



pharmacy & 2011 technology conference

August 27 - 30, 2011 ■ Boston Convention & Exhibition Center ■ Boston, MA

- Date:** Tuesday, August 30, 2011
- Time:** 9:45 a.m. – 10:45 a.m.
- Location:** Boston Convention & Exhibition Center, Meeting Level 2, Room 253 AB
- Title:** **Pharmacy Legislative and Regulatory Update**
ACPE # 0206-0000-11-517-L03-P (0.1 CEU)
- Speaker:** Dennis Wiesner, RPh, CIPP, H-E-B
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Learning Objectives:

At the conclusion of this knowledge-based program, participants will be better able to:

- Explain current state and legislative and regulatory activities related to pharmacy
- Identify state regulatory trends in pharmacy Medicaid reimbursement
- Explain the status of federal health care reform implementation

Don't forget to obtain continuing education credit for your participation in this session. Instructions for processing your statement of credit online are included in your registration bag.

Pharmacy Legislative and Regulatory Update

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State Legislative & Regulatory Update

- Medicaid Reimbursement
 - AAC & Other Reimbursement Changes
- Professional Services
 - MTM, Immunizations
- Electronic Prescribing
- Rx Misuse & Abuse
 - ONDCP Plan, Prescription Monitoring Programs, PSE

Medicaid Reimbursement

- In the states, economic realities forcing states to control Medicaid program costs.
- 3 big trends in “cost containment” affecting pharmacy:
 - AAC
 - Cuts
 - Moving FFS to Managed Care

Medicaid Reimbursement -- AAC

- “Actual Acquisition Cost” (AAC)
- Implemented in 2 states:
 - AL (2010):
 - \$10.64 dispensing fee.
 - AAC based on surveys.
 - OR (2011):
 - Tiered dispensing fee based on annual claims volume -- \$9.68 for < 70,000 claims; \$10.14 for 50,000-69,999 claims; \$14.01 for > 49,999 claims (*note: as of 8/1/11, the dispensing fees and tiers were cut... the cut is detailed in a later slide*).
 - AAC based on surveys.

Medicaid Reimbursement -- AAC

- Other states planning to move to AAC:
 - CA:
 - Enacted budget bill (AB 102) allows Medicaid to adopt AAC as new benchmark.
 - Dispensing fee to be set based on survey of pharmacy providers.
 - While AAC is implemented, CA has submitted SPA to impose 10% cut on current provider fees.

Medicaid Reimbursement -- AAC

- Other states planning to move to AAC (cont):
 - ID:
 - Enacted budget bill (HB 260) directs Medicaid to base reimbursement off of AAC, which would be set via a state or national survey.
 - Dispensing fee to be set based on survey of pharmacies and dispensing fees paid to other payers.
 - Tiered dispensing fees based on annual Medicaid claims volume.

Medicaid Reimbursement -- AAC

- Other states planning to move to AAC (cont):
 - MD:
 - State has initiated the process of moving to AAC
 - In process of doing a cost of dispensing study

Medicaid Reimbursement -- AAC

- Other states planning to move to AAC (cont):
 - NY:
 - Annual state appropriations bill adds that if AAC is available, then it may be used in “lower of” formulas for determining pharmacy reimbursement.
 - Notably, NY Medicaid did not pursue use of AAC (although it now has the option to do so) when the recent SPA for other changes in the pharmacy program was submitted.

Medicaid Reimbursement -- Other Reimbursement Changes

- Other cost-containment measures implemented in 14 states – plus more changes pending in numerous other states
- Mostly cuts, but some other cost-containment strategies implemented as well

Medicaid Reimbursement -- Other Reimbursement Changes

- AK:
 - From AWP-5% to WAC +8%.
 - Dispensing fee from \$3.45-\$11.46 to tiered dispensing fee based on volume, ranging from \$12.12, \$16.98, to \$26.74. Will only pay one dispensing fee per 28 days.
- FL:
 - From WAC+4.75% to WAC+1.5% in the lower of formula.
- GA:
 - 0.5% cut imposed on total reimbursement.

Medicaid Reimbursement -- Other Reimbursement Changes

- IA:
 - *Increase the Medicaid dispensing fee from \$4.57 to \$6.20 (effective 8/1/2011).*
- IN:
 - Cut dispensing fee from \$4.90 to \$3.00 (note: temporary restraining order in effect halting cut).
- ME:
 - Law enacted to make Medicaid co-pays mandatory; Medicaid must notify participants of this change and provide at POS notice to pharmacies if a beneficiary is exempt from a co-pay.

Medicaid Reimbursement -- Other Reimbursement Changes

- MD:
 - Dispensing fee from \$2.69 to 2.56 for non-preferred brands and from \$3.69 to \$3.51 for generics and preferred brands.
- NC:
 - *Enacted state budget gives Medicaid authority to tier dispensing fees to incentivize generic utilization – so far, no action taken to implement any dispensing fee changes.*

Medicaid Reimbursement -- Other Reimbursement Changes

- OR:
 - Change to dispensing fee structure effective 8/1/11:
 - ...from < 50,000 claims = \$14.01; 50,000-70,000 claims = \$10.14; & >70,000 claims = \$9.68.
 - ...to differential fee for chains vs. independents. All chains paid \$9.68 dispensing fee; independents to be paid based on the following tiers: < 30,000 claims = \$14.01; 30,000-50,000 claims = \$10.14; and >50,000 claims = \$9.68.

Medicaid Reimbursement -- Other Reimbursement Changes

- OH:
 - Dispensing fee cut to \$1.80 (enacted as a temporary measure 2 years ago) made permanent.
- SC:
 - In April, from AWP-10% to AWP-13%.
 - In July, from AWP-13% to AWP-16%, plus dispensing fee cut from \$4.05 to \$3.00.
- SD:
 - From AWP-13% to AWP-15%, plus dispensing fee cut from \$4.75 to \$4.30.

Medicaid Reimbursement -- Other Reimbursement Changes

- TX:
 - 3 cuts to the dispensing fee in the past year:
 - 9/2010 – fixed component from \$7.50 to \$7.43; variable component from 2% to 1.98%.
 - 2/2011 – fixed component from \$7.43 to \$7.35.
 - 9/2011- fixed component from \$7.35 to \$6.50.
- VA:
 - From AWP-10.25% to AWP-13.1%
 - Restored planned \$0.25 cut to dispensing fee that was to have taken effect in July 2011. Result, no cut.

Medicaid Managed Care

- With the implementation of the Patient Protection and Affordable Care Act, states are allowed to collect rebates for prescription drugs dispensed to Medicaid beneficiaries enrolled in managed care plans.
- This change, coupled with states' economic challenges and the need to provide Medicaid coverage to a growing patient population, is leading many states to consider expanding the beneficiary population covered under Medicaid managed care.

Medicaid Managed Care

We have seen managed care expansion in the following states this year:

- CA:
 - State budget calls for 10 percent savings through managed care over traditional fee-for-service. Insurers will be given a fixed lump sum for each Medicaid beneficiary rather than directly paying doctors and other providers for individual services.
 - State also obtained a 1115 waiver in fall 2010 and has since greatly expanding patient population covered under managed care.

Medicaid Managed Care

- NJ:
 - As of Oct 1, 2011 approximately 3 million participants will be carved into managed care. Within three years, the remaining 1.5 million Fee for Service participants will be carved into managed care as well.
- NY:
 - Will apply for a Global Waiver and begin to carve in the Aged, Blind and Disabled population. The goal is to expand the carve-in to other portions of the Medicaid population.

Medicaid Managed Care

- OH:
 - Pharmacy no longer carved out of managed care. Beneficiaries that have MCO coverage for other services will now have MCO coverage for pharmacy services – accounts for 77% of Medicaid beneficiaries.
- TX:
 - Expanded Medicaid managed care to the Rio Grande Valley and carved in Medicaid pharmacy benefits statewide.

Professional Services -- MTM

- Growing recognition of the value of pharmacist-provided MTM services:
 - Improves health outcomes for patients with chronic conditions.
 - Provides significant cost-savings to payors.
- Government payors looking to control health program costs open to pharmacist-provided MTM services to achieve cost-savings.

Professional Services -- MTM

In the states...

- CT:
 - SB 1240 enacted to require the Dept of Social Services to contract with a pharmacy organization to provide MTM services.
 - At a minimum, MTM services to include review of patients' medical and prescription history; and development of patient medication action plans to reduce adverse medical interactions and related health problems.

Professional Services -- MTM

- NC:
 - HB 200 (Appropriations Act) included funding for a 2 year MTM pilot program to be administered through Community Care of North Carolina (CCNC).
 - Pilot will determine how to adapt the CheckMeds NC program to the Medicaid program and CCNC's Medical Homes, and the most effective / efficient role for community-based pharmacists.
 - 20 community-based pharmacies will be identified to provide MTM services to targeted group of Medicaid recipients.

Professional Services -- Immunizations

- There is growing recognition for value of pharmacist-immunizers:
 - A recent report on the collaboration between public health departments & community pharmacies during the H1N1 pandemic recognizes pharmacists as "the nation's 'first line resource' for health and wellness" and invaluable in the efforts to increase access to flu prevention during the H1N1 campaign.
 - Recent TRICARE rule notes significant savings to the program (\$1.77 M in 6 months) achieved through allowing TRICARE beneficiaries to obtain vaccines at pharmacies.

Professional Services -- Immunizations

- For several years now, pharmacists in all 50 states have had authority to administer at least some immunizations.
- Scope of authority varies among states. Can be restricted as to...
 - Age of patient who can be vaccinated.
 - Scope of vaccines that can be administered.
 - Allowed by protocol / standing order, or rx-only.

Professional Services -- Immunizations

Pharmacists authority to administer immunization expanded in numerous states.

- AZ (SB 1298):
 - Pharmacists may now administer vaccines to children: can give flu vaccine to 6 yrs & older pursuant to a protocol, and other vaccines to 6-17 yrs pursuant to a prescription.
- AR (SB 130):
 - Pharmacists may now administer vaccines to children: can give flu vaccine to 7 yrs & older pursuant to a protocol, and other vaccines to 7-17 yrs pursuant to a prescription.

Professional Services -- Immunizations

- ID (HB 218):
 - Pharmacists may now administer any vaccine to children to children 12 yrs and older pursuant to a protocol.
- IN (HB 1233):
 - Pharmacists may now administer shingles vaccine pursuant to a protocol.
- KY (SB 40):
 - Pharmacists may now administer broader range of vaccines to children, and may immunize younger children: can give flu vaccine to 9 yrs & older and other vaccines to 12 yrs & older -- all pursuant to a protocol.

Professional Services -- Immunizations

- MD (HB 986 / SB 845):
 - Pharmacists may now administer flu vaccine to children 9 yrs & older.
- NH (SB 93):
 - Pharmacists may now administer pneumococcal vaccine & shingles vaccine to adults pursuant to a protocol.
- NC (SB 609):
 - Pharmacists may now administer flu vaccine to children 14 yrs & older.

Professional Services -- Immunizations

- NY (AB 8030):
 - Extended law giving pharmacists authority to immunize until 2016 (law had been set to sunset in 2012)
- OR (HB 3138):
 - Pharmacists can *prescribe* vaccines to administer to children 11 yrs & older to enable pharmacists to enroll and participate in the CDC's Vaccines for Children Program.
- RI (SB 480):
 - Pharmacists may now administer flu vaccines to children 9 years & older pursuant to protocol.
- WI (AB 40):
 - Pharmacists may now administer vaccines to children 6 years & older.

E-Prescribing -- CDS

- E-prescribing is a well-established and legal practice that has been employed by prescribers & pharmacies throughout the country to improve the quality of patient care and to deliver efficient and cost-effective care to patients.
- However, until only recently, this practice has been allowed only for non-controlled substances prescriptions.

E-Prescribing -- CDS

- The March 2010 Interim Final Rule published by DEA to permit the electronic transmission of all controlled substances prescriptions has finally paved the way for widespread adoption of e-prescribing.
- Since that rule was adopted, a number of states have amended laws and regulations to also permit this practice in conformity with the federal rule.

E-Prescribing -- CDS

- Laws or regulations to permit electronic prescribing of controlled substances prescriptions were finalized in the following states:
 - ID (HB 2): legislation & rules to allow all CDS.
 - KS (KAR 68-20-10a & KAR 68-2-22): rules to allow C III-V only.
 - KY (HB 311) : legislation to allow all CDS.

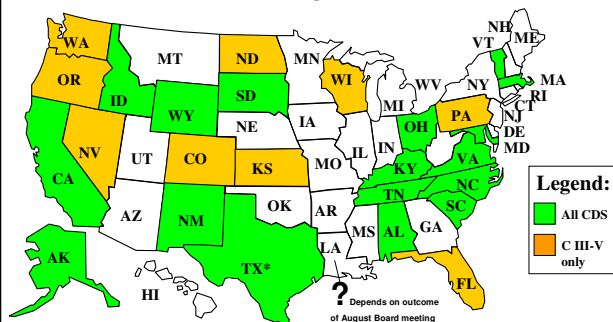
E-Prescribing -- CDS

- LA (SB 223): legislation to allow all CDS – rule change still needed, but BoP is expediting final rules for August 2011.
- NV:
 - AB 199: legislation to allow C II (other schedules already allowed) – rule change still needed.
 - NAC 639.7105: rule amended to clarify that C III-V may be transmitted in accordance with federal requirements.

E-Prescribing -- CDS

- TX (SB 594): legislation to allow C II (other schedules already allowed). Although a rule change still needed to make the rules consistent with the law, the BoP has confirmed that the law will go into effect 9/1/11.
- WY (HB 62 + Pharmacy Practice & CDS Rules): legislation & rules allowing all CDS.

States Allowing E-Rx for CDS



E-Prescribing -- Electronic Prior Authorization Mandates

- Numerous bills introduced to require e-prescribing systems to facilitate immediate e-P/A for prescribed products not on formulary.
 - *Concern:* There are presently no viable e-P/A standards available in the US to facilitate this process. Thus, no existing e-prescribing system could meet this requirement.
- Additionally, some of these measures also prohibit anyone other than a prescriber or a pharmacist from "accessing" electronic prescriptions.
 - *Concern:* This would impede the ability of e-prescribing networks to perform formatting and routing services for electronic prescriptions.

E-Prescribing -- Electronic Prior Authorization Mandates

- Legislation considered in 28 states:
 - AL, CA, CT, FL, GA, HI, IN, KS, LA, ME, MD, MA, MI, MS, MO, NE, NH, NJ, NM, NY, NC, ND, OK, SC, SD, TN, TX, and VT.
- Only one state enacted such a bill:
 - ND (HB 1422):
 - Mandates e-P/A through e-prescribing software systems by 8/1/13.
 - Prohibits communications to influence prescribing decisions at point of care through e-prescribing systems.
 - Establishes HIT advisory committee to establish outline for how best to standardize e-P/A request transactions – must report back findings to legislature by 6/30/12.

Rx Misuse & Abuse -- Federal Activities

- The problem of prescription misuse and abuse is one of shared concern on both the state and federal level.
- Federally, the White House Office of National Drug Control Policy (ONDCP) has taken the lead to try and coordinate federal, state and private stakeholders to address the problem. The agency recently published the "Drug Abuse Prevention Plan" which includes 4 focus areas to accomplish this:
 - Education (of public & practitioners)
 - *Prescription Drug Monitoring Programs*
 - Proper Medication Disposal
 - Enforcement
- ONDCP has held stakeholder meetings with states, practitioner groups, and others to work towards meeting goals that fall under the plan's focus areas.

Rx Misuse & Abuse – State PMPs

- AZ (H.B. 2585):
 - Adds that PMP database will include data from DHS identifying residents who possess a valid registry identification card.
- AR (SB 345):
 - Creates new PMP to track C II-V.
 - The law "encourages" practitioners to access or check info in the database before prescribing, dispensing, or administering medications.
 - Dept of Health to review PMP data to identify individuals who may potentially be obtaining prescriptions in a manner that may represent misuse or abuse. Dept to then notify the practitioners and dispensers who prescribed or dispensed the prescriptions re: any such individuals.

Rx Misuse & Abuse – State PMPs

- CO (H.B. 2585):
 - Law revised to require prescribers & dispensers of CDS to disclose to patients that their info will be entered into PMP and may be accessed – disclosure via method identified by BoP in rule.
- FL (HB 7095):
 - Law revised to require reporting every 7 days.

Rx Misuse & Abuse – State PMPs

- GA (SB 36):
 - Creates new PMP to track C II-V.
 - Dispensers must report rx data weekly.
- IA (SF 286):
 - Law revised to permit pharmacists' / prescribers' agent to delegate access to PMP info on their behalf. (Note: no corresponding mandate to check the PMP data.)

Rx Misuse & Abuse – State PMPs

- KS (KAR 68-21-2):
 - Specifies process to be followed for weeks when no CDS are dispensed.
- ME (LD 1429 / LD 1435):
 - Authorizes info sharing with other state PMPs and establishes parameters under which this may occur.

Rx Misuse & Abuse – State PMPs

- MD (SB 883):
 - Creates new PMP to track C II-V.
 - Release of program data to individuals other than prescriber or dispenser subject to approval by a Technical Advisory Committee.
 - PMP data may not be used as basis for imposing any clinical practice standards.
- MA (105 CMR 700 & 701):
 - Pharmacies must now report customer ID number, as well as the relationship of the customer to the patient.
 - PMP may enter into agreement for interstate exchange of info.

Rx Misuse & Abuse – State PMPs

- MI (HB 4192):
 - Codifies statutory parameters for existing PMP which tracks C II-V.
- MT (HB 83):
 - Creates new “Prescription Drug Registry” to track C II-V.
 - Authorizes BoP to review registry to identify possible misuse / diversion of CDS; BoP may provide such info to prescribers and dispensers as allowed by rule.
 - Note: law contains liability protections for prescribers & dispensers for using, or not using the info from the registry.

Rx Misuse & Abuse – State PMPs

- NE (LB 237):
 - Directs DHHS to enhance or establish technology for prescription drug monitoring, and to promulgate rules to implement this.
- NV (SB 114):
 - Adds liability protections into law for practitioners & dispensers.
 - Adds language permitting interstate sharing of PMP data.

Rx Misuse & Abuse – State PMPs

- NM (16.19.29 NMAC):
 - Pharmacies to report weekly via the ASAP version 4.1 standard for C II-V.
- OH (HB 93):
 - BoP to adopt rules establishing standards & procedures for pharmacists to follow re: review of PMP data.
 - Other state health professional boards to adopt similar rules for the health professionals whom they regulate.

Rx Misuse & Abuse – State PMPs

- OR (OAR 410-121-4000 et. seq.):
 - Implements recently enacted PMP law.
 - Weekly reporting in “ASAP 2007 version 4.1 standard.”
 - Requires pharmacies to notify each patient that their prescription will be reported to the PMP.
- SD (ARSD 20:51:32):
 - Implements recently enacted PMP law.
 - Specifies data to be reported to database.

Rx Misuse & Abuse – State PMPs

- VA:
 - (HB 2255 / SB 1029) Allows practitioners to share PMP data with other practitioners who are treating the same patient.
 - (18 VAC 76-20-40) Pharmacies to report weekly via the ASAP version 4.1 standard.

Rx Misuse & Abuse – “Pill Mills”

- In addition to using PMPs to identify and curb prescription misuse and abuse, some states have concurrently taken steps to address issues with inappropriate prescribing / dispensing that occurs at “pill mills”
- Both FL and OH enacted legislation this year to regulate and license pain management clinics.

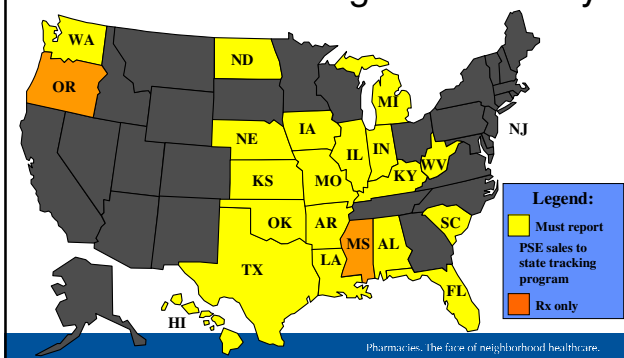
Rx Misuse & Abuse – “Pill Mills”

- FL (HB 7095):
 - Imposes stricter controls over pain-management clinics and dispensing practitioners to ensure that practitioners in these settings serve their patients in a manner that is consistent with acceptable standards of care.
 - Establishes registration requirements for pain management clinics.
- OH (HB 93):
 - Establishes license for pain management clinics.
 - Prohibits sales of CDS to prescribers who do not hold a pharmacy license.

Rx Misuse & Abuse – PSE

- Methamphetamine production continues to be a problem in the United States.
- Both the federal government and states remain focused on how to curb access to excessive amounts of precursor products to stop criminals from obtaining the chemicals necessary to manufacture methamphetamine.
- Two main approaches:
 - Electronic sales tracking programs
 - Rx-Only for PSE

PSE Electronic Logs vs. Rx-Only



Rx Misuse & Abuse – PSE

- Electronic sales tracking programs (19 states) – designed to electronically record sales and alert retailers when a purchaser may be purchasing an amount of PSE in excess of the legal limit.
- The following 5 states enacted legislation in 2011 establishing an electronic sales tracking programs for PSE sales:
 - IN (SB 503); MI (SB 333); ND (SB 2259); NE (LB 20); TX (HB 1137)

Rx Misuse & Abuse – PSE

- Rx-only for PSE sales (2 states) – Both OR and OK have scheduled PSE as C-III
- Numerous others states have pursued this approach in 2011, but to date, have not enacted any such requirement:
 - AL, CA, CO, IN, KS (carried over), ME, MI (still pending), NV, OK (still pending), TX, VA, WI (still pending), WV

Rx Misuse & Abuse – PSE

- In addition to the approaches addressed earlier, one other state made a notable change affecting PSE sales requirements:
 - AR (SB 437):
 - Except for PSE sold upon prescription, pharmacists must make professional determination, based on “a pharmacist-patient relationship,” as to whether or not there is a legitimate medical and pharmaceutical need for PSE based on the following factors: prior medication-filling history; patient screening; and other tools that provide professional reassurance to pharmacist that a legitimate need exists.

Federal Legislative and Regulatory Update

- Medicaid Reimbursement
 - AAC and FULs
- Professional Services
 - MTM and Immunizations
- Debt Limit Agreement
 - Congressional Super Committee

Federal Legislative and Regulatory Update

- Medicaid Reimbursement
 - Proposed rule implementing healthcare reform provision on Medicaid reimbursement expected this month.
 - FULs to be based on no less than 175% of weighted AMP.
 - Weighted AMP posted on a public website
 - Individual AMPs provided to states

Federal Legislative and Regulatory Update

- Medicaid Reimbursement
 - CMS also moving forward with collection of National Average Drug Acquisition Cost (NADAC)
 - Collected by voluntary surveys of pharmacy invoices
 - NADAC posted on a public website
 - States moving to acquisition cost-based product reimbursement must pay dispensing fee based on true cost to dispense
 - Goal is to have database for state use by year end

Federal Legislative and Regulatory Update

- MTM
 - Medicare Part D includes limited MTM benefit
 - Broad eligibility criteria
 - No access standard or reimbursement requirements
 - Federal legislation S. 274/H.R. 891
 - Enhances eligibility criteria
 - Requires reimbursement based on time and intensity
 - Created access standard to provide beneficiary choice of receiving MTM services at local pharmacy

Federal Legislative and Regulatory Update

- Immunizations - TRICARE
 - 2009 rule recognized network pharmacies as providers for administration of flu and pneumococcal vaccines
 - Cost sharing waived for beneficiaries that receive vaccines at network pharmacy
 - 2011 rule broadens to all TRICARE covered vaccines, cost sharing waived
 - Effective August 12th

Federal Legislative and Regulatory Update

- Debt Limit Agreement
 - Agreement by Congress and White House calls for spending cuts of \$1 trillion over ten years – Medicare, Medicaid and Social Security excluded
 - Congressional “Super Committee” to recommend an additional \$1.5 trillion – no exclusions
 - If consensus can’t be reached, fallback mechanism is implemented. Medicaid, Social Security exempt, but 2% cut to all Medicare providers occurs

Federal Legislative and Regulatory Update

- Debt Limit Agreement
 - Congressional activity for remainder of year will focus on spending reductions
 - Reductions in Medicare payments, broadening of Medicare Part B competitive bidding program, and additional fraud, waste and abuse initiatives likely to be considered by Super Committee
 - Pharmacy must highlight role in reducing costs, medication adherence, immunizations, generic utilization, MTM