Nursing Pain Practice: The Need to Consider Policies Governing Prescriptive Authority

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Conflict of Interest Disclosure

- Authors’ Conflicts of Interest:
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Policies Affecting the Regulatory Environment for Pain Management

- Federal controlled substances legislation (Controlled Substances Act) and regulations (Code of Federal Regulations)
- State legislation and regulations
  - Controlled substances
  - Medical and pharmacy practice
  - Intractable Pain Treatment Acts, etc.
- Official state regulatory agency guidelines and policy statements
Why State Policies are Important

- Authorize healthcare practice, medical use of drugs
- Define unprofessional conduct, and prohibit unauthorized distribution of controlled substances
- Restrict prescriptive practices

*Policies can also…*
- Recognize value of controlled substances and pain management
- Encourage pain management
- Address barriers (e.g., concern about regulatory scrutiny)

Principle of Policy Change

*Balance*

- Opioids can be effective, are indispensable
  - Must be available to relieve pain and suffering
- Opioids have a potential for abuse
  - Must be controlled
- “Controlled substance” label does not change medical value of medications
- Efforts to prevent abuse must not interfere with medical practice and patient care

International Sources

- World Health Organization
- International Narcotics Control Board
- UN Commission on Narcotic Drugs
- UN Economic and Social Council
- UN Office on Drugs and Crime
Imperative to Achieve Balance
U.S. Sources

- Institute of Medicine
- National Cancer Institute
- National Institutes of Health
- American Medical Association
- American Cancer Society
- Alliance of State Pain Initiatives
- Center for Disease Control and Prevention
- White House Office of National Drug Control Policy
- Federation of State Medical Boards
- National Association of Attorneys General
- Drug Enforcement Administration

Law Enforcement on the Principle of Balance

“...the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care…”

U.S. Drug Enforcement Administration
2001 Joint Policy Statement

Policy Change/Adoption

- Add language that promotes safe and effective pain relief and palliative care
- Repeal or avoid potential barriers
  - Severe restrictions
  - Archaic terminology
  - Ambiguous requirements
- Content and clarity of policy is essential
  - Unintended consequences
  - Example – Prescription Monitoring Programs

(+ Criteria: Policy Language

Enhance Pain Management

1. Controlled substances necessary for the public health
2. Pain management is general healthcare practice
3. Medical use of opioids is legitimate professional practice
4. Pain management is encouraged
5. Addresses practitioners’ concerns about regulatory scrutiny
6. Prescription amount is insufficient to determine legitimacy
7. Addiction not confused with physical dependence/tolerance
8. Other positive language
   - Category A: Issues related to healthcare professionals
   - Category B: Issues related to patients
   - Category C: Regulatory or policy issues

(- Criteria: Policy Language

Impede Pain Management

9. Opioids are relegated as last resort
10. Opioids are outside legitimate practice
11. Addiction is confused with physical dependence/tolerance
12. Medical decisions are unduly restricted
   - Restrictions based on patient characteristics
   - Mandates consultation for all patients
   - Restricts quantity prescribed or dispensed
   - Undue prescription limitations
13. Prescription validity is restricted
14. Additional undue prescription requirements
15. Other restrictive language
16. Ambiguous language
  Category A: Arbitrary standards for legitimate prescribing
  Category B: Unclear intent contributing to misinterpretation
  Category C: Conflicting or inconsistent policies or provisions

Why a Progress Report Card?
- Simplifies complex evaluation
- Single index of quality to compare states
- Positive context for critical evaluation
- Simplifies measurement of progress
- Supports goal-setting
- Increases visibility of the need to improve pain policy
Distribution of Grades 2000

Number of States

FD  D  D+  C  C+  B  B+  A


Distribution of Grades 2000 & 2012

Number of States

FD  D  D+  C  C+  B  B+  A


National Council of State Boards of Nursing

2007 Policy:
Statement on the Regulatory Implications of Pain Management (May, 2007)
National Council of State Boards of Nursing

**2008 Policy:**
Report of Disciplinary Resources Committee
(September, 2008, pp. 114-324)

The Pearson Report

**2009 Report:**
The American Journal for Nurse Practitioners
(February, 2009, pp. 1-95)

Independent Prescribing Authority (18 states)

- Alaska
- Arizona
- Colorado
- DC
- Hawaii
- Idaho
- Iowa
- Maine
- Maryland
- Montana
- New Hampshire
- New Mexico
- North Dakota
- Oregon
- Rhode Island
- Vermont
- Washington
- Wyoming

Prescribing Requires Formal Physician Involvement
(16 states)
- California
- Connecticut
- Delaware
- Indiana
- Kansas
- Massachusetts
- Minnesota
- Mississippi
- Nebraska
- Nevada
- New Jersey
- New York
- Tennessee
- Utah
- Virginia
- Wisconsin

Prescribing Requires Formal Physician Involvement/Other Limits
(8 states)
- Illinois
- Kentucky
- Louisiana
- Michigan
- North Carolina
- Ohio
- Pennsylvania
- South Dakota

No Prescribing Authority
(9 states)
- Alabama
- Arkansas*
- Florida
- Georgia*
- Missouri*
- Oklahoma*
- South Carolina*
- Texas*
- West Virginia*

* No prescribing authority for Schedule II medications only
Pain Management Policies
\( (n=49) \)

Nursing Regulatory Pain Policy
\( (n=22) \)

Potential Policy Barriers to Nursing Pain Management Practice

- Prescribing authority is prohibited
- Formal physician involvement (??)
- Additional requirements/limitations
  - Supply limits (e.g., 24 hours, 72 hours, 7 days, 30 days)
  - Not for chronic pain (including cancer pain)
- Ambiguous language
- Recent, not widespread, regulatory guidance

Improving Clinical Practice and Patient Care Relating to Pain Care

- Non-policy actions or resources
- Mitigating abuse/diversion extends beyond prescribing practices
- Unevaluated policies
- Policy content ≠ stated intent
- Perceptions ≠ policy content
- Policy change ≠ final step

New York State of Mind Case Example

Nurse Practitioner Association NYS Map
NYS Scope of Practice

- NYS requires a mandatory collaborative written practice agreement (granted 1988)
- NP’s have full prescriptive authority in NYS (acquired in 1992)
- NP’s in NYS can prescribe Schedule II – V controlled substances

NYS Scope of Practice

- Requirements for NPs to practice in NYS
  - Mandated to have a written practice agreement with a specific physician and follow "approved practice protocols"
  - Mandates a retrospective quarterly chart review (can be as little as 1 chart per quarter) by collaborating physician
  - Required to submit a Verification of Practice Protocol Form (4NP) when NPs begin their first practice situation. Once the NP moves to another situation, there is no requirement that a new 4NP form be filed with the SED (State Education Department). However, it is required that a current collaborative agreement be maintained at the practice site.

NYS Scope of Practice

- The State Education Department is responsible for licensing and regulating professional conduct
- The NYS legislature makes legislation that determines the ability/limits of NP practice
Section 95 amends Section 6902(3) of the NY Education Law by adding:

No written practice agreement or written practice protocol shall be required for NPs who provide ONLY primary care services as determined by the Commissioner of Health and who demonstrate to the Dept. of Health in the manner and means required by such department in consultation with the Education Dept., that it is not reasonable to require such agreement or protocols.

This portion of the budget bill was not included in the final approved NYS 2013-14 Budget.

NP Modernization Act
(A.4846A Gottfried/S.4611A Young)

Allows the practice of registered professional nursing by a certified Nurse Practitioner having practiced greater than 3,600 hours to include diagnosis and treatment without a written collaborative practice agreement with a physician.

Effect: This bill when enacted will remove the requirement of a written collaborative practice agreement between a NP and a physician. (For some) NPs will still need to have collaborative relationships with one or more physicians. (For some others) NP practice will be autonomous (it was) and no longer dependent on a physician agreeing to perform patient chart review of the NPs patients.
The NPA monitors hundreds of bills each legislative session to track for potential impact on NP practice

- ISTOP: Internet System for Tracking Over Prescribing to create a real time database for prescribers and pharmacists to use to combat prescriber shopping and Rx drug abuse.
- Effective August 27, 2013.
- NPs and all prescribers are required to participate in the PMP.
- The penalties for non-compliance include fines of up to $5,000 per occurrence.

What do we know about the relationship between state policies governing APN practice and the impact on safe pain management practices?

Impact of individual state policies on APN prescribers ability to deliver effective pain management

- Question: “Do APN’s in states with full RX and practice authority have different attitudes and behaviors regarding opioids in the treatment of chronic pain than those who do not”?
- Study Phases:
  1. initial questionnaire development and face validity determination
  2. questionnaire pilot testing and refinement
  3. assessment of APN’s attitudes and behaviors concerning safe practice when prescribing opioids to treat chronic pain
Focus Group

- In many states, APNs cannot prescribe controlled medicines without entering into a formal collaborative relationship with a physician. To what extent do you believe that this requirement of a formal collaborative relationship inhibits nurses’ prescribing practices?
- What would you consider to be barriers, if any, in your state that can hinder APNs’ role in providing appropriate pain management?
- Do you believe that the nursing regulatory board in your state provides sufficient guidance about treating chronic pain?

Focus Group

- Are you aware of any resources that are available to provide information about current state pain or policy issues?
- What are some ways that the DEA recommends to safeguard controlled substance prescriptions?
- To what extent do APNs’ prescribing practices contribute to abuse and diversion of controlled medicines?
- Can you name some Federal and state responses to controlled substances abuse and diversion?

Next Steps

Instrument Development

- Advanced Practice Nurses Attitudes and Behaviors about Safe Practice of Opioid Prescribing for Chronic Pain Survey (Bruckenthal, Gilson, 2013, in development)
  - Core Competencies for Pain Management: Results of an Interprofessional Consensus Summit. (Fahman, S. et al. 2013)
Advanced Practice Nurses Attitudes and Behaviors about Safe Practice of Opioid Prescribing for Chronic Pain Survey

- 31 item, 5-point Likert Scale
  - Domain 1: Multidimensional Nature of Pain
  - Domain 2: Pain assessment and Measurement
  - Domain 3: Management of Pain
  - Domain 4: Clinical Conditions
  - Domain 5: Regulatory Considerations

Content Validity Index (Polit & Beck, 2006)

- Round 1:
  - I-CVI = .83
  - S-CVI/AVE = .83
  - S-CVI/UA = .54
- Rater proportion relevant rating:
  - Rater 1 = .83
  - Rater 2 = .91
  - Rater 3 = .94
  - Rater 4 = .71
  - Rater 5 = .80
- Round 2:
  - S-CVI/UA = .80

Implications for Practice

- Enhanced educational opportunities for APN's
- Improved patient outcomes
- Provide evidence for future policy development surrounding safe and effective pain management
**Take home message:**

If you are not at the table you are on the menu

- Original author unknown