

Geriatrics, Medication Safety, and the Law

*Pharmacy Society of Rochester,
Rochester Area Society of Health-System Pharmacists,
The Finger Lakes Geriatric Education Center,
St. John Fisher College, and
Wegmans School of Pharmacy
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Karl Williams, R.Ph., Esq.

*Associate Professor
Wegmans School of Pharmacy*

Objectives

- Explore changes in the regulation of controlled substances that affect safety in geriatric populations,
- Discuss regulatory aspects of professional communication designed to promote safety in this population,
- Review the impact of the "State Operations Manual" for care in nursing home populations,
- List opportunities for advocacy designed to translate into a safer medication use process in geriatrics.

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Professional Misconduct Law Reform

- Opportunity for advocacy:
 - Learning from our mistakes...
- Education Law §6509, the “Professional Misconduct” law
 - “Gross negligence” and “negligence”
 - Medication error = negligence
- No working definition under state law

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Controlled Substances



- New York State Bureau of Narcotic Enforcement
- “BNE”

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Electronic Prescribing

- DEA's Interim “Final” Rule
 - June 1, 2010
 - Current focus on prescribing software
- New York state
 - Legislation in 2010
 - Regulations pending...

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Faxes

- Departure of state from federal law
- “Follow-up” prescriptions
 - Fax order
 - Telephone order

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Faxes

- Federal
- NYS
- Long-term care and hospice patient, treat fax CII like an *original*
- Same circumstances, would permit CII dispensing but follow-up is required
 - Only if pharmacy has a vendor contract
- No follow-up required!
- CIII-V follow-up *still* required.
- CIII-V : no follow-up for any circumstance

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Controlled Substances

- New “agent of prescriber” rules of DEA
 - October 6, 2010
- “Authorized” agent
 - Written agreement, no limitation on numbers
- Telephone: CIII-V
- Fax: CII-V
 - CII: hospice and long-term care only

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OBRA-90

- Condition of participation in Medicaid
- Message to states: 'require pharmacists to counsel Medicaid patients or lose federal funding'

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Regulations of the Commissioner of Education

- 8 NYCRR 63.6(b)
 - §63.6(b)7: patient profiles
 - §63.6(b)8: counseling
 - “On-premises” v. “off-premises”
- Advocacy opportunity...

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Profiles: 8 NYCRR §63.6(b)7

- (7) Patient medication profile. [...] Such medication profile shall include,...
- - the patient's name, address, telephone number, gender, date of birth or age,
- - known allergies and drug reactions, chronic diseases,
- - a comprehensive list of medications and relevant devices, and
- - other information reported to the pharmacist appropriate for counseling an individual regarding use of prescription and over-the-counter drugs.
- Pharmacists or pharmacy interns shall conduct a **prospective drug review** before each prescription is dispensed [...]. Such review shall include screening for
 - - potential drug therapy problems due to
 - therapeutic duplication,
 - drug-drug interactions, including serious interactions with over-the-counter drugs,
 - incorrect drug dosage or duration of drug treatment,
 - drug-allergy interactions, and
 - clinical abuse or misuse.

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Counseling: 8 NYCRR §63.6(b)8

- i.) “On-premises” delivery
 - (a) Prior to dispensing a prescription for the first time for a new patient of the pharmacy [...] new medication for an existing patient [...] and/or a change in the dose, strength, route of administration or directions [...], required to personally counsel,

- ii.) “Off-premises” delivery
 - ‘written offer to counsel’ is sufficient (apparently), unless:
 - Prescriber-approved alternative drug dispensed
 - Drug therapy problem is detected, or

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Advocacy Opportunity

- “Local Option Law” S 3510B/A 5502B

- Eliminate Mandatory Mail Order

- Senate action required! It has passed out of insurance committee in the Assembly and is at the floor and ready for a vote.

- Call you elected officials ASAP!
 - Rules Committee: Senators Alessi and Nozzolio

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Other Barriers to Communication

- Cultural

- Health literacy

- Limited English Proficiency
 - Title 6 of the Civil Rights Act of 1964

- NYC “Multilingual Medication” law

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Cultural Barriers

- Distinct cultures are evident;
 - Race, ethnicity, ability, socio-economic, age, gender, sexual orientation, etc.
- Cultural factors influence healthcare decision-making; understanding these can enhance communication, counseling, and improve outcomes.

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Overcoming Cultural Barriers

- Basic advice:
- Recognize cultural differences,
 - Gender, race/ethnicity, disability, socioeconomic, religion, rural/urban, sexual orientation, age, veteran, etc.
- Learn about the cultures served,
- Beware of stereotyping – *individual* beliefs and preferences will always control,
- Use culturally sensitive education approaches,
- Be aware of resources in the community.

– Zweber, A, AJPE, 66, 172-177, 2002.

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Health Literacy

- Estimate: 90 million Americans have limited health literacy skills (Tkacz, VL, et al, AJHP 65 974-981),
- Oral and written communications...affect ability to access care and, also, to understand what to do,
- A barrier to communication that is *independent* of cultural and socio-economic factors

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Overcoming Health Literacy Problems

- 1.) Begin by creating an open environment that will ↓ embarrassment,
- 2.) Find out what the patient already knows,
 - IHS questions:
 - “What did the prescriber tell you the medication is for?”
 - “How did the prescriber tell you to take this?”, and
 - “What did the prescriber tell you to expect?”
- The answers can then guide counseling,
- “Teach back”

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Limited English Proficiency (“LEP”)

- Title VI, Civil Rights Act of 1964:
 - ‘No person,....shall be denied the benefits of,...., any program or activity receiving federal assistance’
 - Must be able to provide “meaningful access”
- Department of Justice LEP Guidance 4-factor test for:
 - # of LEP persons served,
 - Frequency LEP persons come in contact,
 - Nature and importance of the service, and
 - Resources available and the cost.

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Language Access in Pharmacies Act

- NY Lawyers for Public Interest filed complaint with NYAG's office alleging that the top pharmacies in NYC were violating Title VI,
- Settlement and subsequent NYC ordinance now require all ‘chain’ pharmacies to:
 - Translate into top 7 languages,
 - Provide interpreter services for LEP patients
- A 7382/S5000 currently before the legislature

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Labeling Prescriptions: Proposed Changes from USP

- New *general* chapter proposes:
 - Reorganize label emphasizing instructions
 - Simplify language,
 - more explicit intervals,
 - Include purpose (unless patient objects),
 - Limit auxiliary information,
 - Address LEP issues,
 - Improve read-ability: high contrast print, 12-point font, adequate white space, horizontal text only, ...
- Comment period ended on March 31, new rule would be effective in November 2012.
 - (USP 35/NF 30)

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Patient Medication Information (“PMI”)

- FDA tasked with studying the effectiveness of leaflets provided at the dispensing bench,
- A single, FDA-approved process that combines into one document the following:
 - MedGuides,
 - CMI, and
 - PPI’s
- For distribution at the time of dispensing
- Goals: a single easy-to-read document

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Medicare Modernization Act of 2003

- Medication Therapy Management (“MTM”)
- Targeted beneficiaries: individuals with
 - Multiple chronic diseases,
 - Multiple covered Part D drugs,
 - Likely to exceed certain annual costs
- Much is left up to the plans to decide

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Affordable Care Act

- Adjustments to current MTM program:
 - Mandatory services:
 - Annual comprehensive medication review
 - Follow-up interventions
 - Auto-enrollment of targeted individuals
- “MTM in Treatment of Chronic Disease”
 - Patients not enrolled in Med D
 - Administered through AHRQ

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Opportunity for advocacy

- MTM enhancement bill:
 - Medication Therapy Management (MTM) Empowerment Act of 2011 (S. 274)

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CDTM ≠ MTM

- But do we need it to?
- A4579/S2985 permits the following:
 - Adjustment of dosages/therapies under protocol
 - Ordering/interpreting lab values under protocol
 - Assessment of ‘vital signs’
 - Context is most glaring limitation: *teaching hospitals*
 - Modest experience and CE requirements
- MTM stands independently, CDTM is a refining but not crucial element

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Risk Evaluation and Mitigation Strategy, or “REMS”

- FDA Amendments Act of 2007
- This is all about *communication* of risk
 - Vioxx, bromfenac, terfenadine, astemizole, Posicor, cisapride, etc., all withdrawn because of communication issues
- Consider the resources expended to place a drug on the market

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REMS

- Any time FDA perceives a communication-related safety issue it can demand manufacturers submit a proposed plan:
 - Patient communication PPI or MedGuide, and/or
 - Professional communication plan, and/or
 - Other “Elements To Assure Safe Use” (EASU)
 - Additional training,
 - Limitations on dispensing (specialty pharmacies, certified dispensers),
 - Limitation on administration sites,
 - Safe use conditions

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Long-acting Opioids: the Rematch

- Hydromorphone, oxycodone, morphine, oxymorphone, methadone, TD fentanyl, and TD buprenorphine
- Discussion began February of 2009, formally proposed in July 2010, and *rejected* in committee; it didn't *require* training of prescribers.
 - In April 2011 the White House issued a multi-agency plan to curb abuse and diversion of Rx drugs
 - FDA then announced a new REMS for these products that will likely include a MedGuide and mandatory training.

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MedGuide Distribution in hospitals

- FDA Draft Guidance, Feb. 2011
- would not require distribution of MedGuides for inpatients and outpatients when the medication or biological is administered by a health professional.

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Medicare Part D Changes Affordable Care Act

- The “Doughnut hole” to be eliminated by 2020
 - 25% co-insurance
 - 50% discount for branded medication
 - CMS will gradually phase in subsidies
 - Catastrophic coverage threshold will still exist
 - 5% co-insurance paid by patient
- Eliminate exclusions for:
 - Benzodiazepines, barbiturates, and OTC tobacco cessation products

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Nursing Home Care 101

- Federal guidelines ensuring safe medication therapy
 - “F-Tags” # 425 “Pharmaceutical Services and Procedures”
- F-tag 428 “Medication Regimen Review” by a pharmacist
 - Top 10 drug-drug interactions, Beers list
 - Discrepancies
 - “Geriatric Syndromes”, acute change in condition
- F-tag 329 “Unnecessary Medications”
 - Lowest effective dose of psychoactive medication
- F-tag 309 “Quality of Life” and pain control

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Top 10 Drug-Drug Interactions

(Multi-disciplinary Medication Management Project, www.ncoap.org/2012/12/23/Top10DrugInteractions , accessed 5/20/2011, 11:20AM)

- Warfarin-NSAIDS
- ACEI- K+ supplements
- Warfarin-sulfa
- ACEI-spirolactone
- Warfarin-macrolides
- Digoxin-amiodarone
- Warfarin-quinolones
- Digoxin-verapamil
- Warfarin-phenytoin
- Theophylline-quinolones

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F-tag 329 Unnecessary Medication

- Medication use without a adequate indication,
- Excessive dose/duration,
 - E.g., antipsychotics, sedative/hypnotic, other neuro-psych agents
- Required monitoring is absent,
- Inappropriate usage indicating dose should be reduced/discontinued, (e.g., duplication),
- Combination of the above.

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F-329: Lowest Effective Psychotropic Medication Dose

- Gradual dose reduction (GDR)
- Antipsychotics
 - GDR in 2 separate quarters 1st year, then annually unless "clinically contraindicated"
- Sedative/hypnotic
 - If used routinely (>/= 50%) each quarter unless "clinically contraindicated"
- Clinically contraindicated
 - » Symptoms return or worsen after most recent GDR,
 - » Documented by prescriber

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Current Focus of OIG:
Atypical Antipsychotics

- **OIG study published May 2011** (OIG-07-08-00150, May 5, 2011)
- Sen. Grassley (Iowa) request,
 - Medicare Part D and off-label use
 - CMS “unnecessary use” standards
 - Black-box warning in connection with dx. of dementia
- 14% of 2.1 million residents received,
- 83% associated with off-label condition
- 51% of claims did not comply with Med D
- 22% of claims did not comply with CMS

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OIG Recommendations

- 1) Facilitate access to information regarding review of coverage determinations,
- 2) Assess adequacy of survey/certification processes to provide necessary safeguards for patients,
- 3) Explore other means of “promoting compliance”,
- 4) Take action w/regard to “erroneous payments”.

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“Discrepancies”

- Review of MAR missed doses
- Delay in beginning therapy

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Opportunities for Advocacy

- Eliminate mandatory mail order pharmacy programs
 - A 5502B/S 3510B
 - The game is in the Senate and this is the last week of session.

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Immunization expansion and reform

- A 6301/ S 3808
 - Eliminate the sunset,
 - Eliminate the 'in-county' restriction for collaboration,
 - Expand the breadth of vaccine coverage,
 - Allow qualified interns to participate.

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Regulatory Reform

- Co-mingling regulations

- CDTM

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Questions/Discussion

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- kwilliams@sjfc.edu

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