based treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from addiction.

In this context, the Board recognizes the body of evidence for the effectiveness of buprenorphine in the office-based treatment of opioid addiction [38], when such treatment is delivered in accordance with current standards of care and the requirements of the Drug Addiction and Treatment Act of 2000 (DATA 2000) and state medical licensing boards.

Federal Requirements to Prescribe Buprenorphine for Addiction: Physicians who wish to treat opioid addiction with buprenorphine in their medical offices must demonstrate that they have met the requirements of the DATA 2000 legislation and obtained a waiver from SAMHSA.¹ To qualify for such a waiver, physicians must hold a current controlled substance registration with the Drug Enforcement Administration and a current license in the state in which they practice. They also must meet one or more of the following qualifications [39]:

- Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;
- Subspecialty board certification in addiction medicine from the American Osteopathic Association;
- Addiction certification from the American Board of Addiction Medicine;
- Completion of not less than eight hours of training related to the treatment and management of opioid addiction provided by the American Academy of Addiction Psychiatry, the American Society of Addiction Medicine, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or other approved organizations; or¹
- Participation as an investigator in one or more clinical trials leading to the approval of an opioid drug in Schedule III, IV, or V or a combination of such drugs for treatment of opioid-addicted patients.

To obtain a waiver, a physician must notify SAMHSA in writing of his or her intent to prescribe an approved opioid medication to treat addiction, certifying the physician's qualifications and listing his/her DEA registration number. SAMHSA will then notify DEA whether a waiver has been granted. If SAMHSA grants a waiver, DEA will issue an identification number no later than 45 days after receipt of the physician's written notification. (If SAMHSA does not act on the physician's request for a waiver within the 45-day period, DEA will automatically assign the physician an identification number.) This process is explained, and can be accessed at the following website: <http://buprenorphine.samhsa.gov/howto.html>.

¹ The "waiver" allows an exception to the Harrison Narcotics Act of 1914, which made it illegal for a physician to prescribe an opioid to any patient with opioid addiction for the purpose of managing that addiction or acute withdrawal. Prior to DATA 2000, the only exception to the Harrison Act was federal legislation that allowed the establishment of methadone maintenance treatment (MMT) clinics, now referred to as Opioid Treatment Programs (OTPs). That exception only allowed the use of methadone to treat addiction or withdrawal within specially licensed and regulated facilities, but not in office-based medical practice.

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If a physician wishes to prescribe or dispense an appropriately available and approved opioid medication for maintenance treatment or detoxification (so as to fulfill the requirements of DATA 2000) on an emergency basis before the 45-day waiting period has elapsed, the physician must notify SAMHSA and the DEA of his or her intent to provide such emergency treatment.

In addition to a waiver, a physician who wishes to prescribe buprenorphine or another approved opioid for the treatment of addiction in an office setting must have a valid DEA registration number and a DEA identification number that specifically authorizes him or her to engage in office-based opioid treatment.

Prescription Requirements: Prescriptions for buprenorphine and buprenorphine/naloxone must include full identifying information for the patient, including his or her name and address; the drug name, strength, dosage form, and quantity; and directions for use. Prescriptions for buprenorphine and/or buprenorphine/naloxone must be dated as of, and signed on, the day they are issued (21 CFR 1306.05[a]). Both the physician's regular DEA registration number and the physicians' DATA 2000 identification number (which begins with the prefix X) must be included on the prescription (21 CFR 1301.28 [d][3]). [39]

For detailed guidance, physicians are referred to the Buprenorphine Clinical Practice Guidelines published by CSAT/SAMHSA, which can be accessed at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

State Medical Board Requirements: The (state medical board) will determine the appropriateness of a particular physician's prescribing practices on the basis of that physician's overall treatment of patients and the available documentation of treatment plans and outcomes. The goal is to provide appropriate treatment of the patient's opioid addiction (either directly or through referral), while adequately addressing other aspects of the patient's functioning, including co-occurring medical and psychiatric conditions and pressing psychosocial issues.

SECTION II: GUIDELINES

Multiple studies have shown that opioid addiction treatment with buprenorphine can be successfully integrated into office practice by physicians who are not addiction specialists. In such studies, patient outcomes are comparable to or better than outcomes of patients treated in specialized clinics [40-48]. However, as in the treatment of any medical disorder, physicians who choose to offer addiction treatment need to understand the nature of the underlying disorder, the specific actions of each of the available medications (as well as any associated contraindications or cautions), and the importance of careful patient selection and monitoring [40].

The Board has adopted the following guidelines for the treatment of opioid addiction in office- based settings. The guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of accepted professional practice.

Physician Qualifications: The diagnosis and medical management of opioid addiction should be based on current knowledge and research, and should encompass the use of both pharmacologic and nonpharmacologic treatment modalities. Thus, before beginning to treat patients for opioid addiction, the physician should become knowledgeable about opioid addiction and its treatment, including the use of approved pharmacologic therapies and evidence-based nonpharmacologic therapies [49-50].

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As described in the Preamble, physicians who wish to prescribe or dispense buprenorphine for the treatment of opioid addiction must meet the requirements of DATA 2000 [51], which are that the physician must be licensed in the state, have a valid DEA controlled substances registration and identification number, comply with federal and state regulations applicable to controlled substances, and hold a current waiver [39].

In addition to these requirements, DATA limits the number of patients that a physician is permitted to treat at any one time to 30 in the first year after obtaining a waiver, and to 100 patients thereafter. The physician who wishes to treat more than 30 patients after the first year must file an application with the DEA to extend his or her waived capacity to do so [39,51].

DATA 2000 also requires that a physician who wishes to treat opioid addiction with buprenorphine in an office setting must demonstrate a capacity to offer (or refer patients for) appropriate counseling and other ancillary services, and to recognize when those services are needed [51].

Physicians are not permitted to delegate the prescribing of buprenorphine to non-physicians. Even physicians who hold DEA registrations to prescribe controlled substances for other conditions are not allowed to prescribe buprenorphine for the treatment of addiction unless they meet the DATA requirements and hold a waiver. However, non-physician professionals can play an active role in evaluating and monitoring patients and providing other elements of care, in accordance with state regulations and rules governing physician supervision [52].

Physicians should consult the DEA regulations (Title 21 US Code of Controlled Substances Act 1301.28 and 21 USC 823 9GO(2)(G) [51] and the resources available on the DEA's website (at www.deadiversion.usdoj.gov), as well as (*any relevant documents issued by the state medical board*) for specific rules governing the issuance of prescriptions for controlled substances.

Patient Assessment: The objectives of the patient assessment are to determine a given patient's eligibility for treatment, to provide the basis for a treatment plan, and to establish a baseline measure for use in evaluating a patient's response to treatment. Accordingly, the assessment should be designed to achieve the following [49,53]:

- Establish the diagnosis of opiate addiction, including the duration, pattern and severity of opioid misuse; the patient's level of tolerance; results of previous attempts to discontinue opioid use; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid use and current withdrawal status.
- Document the patient's use of other substances, including alcohol and other drugs of abuse.
- Identify comorbid medical and psychiatric conditions and disorders and to determine how, when and where they will be addressed.
- Screen for communicable diseases and address them as needed. Evaluate the patient's level of physical, psychological and social functioning or impairment;
- Assess the patient's access to social supports, family, friends, employment, housing, finances and legal problems.
- Determine the patient's readiness to participate in treatment.

Assessment usually begins at the time of the patient's first office visit and continues throughout treatment. While the evidence is not conclusive, consensus opinion is that an initial patient assessment is of higher quality when it includes a medical and psychiatric history, a substance abuse history, and an evaluation of family and psychosocial supports, as well as a pregnancy test for all women of childbearing age. The physical examination,

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if performed during the initial assessment, can be focused on evaluating neurocognitive function, identifying sequelae of opioid addiction, and looking for evidence of severe hepatic dysfunction [10,53].

As a general rule, a urine drug screen or other toxicologic screen should be part of the initial evaluation to confirm recent opioid use and to screen for unreported use of other drugs. Ideally, this drug screen should include all opioids commonly prescribed and/or misused in the local community, as well as illicit drugs that are available locally [54]. It also is advisable to access the patient's prescription drug use history through the state's prescription drug monitoring program (PDMP), where available, both to confirm compliance in taking prescribed medications and to detect any unreported use of other prescription medications.

Information from family members and significant others can provide useful additional perspectives on the patient's status, as can contact with or records from clinicians who have treated the patient in the past [46].

Treatment Planning: There is an emerging consensus among addiction experts that treatment medications such as buprenorphine should be considered as an option for every opioid-addicted patient [38]. However, the failure to offer medication-assisted treatment does not in itself constitute substandard care. No single treatment is appropriate for all persons at all times. Therefore, an individualized treatment plan is critical to the patient's ultimate success in returning to productive functioning [5,54].

The treating physician should balance the risks and benefits of medication-assisted treatment in general – and treatment with buprenorphine in particular – against the risks associated with no treatment or treatment without medication [4,55]. The various options include:

- Simple detoxification and no other treatment;
- Detoxification followed by antagonist therapy;
- Counseling and/or peer support without medication-assisted therapy;
- Referral to short- or long-term residential treatment;
- Referral to an OTP for methadone maintenance; or
- Treatment with buprenorphine or buprenorphine/naloxone in an office-based setting.

Patients may be suitable candidates for treatment with buprenorphine even if past treatment episodes were not successful [50].

If a decision is made to offer the patient treatment with buprenorphine, the risks associated with possible misuse and diversion are such that the combination buprenorphine/naloxone product is preferable for most patients [38,40,43]. The monoproduct should be used only rarely except in pregnant women, for whom it is the preferred formulation [53].

Psychosocial and other nonpharmacologic interventions often are useful components of treatment [48,50,55]. Such interventions typically work best in conjunction with medication-assisted therapies; in fact, there is some evidence that the combination of pharmacologic and non-pharmacologic interventions may be more effective than either approach used alone [56]. As noted earlier, the ability to offer patients psychosocial supports, either on-site or through referral, is a requirement of the DATA 2000 legislation.

Educating the Patient: Every patient to whom buprenorphine is prescribed should be cautioned to follow the directions exactly, particularly during the induction stage. Critical issues involve when to begin dosing, the frequency of subsequent doses, and the importance of avoiding the use of any other illicit or prescription opioid.

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Concurrent use of non-opioid sedating medications or over-the-counter products also should be discussed, and patients should be advised to avoid the use of alcohol [7].

Patients should be cautioned about potential sedation or impairment of psychomotor function during the titration phase of induction with buprenorphine [57].

Finally, because opioids can contribute to fatal overdoses in individuals who have lost their tolerance to opioids or in those who are opioid-naïve (such as a child or other family member), proper and secure storage of the medication must be discussed. Particularly where there are young people in the patient's home, the subject of safe storage and use should be revisited periodically throughout the course of treatment, with the discussions documented in the patient record [57].

Informed Consent: Although agonist medications such as buprenorphine clearly are effective for the treatment of opioid dependence, they do entail a substitute dependence on the prescribed medication to replace the prior dependence on the misused opioid [46]. This issue should be thoroughly discussed with the patient in terms of potential risks and benefits as part of the informed consent process. Patients and family members often are ambivalent about agonist treatment for this reason and their concerns may influence subsequent treatment choices. Possible topics of discussion include the difference between addiction and physical dependence (including an explanation of why agonist therapy is not simply “switching one addiction for another”), the likelihood of relapse with and without medication-assisted treatment, the projected duration of treatment, the potential for successfully tapering from agonist therapy at some point in the future, and the role and importance of adjunctive therapies such as counseling and peer support. With the patient's consent, this conversation could include family members, significant other(s), or a guardian [7].

A written *informed consent* document, discussed with and signed by the patient, can be helpful in reinforcing this information and establishing a set of “ground rules.” The practitioner should document the informed consent in the patient's medical record [58].

Treatment Agreement: The terms of treatment agreements vary widely, but typical provisions include an acknowledgement of the potential benefits and risks of therapy and the goals of treatment; identification of one provider and one pharmacy from whom the patient will obtain prescriptions; authorization to communicate with all providers of care (and sometimes significant others) and to consult the state's Prescription Drug Monitoring Program (PDMP), if one is available; other treatments or consultations in which the patient is expected to participate, including recovery activities; avoidance of illicit substances; permission for drug screens (of blood, urine, saliva or hair/nails) and pill counts as appropriate; mechanisms for prescription renewals, including exclusion of early renewals; expected intervals between office visits; and specification of the conditions under which therapy will be continued or discontinued [59].

The agreement also should include a statement instructing the patient to stop taking all other opioid medications unless explicitly told to continue. Such a statement reinforces the need to adhere to a single treatment regimen. Inclusion in the agreement of a pharmacy address and telephone number reinforces to the patient the importance of using one pharmacy to fill prescriptions.

Finally, the treatment agreement should set forth the objectives that will be used to evaluate treatment success, such as freedom from intoxication, improved physical and psychosocial function, and adherence to the treatment regimen [59].

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Copies of the treatment agreement and informed consent should be provided to the patient and all other care providers, and file in the patient's medical record. The agreement should be reviewed regularly and adjusted as needed [58].

Induction, Stabilization, and Follow-up: The goal of induction and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues or markedly reduces the use of other opioids without experiencing withdrawal symptoms, significant side effects, or uncontrollable craving for the drug of abuse [60].

The initial induction process requires a higher degree of attention and monitoring than the later maintenance phase [59]. Particular attention should be given to the timing of the initial doses so as to minimize untoward outcomes. Withdrawal symptoms can occur if either too much or too little buprenorphine is administered (i.e., spontaneous withdrawal if too little buprenorphine is given, precipitated withdrawal if buprenorphine is administered while the opioid receptors are substantially occupied by an opioid agonist). Undermedication or overmedication can be avoided through a flexible approach to dosing, which sometimes requires higher doses of treatment medication than expected, and by taking into account patient-reported symptoms [61].

The stabilization phase is focused on finding the right dose for an individual patient. A patient is stabilized when the dose allows him or her to conduct activities of daily living and to be aware of his or her surroundings without intoxication and without suffering withdrawal or distressing drug craving [61-62]. Although there is no precise way to determine in advance what the optimal dose for a particular patient will be [63], most patients are likely to stabilize on eight to 24 mg of buprenorphine per day, although some may need doses of up to 32 mg per day [64].

Buprenorphine blood concentrations stabilize after approximately seven days of consistent dosing [17]. If withdrawal symptoms subsequently emerge during any 24-hour dosing interval, the dose is too low and should be increased [64]. Medical factors that may cause a patient's dose requirements to change include (but are not limited to) starting, stopping, or changing the dose of other prescription medications; onset and progression of pregnancy; onset of menopause; progression of liver disease; and significant increase or decrease in weight [61].

Dose adjustments generally can be made in increments of 2 mg/day. Because buprenorphine has a long plasma half-life and an even longer duration of action at the mu opioid receptor, five days should be allowed between dose adjustments [53].

Patient adherence to medication regimens and session appointments is associated with better treatment outcomes, and regular monitoring can help patients plan for possible obstacles and teach them ways to handle any problems that occur [65]. Regular assessment of the patient's level of engagement in treatment and the strength of the therapeutic alliance allows for modification of the treatment plan and level of care in response to the patient's progress or lack thereof [56].

Early in treatment, medications should be prescribed and follow-up visits scheduled commensurate with the patient's demonstrated stability. Until patients have shown the ability to be compliant with the treatment plan and responsible with their medication supplies, and have discontinued high-risk behaviors and associated diversion risks, they should be seen more frequently and given supplies of medication only as needed until the next visit. As patients demonstrate stability and the risk declines, they can be seen less often (typically once a month) and prescribed larger supplies of medication [46,59].

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Patient monitoring during follow-up visits should address the following points [46,54,59,66]:

- Whether the patient continues to use alcohol or illicit drugs, or to engage in non-medical use of prescription drugs;
- The degree of compliance with the treatment regimen, including the use of prescribed medications as directed;
- Changes (positive or negative) in social functioning and relationships;
- Avoidance of high-risk individuals, situations, and diversion risk;
- Review of whether and to what degree the patient is involved in counseling and other psychosocial therapies, as well as in self-help activities through participation in mutual support meetings of groups such as Narcotics Anonymous;
- The presence or absence of medication side effects; and
- The presence or absence of medical sequelae of substance use and its remission.

The patient's compliance with regard to use of prescribed buprenorphine and avoidance of other opioids should be monitored through patient report, regular toxicologic analyses [54], reports from significant others, and regular checks of the state's Prescription Drug Monitoring Program, where available [46].

Individuals being treated with medication-assisted therapy often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning. Such positive changes should be acknowledged and reinforced by the prescribing physician whenever possible. Reducing the frequency of monitoring visits, with their associated costs, and increasing the patient's responsibility for medications are examples of how positive, responsible behaviors can be reinforced [46,67].

Adjusting the Treatment Plan: Treatment outcomes typically are positive for patients who remain in treatment with medication-assisted therapies such as buprenorphine [46,68]. However, some patients struggle to discontinue their misuse of opioids or other drugs, are inconsistent in their compliance with treatment agreements, or succeed in achieving some therapeutic goals while not doing well with others [69].

Behaviors that are not consistent with the treatment agreement should be taken seriously and used as an opportunity to further assess the patient and adapt the treatment plan as needed. In some cases, where the patient's behavior raises concerns about safety or diversion of controlled medications, there may be a need to refer the patient for treatment in a more structured environment (such as an OTP) [69]. However, behavior that violates the treatment agreement or a relapse to nonmedical drug use do not constitute grounds for automatic termination of treatment. Rather, they should be taken as a signal to reassess the patient's status, to implement changes in the treatment plan (as by intensifying the treatment structure or intensity of services), and to document such changes in the patient's medical record [46].

Whenever the best clinical course is not clear, consultation with another practitioner may be helpful. The results of the consultation should be discussed with the patient and any written consultation reports added to the patient's record [59].

Patients with more serious or persistent problems may benefit from referral to a specialist for additional evaluation and treatment. For example, the treatment of addiction in a patient with a comorbid psychiatric disorder may be best managed through consultation with or referral to a specialist in psychiatry or addiction

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psychiatry [10]. In other instances, aberrant or dysfunctional behaviors may indicate the need for more vigorous engagement in peer support, counseling, or psychotherapies, or possibly referral to a more structured treatment setting [56].

Preventing and Managing Relapse: Relapse always should be ruled out as a reason for loss of stability [56]. Relapse to drug use has been described as “an unfolding process in which the resumption of substance abuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli” [70]. It rarely is caused by any single factor; rather, it is a dynamic process in which the patient’s readiness to change interacts with other external and internal factors [59, 71]. Patients in relapse vary in the quantity and frequency of their substance use, as well as the accompanying medical and psychosocial sequelae.

Clinical strategies to prevent and address relapse generally encompass the following steps [10,61,71]:

- Identify environmental cues and stressors that act as relapse triggers.
- Help patients develop skills to cope with or manage negative emotional states;
- Help the patient work toward a more balanced lifestyle.
- Understand and manage craving.
- Identify and interrupt lapses and relapses. Patients should have an emergency plan to address a lapse so that a full-blown relapse can be avoided. If relapse does occur, be prepared to intervene.
- Develop a recovery support system. Families are more likely to provide such support if they are engaged in the treatment process and have an opportunity to ask questions, share their concerns and experiences, and learn practical coping strategies and behaviors to avoid.

It should be noted that lack of adherence to pharmacologic regimens occurs in a substantial portion of patients being treated for addiction, with some studies reporting that a majority of patients fail to follow the treatment plan at some point in their care. Retention in treatment also is a problem [72]. This is no different from the challenges encountered in managing any chronic disease, such as diabetes, hypertension, epilepsy, and other potentially life-threatening disorders [46], and is not an indicate to terminate treatment.

Patients who continue to misuse opioids after sufficient exposure to buprenorphine and ancillary psychosocial services or who experience continued symptoms of withdrawal or craving at 32 mg of buprenorphine should be considered for therapy with methadone [5,7,52,73].

Duration of Treatment: Available evidence does not support routinely discontinuing medication-assisted treatment once it has been initiated and the patient stabilized. However, this possibility frequently is raised by patients or family members. When it is, the physician and patient should carefully weigh the potential benefits and risks of continuing medication-assisted treatment and determine whether buprenorphine therapy can be safely discontinued [74].

Studies indicate that opioid-dependent patients are at high risk for relapse when medication-assisted therapy is discontinued, even after long periods of stable maintenance [7,74]. Research also shows that longer duration of treatment is associated with better treatment outcomes [75]. Such long-term treatment, which is common to many medical conditions, should not be seen as treatment failure, but rather as a cost-effective way of prolonging life and improving the quality of life by supporting the natural and long-term process of change and recovery. Therefore, the decision to discontinue treatment should be made only after serious consideration of the potential consequences [3,7-8].

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As with other disease processes, the continuation of medication-assisted treatment should be linked directly to the patient's response (for example, his or her attainment of treatment goals). Relapse risk is highest in the first six to 12 months after initiating abstinence, then diminishes gradually over a period of years. Therefore, it is reasonable to continue treatment for at least a year if the patient responds well [3,7,10].

If buprenorphine is discontinued, the patient should be tapered off the medication through use of a safely structured regimen, and followed closely [46]. It may be necessary to reinstate pharmacotherapy with buprenorphine or a different medication or other treatment services if relapse appears imminent or actually occurs [59]. Such relapse poses a significant risk of overdose, which should be carefully explained to the patient [74]. Patients also should be assured that relapse need not occur for them to be reinstated to medication-assisted therapy [46].

Medical Records: Accurate and up-to-date medical records protect both the physician and the patient. In the event of a legal challenge, detailed medical records that document what was done and why are essential elements of the practitioner's defense [75-76].

A written informed consent and a treatment agreement articulating measurable treatment goals are key documents. The treatment agreement should be updated as new information becomes available. Both the informed consent and treatment agreement should be carefully explained to the patient and signed by both the patient (or guardian) and the treating physician [76]. The medical record should clearly reflect the decision-making process that resulted in any given treatment regimen.

The first page of the patient's chart should contain a summary of the information needed to understand the treatment plan, even without a thorough knowledge of the patient. This includes some demographic data, the names of other practitioners caring for the patient, all diagnoses, therapies employed, and a list of all medications prescribed. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [10,76].

Other documents that should be part of the medical record, where available, include [10,74,76]:

- Diagnostic assessments, including the patient history, physical examination, and any laboratory tests ordered, with their results;
- Actual copies of, or references to, medical records of past hospitalizations or treatments by other providers;
- The treatment plan, treatment agreement, and informed consent;
- Authorization for release of information to other treatment providers;
- Documentation of discussions with and consultation reports from other health care providers; and
- Medications prescribed and the patient's response to them, including any adverse events.

The medical record also must include all prescription orders, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [75].

Monitoring visits should be carefully documented in the medical record, along with any subsequent changes to the treatment plan [10,76]. The patient's record also should contain documentation of steps taken to prevent the diversion of treatment medications, including any communications with other treating physicians and, where

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available, use of the state's prescription drug monitoring program to verify that all prescribed medicines have been obtained and that no other prescriptions for controlled drugs have been dispensed without the physician's knowledge [77-78].

Records (including drug logs, if buprenorphine is dispensed in the office) should be up-to-date and maintained in an accessible manner, readily available for review [75]. Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [10,74,76].

Physicians who treat patients for addiction must observe the special confidentiality requirements of federal law 42 CFR, Part 2, which addresses the confidentiality of patients being treated for alcohol or drug addiction. 42 CFR includes a prohibition against release of records or other information without the patient's consent or a valid court order, or in cases of a bona fide medical emergency, or in the course of mandatory reporting of child abuse [7].

SECTION III: DEFINITIONS

Accurate use of terminology is essential to understanding office-based treatment of opioid addiction [70]. However, terminology in this area is changing. For many years, the most commonly used terms have been "drug abuse" and "drug dependence," with the latter indicating a severe condition considered synonymous with the term "addiction" (the chronic brain disease). The terms "abuse" and "dependence," in use since the third edition of the *Diagnostic and Statistical Manual of Mental Disorders* [79] will be replaced in the forthcoming fifth edition [80] by the term "substance use disorder." Other new terms include "opioid use" for the activity of using opioids benignly or pathologically, and "opioid use disorder" for the disease associated with compulsive, out-of-control use of opioids.

For the purposes of this Model Policy, the following terms are defined as shown.

Abuse: The definition of "abuse" varies widely, depending on the context in which it is used and who is supplying the definition. For example, in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* [81], the American Psychiatric Association defines drug abuse as "a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors." The *DSM V*, to be published in 2013, replaces the term "abuse" with "misuse" [80].

Addiction: Addiction is widely defined as a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm [56]. (As discussed below, physical dependence and tolerance are normal physiological consequences of extended opioid therapy and are not the same as addiction.)

A recent definition of addiction, adopted by the American Society of Addiction Medicine in 2011, reads as follows: "Addiction is a primary, chronic disease of ~~brain reward, motivation, memory and related~~ circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal

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relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death” [82].

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act [75], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs [83]. Civil and criminal sanctions for serious violations of the statute are part of the government’s drug control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA [75], confers responsibility for scheduling controlled substances on the FDA and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other, but that both are necessary to ensure the public welfare. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

Most opioids are classified as Schedule II or III drugs under the CSA, indicating that they have a high potential for abuse and a currently accepted medical use in treatment in the U.S., and that abuse of the drug may lead to psychological or physical dependence [75]. (Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled substances have some potential for abuse.)

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [76]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (ICD- 10) of the World Health Organization (WHO) [84] and the *Diagnostic and Statistical Manual* (DSM) of the American Psychiatric Association [80,81]. In the DSM-IV-TR, a diagnosis of “substance dependence” meant addiction. In the upcoming DSM V, the term dependence is reestablished in its original meaning of physiological dependence; when symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings [80].

It may be important to clarify this distinction during the informed consent process, so that the patient understands that physical dependence and tolerance are likely to occur if opioids are taken regularly for a period of time, but the risk of addiction is relatively low unless the patient has additional risk factors. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid” [8].

Detoxification: Detoxification (also termed “medically supervised withdrawal”) refers to a gradual reduction, or tapering, of a medication dose over time, under the supervision of a physician, to achieve the elimination of tolerance and physical dependence [85].

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“Detoxification” is a legal and regulatory term that has fallen into disfavor with some in the medical community; indeed, some experts view “detoxification” as a misnomer because many abusable drugs are not toxic when administered in proper doses in a medical environment [86].

Diversion: The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [75].

Pharmaceuticals that make their way outside this closed system are said to have been “diverted” from the system, and the individuals responsible for the diversion (including patients) are in violation of the law. The degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [30,87].

Maintenance Treatment: Maintenance treatment involves the dispensing or administration of an opioid medication (such as methadone or buprenorphine) at a stable dose and over a period of 21 days or more, for the treatment of opioid addiction. When maintenance treatment involves the use of methadone, such treatment must be delivered in an Opioid Treatment Program (OTP). However, maintenance treatment with buprenorphine may be delivered in either an OTP or a medical office by a properly credentialed physician [7].

Medication-Assisted Treatment (MAT): MAT is any treatment for opioid addiction that includes a medication (such as methadone, buprenorphine, or naltrexone) that is approved by the FDA for opioid detoxification or maintenance treatment. MAT may be provided in a specialized OTP or, for buprenorphine or naltrexone, in a physician’s office or other health care setting [7,55].

Misuse: The term misuse (also termed non-medical use) incorporates all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [56].

Opioid: An opioid is any compound that binds to an opioid receptor. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [7,51,83]. Most physicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader, more appropriate term because it includes the entire class of agents that act at opioid receptors in the nervous system, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM); drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for, including the most common currently used and misused prescription opioids, may well be present in the sample that was analyzed.

Opioid agonists are compounds that bind to the mu opioid receptors in the brain, producing a response that is similar in effect to the natural ligand that would activate it. With full mu opioid agonists, increasing the dose produces an more intense opioid effect. Most opioids that are misused, such as morphine and heroin, are full mu opioid agonists, as is methadone.

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Opioid partial agonists occupy and activate the opioid receptors, but the activation they produce reaches a plateau, beyond which additional opioid doses do not produce a greater effect. It should be noted that the plateau (or “ceiling effect”) may limit a partial agonist’s therapeutic activity as well as its toxicity. Buprenorphine is a partial mu opioid agonist.

Opioid antagonists bind to and block the opioid receptors and prevent them from being activated by an opioid agonist or partial agonist. Naltrexone and naloxone both are opioid antagonists, and both can block the effect of opioid drugs.

Opioid Treatment Program (OTP) (sometimes referred to as a “methadone clinic” or “narcotic treatment program”): An OTP is any treatment program certified by SAMHSA in conformance with 42 Code of Federal Regulations (CFR), Part 8, to provide supervised assessment and medication- assisted treatment of patients who are addicted to opioids. An OTP can exist in a number of settings, including intensive outpatient, residential, and hospital facilities. Treatments offered by OTPs include medication-assisted therapy with methadone, buprenorphine or naltrexone, as well as medically supervised withdrawal or detoxification, accompanied by varying levels of medical and psychosocial services and other types of care. Some OTPs also can provide treatment for co-occurring mental disorders [58].

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential [88]. As used in the ASAM Patient Placement Criteria, “recovery” refers to the overall goal of helping a patient achieve overall health and well-being [56]. SAMHSA’s 10 guiding principles recognize that recovery [89]:

1. Emerges from hope;
2. Is person-driven;
3. Occurs via many pathways;
4. Is holistic;
5. Is supported by peers and allies;
6. Is supported through relationship and social networks
7. Is culturally-based and influenced;
8. Is supported by addressing trauma;
9. Involves individual, family and community strengths and responsibility;
10. Is based on respect.

Relapse: Relapse has been variously defined as “a breakdown or setback in a person’s attempt to change or modify any target behavior” and as “an unfolding process in which the resumption of substance misuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli” [70]. Relapse rarely is caused by any single factor and often is the result of an interaction of physiologic and environmental factors [59].

The term *lapse* (sometimes referred to as a *slip*) refers to a brief episode of drug use after a period of abstinence. A lapse usually is unexpected, of short duration, with relatively minor consequences, and marked by the patient’s desire to return to abstinence. However, a lapse also can progress to a full-blown relapse, marked by sustained loss of control [56].

Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug’s effects over time [76]. Tolerance may occur both to an opioid’s

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analgesic effects and to its unwanted side effects, such as respiratory depression, sedation, or nausea. Most investigators agree that absolute tolerance to the analgesic effects of opioids does not occur. In general, tolerance to the side effects of opioids develops more rapidly than does tolerance to the drug's analgesic effects.

Tolerance may or may not be evident during treatment with opioids and is not the same as addiction [70].

Trial Period: A period of time, which can last weeks or even months, during which the efficacy of a medication or other therapy for the treatment of addiction is tested to determine whether the treatment goals can be met. If the goals are not met, the trial should be discontinued and an alternative approach (i.e., a different medication or non-pharmacologic therapy) adopted [76].

Waiver: A documented authorization from the Secretary of Health and Human Services, issued by SAMHSA under the DATA 2000 regulations, that exempts a qualified physician from the rules applied to OTPs and allows him or her to use buprenorphine for the treatment of addiction in office-based practice [51].

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