From: Rocco, Phil
Sent: Tuesday, December 27, 2005 4:43 PM
To: Gaither, Amy
Attachments: 120rule.doc; abuse&use.doc; mythofadd.ppt

NJ 120 rule,

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The Role of the Board

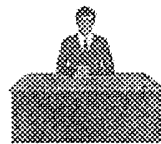
The New Jersey State Board of Pharmacy, the oldest professional licensing board in the state, was established in 1877. It was established to protect the public by regulating the dispensing of drugs. This purpose has evolved and expanded over the past century. Today, the Board functions to protect the health, safety, and welfare of the people of New Jersey by promulgating regulations that set standards of practice; determine the qualifications of applicants for examination; establish licensing and continuing education requirements; test for competence; investigate consumer complaints; and discipline those who do not practice according to established standards.

Keeping Pace with Change

The Board has been receiving an increasing number of inquiries about the regulation of out-of-state pharmacies, Internet pharmacies, legality of prescriptions generated by computers or Palm Pilots, centralized prescription processing and fulfillment, and electronic signature.

The practice of pharmacy is changing dramatically. The challenge for the Board is to keep pace with this changing environment. When formulating new or changing existing regulations, the Board is always mindful of its duty to protect the health, safety, and welfare of New Jersey consumers. Recently, the Board completed its work on regulations concerning continuing education, technicians, and electronic transmission of prescriptions in the retail setting.

These new proposals are in various stages of the review, approval, publication, and adoption process. You can watch for and track the publication and adoption process via the Web sites provided. This *Newsletter* will also be utilized to inform and advise licensees of statute and regulation changes.



From the Desk of the Director of Pharmacy – H. Lee Gladstein, RP

The following are questions frequently asked of the director of pharmacy:

Q: On a Schedule II prescription, when can I dispense more than 120 units or a 30-day supply of medication?

A: The Board of Medical Examiners Regulation N.J.A.C. 13:35-7.6(b) provides the answer:

"A practitioner may exceed the 120 dosage unit limitation for Schedule II controlled substances, if the practitioner follows a treatment plan designed to achieve effective pain management which has been tailored to the needs of a patient who is suffering from cancer, intractable pain or terminal illness…"

[illegible] medications.

Q: What is required on the label of dispensed medications relating to expiration date?

A: Information that is required on a prescription label is detailed in N.J.A.C. 13:39-5.9. Part of the required information includes the expiration date. Specifically, 13:39-5.9 (a) - 12 reads:

"The expiration date, if dispensed in any packaging other than the manufacturer's original packaging. For purposes of this paragraph, 'expiration date' means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container."

Q: Do I have to wear an identification tag?

A: N.J.A.C. 13:39-6.3 reads:

"Each licensee shall wear an identification tag which shall include at least the pharmacist's first name, the first initial of his or her last name, and the designation 'Pharmacist'."

N.J.A.C. 13:39-6.7 (d) reads:

"Supportive personnel shall wear an identification tag, which shall include at least their first name, the first initial of their last name, and title."

Q: Under what conditions can I dispense an emergency supply of medication?

A: N.J.A.C. 13:39-6.1 (b) reads:

"A pharmacist may dispense an emergency supply (no more than a 72 hour quantity) of a chronic maintenance drug (except controlled dangerous substances) or device in the absence of a current valid prescription, if, in his or her professional judgment, refusal would endanger the health or welfare of the patient."

Some Helpful Tips and Reminders From Common Compliance Issues Noted During Inspections

- Both the original and renewal pharmacy permit are required to be displayed.
- Both the licensee's original wall certificate and renewal certificate are required to be displayed.
- Drug Utilization Review Council placards must be displayed in two locations -- at the entrance and in the dispensing area as per N.J.S.A. 24:6E-10.
- Medication present in the active stock inventory without lot and expiration dates on the label are considered misbranded and violate N.J.A.C. 13:39-7.13.
- Prescriptions for Control Dangerous Substance medications must be filled within 30 days of issue.

Article Summary: Trends in Medical Use and Abuse of Opioid Analgesics
JAMA, April 5th, 2000—Vol 283, No. 13 pages-1710-1714
By Joranson DE, Ryan KM, Gilson AM, Dahl JL

Context: Although numerous nonpharmacologic treatments can be used to relieve pain, the use of opioids in the class of morphine is the cornerstone of pain management. p.1710. col 1. par 1.

Health care professionals may be reluctant to prescribe, administer, dispense, or stock controlled substances for fear of causing addiction or contributing to the drug abuse problem. P.1710. col 1. par 2.

Objective: To evaluate the proportion of drug abuse related to opioids and the trends in medical use and abuse of 5 opioids used to treat severe pain.

Methodology: This was a retrospective study from 1990 to 1996 that used data from a national sample of hospital emergency department admissions resulting from drug abuse. (DAWN-Drug Abuse Warning System). The medical use of opioids in grams and grams per 100,000 population was obtained by the ARCOS-Automation of Reports and Consolidated Orders System.

Medical use results of the 5 opioids was as follows:
Increases: Morphine 59% , Fentanyl 1168%, Oxycodone 23%, Hydromorphine 19%
Decreases: Meperidine 35%

Drug Abuse Results:
For opioid analgesics, the total number of mentions increased from 32430 in 1990 to 34563 in 1996 (6.6% increase), but declined as a percentage of total mentions from 5.1% to 3.8% in 1996. Illicit drugs (cocaine, heroin, LSD, Marijuana ect.) is the only category of drug abuse that exhibited a continual increase in both number of mentions and percentage of total mentions over the study. p1712. col.2. par.1.

Abuse results for the 5 opioids was as follows:
Decreases: Fentanyl 59%, hydromorphone 15%, Meperidine 39%, oxycodone 29%
Increases: Morphine 3%

According to the WHO, increasing medical use of opioids is one indication that progress is being made to improve pain management. Despite these increases, pain is still inadequately treated due to numerous barriers to pain management. P 1712. col 2-3. par 3.

Conclusion: The present trend of increasing medical use of opioid analgesics to treat pain does not appear to be contributing to increases in the health consequences of opioid analgesic abuse. P 1713. col 3 par 4.

Cephalon Annual Sales Meeting

The Myth of Addiction

By Phillip Rocco

February 22-28

CONFIDENTIAL

Terms to Know!!!

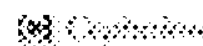
Addiction "a disease"

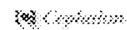
- psychological component
- drug-seeking behaviors
- nonmedical use of drug despite potential harm

- Pseudo-addiction "the problem"
  - iatrogenic problem - inadequate analgesia
- Tolerance
  - rare in cancer patients
  - not relevant to efficacy if agents and dosage are adjusted
- Physical Dependence
  - natural process; weaning from drug is a simple medical process

Apply the terms to the call!

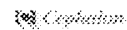
- Never Refer to Addiction when talking about opioids-especially Actiq!
- Addictionist actually use it-benefit
- Patients using opioids are Physically Dependent-just like coffee, food, chocolate & sex?
- Difference between "Wants" & "Needs"





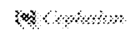
Apply the terms on the call!-REALITY

- Why is Pseudo-addiction the problem?
  - Oncologist treat the disease = money
  - Pain Specialist/APM's do procedures = money
  - No $$$$ in pain assessment!
  - Health Care Professionals (FP's, IM's, Neurologist, Pharmacist ect.) have fear of losing license.
  - Who is doing the medical management?



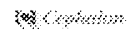
Barriers to Effective Pain Management: Healthcare Professionals

- Not trained in pain management
- Lack of knowledge about current therapies
- Fear of prescribing Schedule II drugs
- **Fear of addiction**
- Fear of analgesic tolerance
- Fear of side effects
- Subjective nature of pain



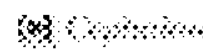
Barriers to Effective Pain Management: Patients and Caregivers

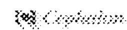
- Reluctance to report pain
  - Belief that pain is inevitable: "suffer in silence"
  - Fear that pain indicates advanced disease
  - Fear of distracting doctors from active treatment
- Reluctance to take pain medications
  - **Fear of addiction**
  - Fear of appearing weak
  - Cultural barriers or religious concerns
  - Discomfort with route of administration
  - Fear of unmanageable side effects



Barriers to Effective Pain Management: Healthcare Systems

- Low priority given to pain management
- Inadequate reimbursement
- Restrictive regulation of controlled substances
- **Failure to clearly distinguish**
  - **appropriate medical use**
  - **“street abuse”**
- Pain treatment not accessible





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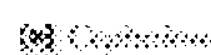
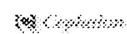
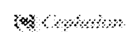




CONTEXT

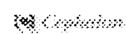
- Although numerous nonpharmacologic treatments can be used to relieve pain, the use of opioids in the class of morphine is the cornerstone of pain management. p.1710. col 1. par 1.

  Health care professionals may be reluctant to prescribe, administer, dispense, or stock controlled substances for fear of causing addiction or contributing to the drug abuse problem. P.1710. col 1. par 2.



OBJECTIVE

- To evaluate the proportion of drug abuse related to opioids and the trends in medical use and abuse of 5 opioids used to treat severe pain.



METHODOLOGY

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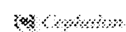

Drug Use Results:

- Increases:
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- Decreases:
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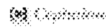

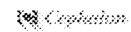

DRUG ABUSE RESULTS

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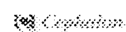

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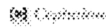

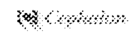

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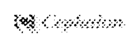
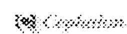


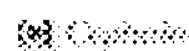
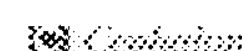
CONCLUSION

- The present trend of increasing medical use of opioid analgesics to treat pain does not appear to be contributing to increases in the health consequences of opioid analgesic abuse. P 1713. col 3 par 4.



Other Studies:

Study	Pain Source	# of Pts.	#Addicted
Porter & Jick (1980)	Various	11,882	4
Perry & Heidrick (1982)	Non-malignant	10,000	0
Taub (1982)	Non-malignant	313	*13
Portenoy & Foley (1986)	Non-malignant	38	**2

Totals:

- *8 pt. w/prior hx of substance abuse

  **both w/prior hx of substance abuse

Totals 22233 Treated

15 addicted (10 w/prior hx of disease)

0.06% chance of becoming addicted