

Legal Traps to avoid

Or

**How *NOT* to appear  
before the Ohio Board  
of Nursing**

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# Objectives:

- The APN will, through the use of clinical vignettes, be able to:
  - Understand key components of the Ohio Nurse Practice Act that impact APN practice
  - Understand key components of the Ohio Pharmacy Practice Act that impact APN practice
  - Understand key components of the Ohio Medical Practice Act that impact APN practice

# What's the issue here?

- Suzy Newgrad, CNP
  - obtained her MSN in June 2007
  - Applied for and was issued her COA and CTP-E in July 2007
  - Started her new job and signed the practice SCA, and notified the Board of her practice addresses, and list of names of collaborating physicians

- Suzy then completed her CTP-E requirements of 500 supervised and 1000 unsupervised hours of prescribing.
- Currently (17 months later) Suzy continues to prescribe under her initial CTP-E license
- *What legal pitfalls might Suzy have encountered?*

# What is a CtP-E?

- CtP-E = Certificate to Prescribe – “Externship”
  - First prescribing license until APN meets criteria of supervised hours of prescribing
  - APN can prescribe when license received
  - Must be “supervised” for prescribing component of practice
  - 500 hours direct supervision (on site)
  - Another prescribing APN can supervise 200 of these hrs.
  - 1000 hours indirect supervision (physician can be off site)



# CtP-E

- The initial CTP-E is only good for a one year period
  - If requirements are not met within one year the APN must contact the Board for an extension of another year
    - (max of 2 yrs total, no extra cost involved)
- After externship requirements are completed, the APN must submit an attestation form signed by the collaborating physician that requirements have been met. The Board will then issue a CTP

# What's the issue here?

- Cynthia Clapp, CNM, has a patient who has a positive result for Chlamydia. Cynthia gives her a prescription and tells her partner who is present that he also needs treated. He says he has no provider, and asks her to write him a prescription.
- *What potential legal pitfalls might Cynthia encounter?*

# What is scope of practice?

Scope of practice is the parameters of professional performance, responsibility and accountability identified and defined by national professional organizations

Each type of APN practice identifies standards and parameters of care

In ORC, each APN group has identifiable parameters consistent with national bodies.

**NO “Laundry list” in Ohio law!**



# Who can we prescribe for?

- *Legitimate patients*
  - *maintain a clinical relationship*
    - Chart and office visits
- Also can write Rx for family and friends  
(in certain limited situations)
  - Recently clarified in PA bill
  - Only in emergency situations
  - Only for a limited time to cover emergency



# What's the issue here?

- Julie Juvenile, CRNP is a pediatric NP who provides multiple vaccinations during her busy clinical days. She directs her medical assistant to administer the vaccinations because they are time consuming.
- *What legal pitfalls might Julie have encountered?*

# Key points of Medical Law

- Delegation 4731.053
  - *Currently only physicians can delegate to unlicensed assistive personnel*
  - List of criteria for delegation in rules: 4731-23-02

# What's the issue here?

- Harry Highlow, CRNP is an FNP. He is seeing a patient with a long history of manic depression. Harry writes a prescription for Lithium.
- *What potential legal pitfalls might Harry encounter?*

# Prescriptive

- Prescribe in compliance with the formulary

- Use latest version of the formulary available at [www.nursing.ohio.gov](http://www.nursing.ohio.gov)
- CPG meets several times each year; revised formulary is posted on the BoN website shortly after

# What's the issue here?

- Francine Forgetful, a psych NP with prescriptive authority, has stumbled across the B.o.N. website. She is surprised when she looks under the license verification section and sees that her certification has lapsed!
- *What potential legal pitfalls might Francine have encountered?*

# What credentials are needed for an APN to practice in Ohio?

- Certificate of Authority
- *Current National Certification*
- RN license



# Key Points to maintain an active COA

- If your national certification is expired by even one day, then your COA and CTP are **invalid**.
  - If you are working on an invalid COA, this could become a **FELONY** conviction
    - Potential “domino effect”
  - Ohio BON will not accept **back dated** certification renewals

## Slightly different scenario

- Francine Forgetful, now decides to check on the DEA (diversion) website and is surprised when she sees that her DEA certification has also lapsed. She often prescribes lorazepam (Ativan; a scheduled drug)
- *What potential legal pitfalls might Francine have encountered?*

# Additional DEA considerations

- Active CTP/CTP-E **plus** a current DEA are needed to prescribe controlled substances
  - A DEA is not needed for prescribing legend (non controlled) drugs
  - Prescribing controlled substances on a lapsed DEA could result in a **FELONY** conviction
- **Maintaining a current DEA does not negate the Ohio requirement for an active CTP or CTP-E**

# What's the issue here?

- Hillary Hyper, CRNP, is a peds NP. She has a patient who, after a formal multidisciplinary evaluation, has a diagnosis of ADHD. Hillary feels the child may benefit from a therapeutic trial of Concerta.
- *What potential legal pitfalls might Hillary encounter?*

# Controlled Meds

- Schedule III thru V may be prescribed per patient need, if on formulary
- Major limits on Schedule IIs; No Ritalin, Concerta, Seconal, etc
- APN's Rxs for Schedule II stimulants has been the biggest problem that the BoP has had w/ APNs

# Controlled Meds

- APNs may prescribe Schedule III – IV within DEA guidelines
  - One month and up to 5 refills
- *Currently* APNs may only prescribe Schedule II drugs to terminally ill patients
  - Previously prescribed by a physician
  - Not longer than 24 hour supply

## The future of Schedule II ?

- OAAPN has reintroduced a bill to remove the restrictions on Schedule II prescribing for Ohio's APNs
  - Until this bill passes, Ohio APNs may not prescribe Schedule II meds (including Ritalin and Concerta) under his or her own license

# What's the issue here?

- Mary Migraine, CNM saw her patient, Lucy, (also her neighbor) in Mary's office for her annual gyn exam. "Oh by the way", Lucy reported to Mary her chronic headache problems, and asked Mary to renew her prescription for these headaches.
- Mary provided the prescription.

- Mary ran into Lucy many times over the next six months, and continued to refill her headache medicine upon request without further office visits.
- *What potential legal pitfalls might Mary have encountered?*

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  - maintain a **clinical relationship**
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  - (in certain limited situations)
  - Recently clarified in PA bill
  - **Only in emergency situations**
  - **Only for a limited time to cover emergency**



# Ohio Medical Law

- Management of intractable pain  
4731.052
  - Criteria for evaluation, charting exam, diagnosis, plan, drug, dosage, amount and whether Rx'd or supplied or administered
  - APNs will be held to same standards for Schedule II - V medications

# OARXRS

- ORC 4729.75.84 implemented 1/1/05
- Authorizes Board of Pharmacy (BoP) to
  - Collect Rx data
  - Analyze Rx data
  - Distributes Rx data
- *Purpose: to monitor prescriber practices and / or abuse by prescribers or patients regarding all controlled substances* and carisoprodol (soma) and tramadol (Ultram)

# OARxRS

- How does it work?
  - Pharmacists mandated to submit data
  - OARxRS staff monitors for suspicious patterns of abuse or diversion
  - OARxRS releases data to registered prescribers, appropriate regulatory bodies, and police

Questions?



# Detailed Review of Ohio's APN Laws \*

- \*Or;

What you  
need to know  
to stay  
out of trouble!



# Where can I find Ohio's Laws on Nursing?

- **ORC (Ohio Revised Code)**
  - **Includes all Ohio laws**
  - **Enacted by the Ohio legislature**
  - **Nurse Practice Act - section 4723**
- **OAC (Ohio Administrative Code)**
  - **Rules that define law**
  - **Written by the regulatory boards**
  - **Must be consistent with the law**
  - **Typically more specific than the law**



# How Do I Find the Text of the Ohio Law/Rules Pertaining to APNs?

- [www.nursing.ohio.gov](http://www.nursing.ohio.gov) Ohio Board of Nursing Home Page
- **Law & Rule** (left side of home page)
  - Chapter 4723-8: Certification, Registration of Nurse-Midwife and Other Specialties
  - Chapter 4723-9: Course of Study in Advanced Pharmacology
- **Advanced Practice** (left side of home page)
  - Selected Sections from Chapter 4723,ORC
  - Chapter 4723-9 Prescriptive Authority

# What Professional Board Regulates APNs in Ohio?

## The Ohio Board of Nursing

Protection of the  
public  
Issues renewals,  
revokes, licenses  
Assures basic  
requirements for  
practice are met  
Sets criteria for  
licensure and  
revocation per ORC  
and OAC



# What license does an APN need to practice in Ohio?

- RN license
- Current National Certification
- Certificate of Authority

# What is title protection?

- Title restricted to individuals who have achieved specific requirements.
- Only formally trained and licensed individuals may identify themselves as an APN



# Why is title recognition important?

- Legal recognition for practice
- Recognition linked to reimbursement
- Helps meet federal and state reimbursement guidelines



# What is scope of practice?

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# Example Scope of Practice – CRNP

- The ORC states that Ohio CRNPs provide *“preventative and primary care services and evaluate and promote patient wellness.”*



# CRNP

- Clinical practice areas include acute care and subspecialty care
- In addition to clinical care, CRNP's scope may include education, research, and consultation



# When is physician supervision of APNs required in Ohio?

- **VERY FEW CIRCUMSTANCES!**

- **CRNAS**

- **APNs**

- in “externship”

- portion of the Certificate to

- Prescribe (CtP-E) -

- only for prescribing functions



# What is physician / APN collaboration?

- Physician / APN relationship specified by ORC
- Independent practice within scope
- Consult / collaborate as needed
- SCA may limit scope but not expand



# Does my physician need to be “on site”?

- CRNA’s – YES !
- APN - only during 500 of the 1500 supervised hours of prescribing required in the externship



# What about when my doc is not around?

- In collaborative relationship physician must always be “available”
  - in person
  - or by telecommunications
  - No “on site” requirement in ORC
  - Need plan for emergency coverage in case regular physician is away



# Doctor on Site

- Don't confuse this with Medicare “incident to” billing guidelines which require that a physician be present in the office in order to bill under the physician's name



# What is the “SCA”?

- The “SCA” = the Standard Care Arrangement between the APN and physician
  - Formal document of collaborative relationship
    - Keep on file at practice location(s)
    - BoN does not need a copy, but can ask to see it

# Who needs an SCA?

- CRNPs, CNMs, CNSs
  - Psych CNSs don't need, unless they are prescribing
  - CRNAs are not required to have SCA
- Required by ORC and OAC
  - ORC 4723.431
  - OAC 4723-8-04, 4723-8-05
- APN may not practice without current SCA

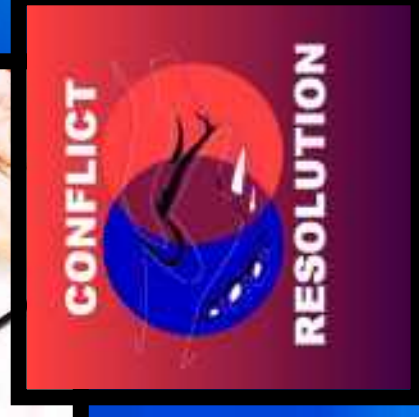
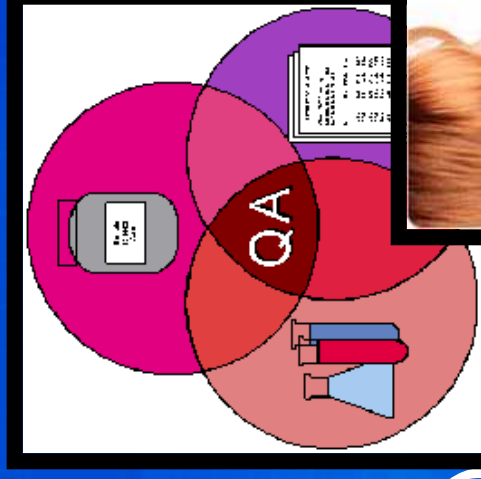
# What is in the SCA?

- A Statement of services
  - Can repeat scope as in law,
  - or further elaborate
- A plan for incorporation of new procedures
- Criteria for referral of clients
  - Also regular review of referrals
  - Plan for emergency coverage



# What is in the SCA? (continued)

- Quality assurance measures
  - Regular chart reviews
  - Annual (or more) review of SCA
- Plan for resolution of disputes
- Plan for care of children up to age 3 (if applicable)



# What about the travel time requirement?

- There is a travel time requirement for prescribers and their collaborating physicians

- Since practices vary widely, no single time was suitable
- It has been left to the APN and physician to set a minimum physician “response time” for being able to be on site for patient evaluation

- This must be addressed in the SCA



# What additional SCA components are needed for prescribers?

- Provisions to allow in person physician evaluations as indicated
- Prescribing parameters if “off label” indications are used (approved list)
- Semi annual review of prescribing practices
- Any other parameters



# Who needs to sign the SCA?

- The APN and physician must sign (each year)
  - Must be signed by all participating APNs and MDs
    - Exception is emergency coverage
  - Notary signature NOT required
  - SCA template available through OAAPN



# Review of Prescriptive Authority

- Gained this authority with passage of Sub HB 241 in 2000

## For qualified APNs

- Master's prepared
- 45 hours pharmacology
  - Within 3 years of application for license
- Complete externship requirements



- APN must have current Certificate to Prescribe (CtP) in addition to other licenses
  - Open to eligible CNMs, CRNPs & CNSs



# What does the APN need to be eligible to prescribe?

- 45 contact hours in pharmacology (as of 10/1/04)
  - In University or approved continuing ed format. Can combine some courses
- Master's degree
- To renew, the APN needs 12 pharm CEs every 2 years in addition to other continuing education (24 hours for RN)



# What is a CtP-E?

- CtP-E = Certificate to Prescribe – “Externship”
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  - APN can prescribe when license received
  - Must be “supervised” for prescribing component of practice
    - 500 hours direct supervision (on site)
    - Another prescribing APN can supervise 200 of these hrs.
    - 1000 hours indirect supervision (physician can be off site)



# What about this ratio of APNs to physicians?

- Ratios “3 to 1”
  - for purposes of prescribing, a physician may not collaborate with more than three APNs at the same time (4723.431)
  - Does not limit employment numbers
  - Does not limit regular APN practice
- applies to prescribing ONLY
  - Not being monitored, but might be considered in investigations



# What about sample drugs?

- May provide samples of any drug that APN can legally prescribe
  - Check **FORMULARY!**
- Samples must be provided unaltered and without charge
- Amount cannot exceed 72 hour supply
  - or smallest commercially available package
- Can't give samples of any DEA schedule drug (controlled substances)
- Caution: newly approved FDA drugs



# What about dispensing stock medications?

- What are stock medications?
- APNs may only dispense or furnish stock medications IF:
  - Health department
  - Federally funded
  - Primary care
  - Non profit
  - Complete or partial treatment supply
  - Maintain safety standards set by rules



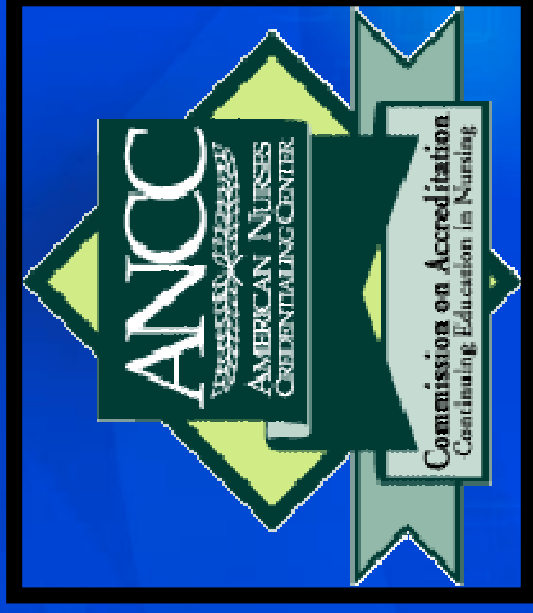
# What about dispensing stock medications?

- Specific categories of drugs:
  - Original bill - Antifungals, Antibiotics, Contraceptives, Prenatal Vitamins, Scabicides
  - New categories added with PA bill – Asthma drugs, antihypertensives, diabetic meds, anti lipidemics (effective May 17, 2006: Senate Bill 154)



# Summary of Key Compliance Points: Licensure

- Keep licenses and certification current
  - Renewal of RN, COA, CtP every 2 years
  - odd numbered years in summer
    - See dates on current licenses



# Summary of Key Compliance Points: Licensure

- National Certification
  - Required prior to obtaining COA
  - Approved certifying organization
    - See BoN website for list of approved organizations
  - APN MUST notify the BoN in writing (with a copy of current certification) when certification is renewed
  - You CANNOT PRACTICE without CURRENT national certification

# Summary of Key Compliance Points: Current Information

- Keep the BoN informed:
  - Whenever practice changes (change of physician collaborators, change of APNs practice affiliation)
    - Must do within 30 days of change
  - Whenever you change your address
    - Failure to renew not excused for lack of receiving a notice at a new address



# Summary of Key Compliance Points: SCA



- Keep SCA current
  - Must be current to practice
  - Must be reviewed, re-signed every year
    - Signed by each collaborating physician & APN
  - Copy must be kept at every practice location
  - Off label list should be reviewed for additions or deletions
    - Off label use should be supported by literature, and agreed upon by APN and doc

# Summary of Key Compliance Points: Prescriptive

- Prescribe in compliance with the formulary
  - Use latest version of the formulary available at [www.nursing.ohio.gov](http://www.nursing.ohio.gov)
  - CPG meets April and October; revised formulary is posted on the BoN website shortly after that.

# Summary of Key Compliance Points: Prescriptive

- Sign 5 digit CtP number on every prescription (or preprint)
  - DEA # not needed unless scheduled drug or new pharmacy
  - Dangerous to preprint DEA # due to risk of fraud
- [www.dea.gov](http://www.dea.gov) Diversion Control and Prescription Drugs
  - On-line application (DEA-224)
  - Apply once you obtain CtP-E
  - Controlled Substance List

# Summary of Key Points: Prescriptive

- Drugs approved for FDA indications only
  - “off label” use only OK if already on formulary and listed in your SCA
- Prescribe only for legitimate patients
  - Family and friends only in emergency situations

# Summary of Key Compliance Points: Chart Reviews

- Review for quality improvement
  - Chart reviews at least 2x year
    - for prescribing practices
    - Random sampling
    - At least 1x / year for other aspects of practice
      - “Regular” reviews of referrals and care outcomes
      - Use discussion to evaluate care and improve practice
      - Document reviews



# Summary of Key Compliance Points: Continuing Ed

- Keep continuing education current
- Requires at least 12 hrs. of pharm CE
  - in addition to 24 hrs. required for RN license
    - CE from BoN approved provider
  - Don't wait until last minute to try to complete courses
    - Board does random audits of continuing education
- Don't forget requirements to keep certification current



# Where can I find Ohio's Pharmacy Laws?

- **ORC (Ohio Revised Code)**
  - Includes all Ohio laws
  - Enacted by the Ohio legislature
  - Pharmacy Practice Act - section 4729
- **OAC (Ohio Administrative Code)**
  - Rules that define law
  - Written by the regulatory boards
  - Must be consistent with the law
  - Typically more specific than the law

# Ohio Pharmacy Board

## contact information:

- Executive Director : William Winsley, M.S.  
R.Ph.\*  
Ohio State Board of Pharmacy  
77 S. High Street – Room 1702  
Columbus, Ohio 43215-6126  
Phone: (614) 466 4143
- Email: [exec@bop.state.oh.us](mailto:exec@bop.state.oh.us)
- Website: [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)

\*Thanks to Bill for Pharmacy information that follows

# Key Points of Pharmacy Law

- Must be licensed w/ the BoN
- APN is the prescriber, the collaborating doc is NOT
- May transmit RX in writing / fax / oral or BoP approved electronic means
- Same practice restrictions as collaborating physicians

# Key Points of Pharmacy Law

- DEA number for APNs begin w/ “M”
- Schedule III thru V may be prescribed per patient need, if on formulary
- Major limits on Schedule IIs; No Ritalin, Concerta, Seconal, etc
- APN’s Rxs for Schedule II stimulants has been the biggest problem that the BoP has had w/ APNs

# Key Points of Pharmacy Law

- May supply non controlled samples w/ 72 hour limit (smallest sample)
- Supply and Stock drugs limited to specific sites
  - Sites specified in OAC (public health clinics, free clinics, federally funded clinics, etc
- CtP license number on all RxS
  - NPI number optional, CtP number required

# Key Points of Pharmacy Law

- BoP Rx format rule: 4729-5-13
- Pre Printed scripts w/ multiple drugs listed OK BUT limited to one drug chosen per script
- No controlled substances may be listed on pre printed script w/ multiple choices

# Key Points of Pharmacy Law

- Format rule (continued)
- Hand written / typed Rxs may contain no more than 3 Rxs per blank
- Controlled substances limited to one drug entry per blank
- Quantity must be written in word and numeral (i.e. twenty, 20)
- Approved electronic scripts exempt from above rule

# Key Points of Pharmacy Law

## Manner of issuance of a prescription (4729-5-30)

- Must be for legitimate medical purpose within usual course of practice
- Pharmacists have a mandate to watch for problems and deal with them
- Must be dated and manually signed on date issued
  - NO presigned or post dated scripts

# Key Points of Pharmacy Law

## Manner of issuance of a prescription (4729-5-30)

- Full name and address of both prescriber and patient , drug name and strength, quantity to be issued, specific directions, and refill authorizations
  - Must have specific directions; don't use “as directed’
  - Refill number must be specific; no “refill PRN”

# Key Points of Pharmacy Law

## Manner of issuance of a prescription (4729-5-30)

- For Schedule III – V; no refills beyond 6 months / 5 refills
- For Schedule V and non controlled meds, no refills beyond one year.
- Phone orders transmitted by prescriber's agent requires full name of the agent
- Patient may not fax Rx to pharmacy
- Fax from Prescriber's office OK, except for Schedule II
  - Exemption for Hospice patients

# OARXRS

- ORC 4729.75.84 implemented 1/1/05
- Authorizes BoP to
  - Collect Rx data
  - Analyze Rx data
  - Distributes Rx data
- Purpose to monitor prescriber practices and / or abuse by prescribers or patients regarding all controlled substances and carisoprodol (soma) and tramadol (Ultram)

# OARxRS

- All substances contained in OARxRS program
  - Data not available to public
  - No liability to prescribers who use data
- Patients included in database:
  - Outpatient Schedule Rx
  - Hospice
  - Assisted living
  - Jails
  - Hospital employees
  - Out of state pharmacies

# OARXRS

- Patients NOT included:
  - Inpatients
  - Physician dispensed
  - ER dispensed for < 24 hours
  - Schedule V OTC sales

# OARxRS

- How does it work?
  - Pharmacists mandated to submit data
  - OARxRS staff monitors for suspicious patterns of abuse or diversion
  - OARxRS releases data to registered prescribers, appropriate regulatory bodies, and police

# OARxRS

- How do I participate in this program?
- Go to BoP home page
  - [www.ohiopmp.gov](http://www.ohiopmp.gov)
  - Find link to register for OARxRS
  - Follow directions!
  - Questions or difficulties? Contact
- Contact: Danna E. Droz, R.Ph., JD  
PMP administrator  
Ohio State Board of Pharmacy  
[www.ohiopmp.gov](http://www.ohiopmp.gov)  
(614) 466 4143

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# Ohio Medical Board

- Address:  
30 E. Broad St., 3<sup>rd</sup> floor  
Columbus, Ohio 43215-6127
- Phone: (614) 466 3934
- Website: [www.med.ohio.gov](http://www.med.ohio.gov)

# Key points of Medical Law

- Delegation 4731.053
  - Currently only physicians can delegate to unlicensed assistive personnel
  - List of criteria for delegation in rules: 4731-23-02

# Key points of Medical Law

- Standard Care Arrangement 4731.27
  - Similar to Nurse Practice Act language
  - Adds language specifying need for parties to cooperate in any investigations by any regulatory board (nursing, medicine, pharmacy) for any question of practice infractions
  - After investigatory, any responsibility for disciplinary action rests with the home Board

# Key points of Medical Law

- “Unauthorized” practice 4731.34
  - Language prohibiting non physicians from representing themselves as a medical doctor
    - Can’t use the title “Dr” if it implies being an M.D. or D.O. or D.V.M

# Key points of Medical Law

- Management of intractable pain 4731.052
  - Criteria for evaluation, charting exam, diagnosis, plan, drug, dosage, amount and whether Rx'd or supplied or administered
  - APNs will be held to same standards for Schedule II - V medications

# Other considerations

- Tamper proof Rx blanks
  - Effective April 1, 2008 for Medicaid patients
  - All legend drugs and Scheduled drugs must be on tamper proof blanks
- [www.CMS.gov](http://www.CMS.gov)

**Best Wishes to You for  
Excellence in APN Practice !**



# Resource page

- Ohio Association of Advanced Practice Nurses
  - <http://www.aaapn.org>
  - Much info and links
    - Legislative information
    - Job lists (members only)
    - Links to Board of Nursing and other boards
    - Links to many other nursing organizations
  - Toll Free # (866) 668 3839

# Resource page

- Ohio Board of Nursing
  - <http://www.nursing.ohio.gov>
  - (614) 466 3947 / APN line (614) 466 6180
  - General APN questions = [apn@nursing.ohio.gov](mailto:apn@nursing.ohio.gov)

# Resource page

- Ohio Board of Pharmacy
  - Exec. Dir.= William T. Winsley, MS, RPh
  - <http://pharmacy.ohio.gov>
  - (614) 466 4143
- Ohio Medical Board
  - Exec. Dir = Richard A. Whitehouse, Esq.
  - <http://med.ohio.gov>
  - 614-466-3934

# Resource page

- <http://www.guideline.gov>
  - Health guidelines (AHRQ – national guideline clearinghouse - Institute for Clinical Systems Improvement (ICSI). = Preventive services for adults and children.) Excellent site for all specialties
- <http://www.jcaho.org>
  - JCAHO
- <http://www.cdc.gov>
  - Centers for disease control – huge site, many resources

# Resource page – (only a start)

- [www.title10-training.org](http://www.title10-training.org)
- <http://www.cemedicus.com>
  - (Free compliments of Merck medical)
- [Cme.medscape.com](http://Cme.medscape.com)
  - [Need to login, but free](#)
- <http://www.rossce.com/default.asp?pageID=14&itemID>
  - (Ross labs continuing ed offerings [free?])
- [www.ClinicalMedicineToday.com](http://www.ClinicalMedicineToday.com) Free –  
but need high speed media viewing capabilities
  - Good stuff on antibiotics and osteoporosis