Medication Safety and Health Care Reform: The Impact of Reform's New Regulations on Hospital and Health System Pharmacy Practice in Rural Communities

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TOGETHER WE MAKE A GREAT TEAM

Overview of Presentation

- Health Care Reform Issues
  - Medication Therapy Management Grants
  - Medical Home vs. Community Health Centers
  - Accountable Care Organizations
  - 340B Drug Pricing Program
- Risk Evaluation and Mitigation Strategies (REMS)
- Safe Use Initiative
- Meaningful Use
- Benefits of Multidisciplinary Collaboration
- Pharmacists' Role
- Rural Implications

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Macro-Influencers on Health System Pharmacy Practice

- Healthcare Model Influencers
  - National economy level
  - Health care reform level
- Revenue Influencers
  - Health system level
  - Drug reimbursement level
- Workload Influencers
  - Regulator level
  - Practice model level

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Setting the Stage

- ASHP policy provides our advocacy framework:
  - Utilize pharmacists' services
  - Obtain provider status under CMS Medicare payment rules
  - Address workforce issues including pharmacy residency programs
- ASHP lobbied for the provisions impacting pharmacy & played a key role in securing several provisions that will positively impact the profession of pharmacy

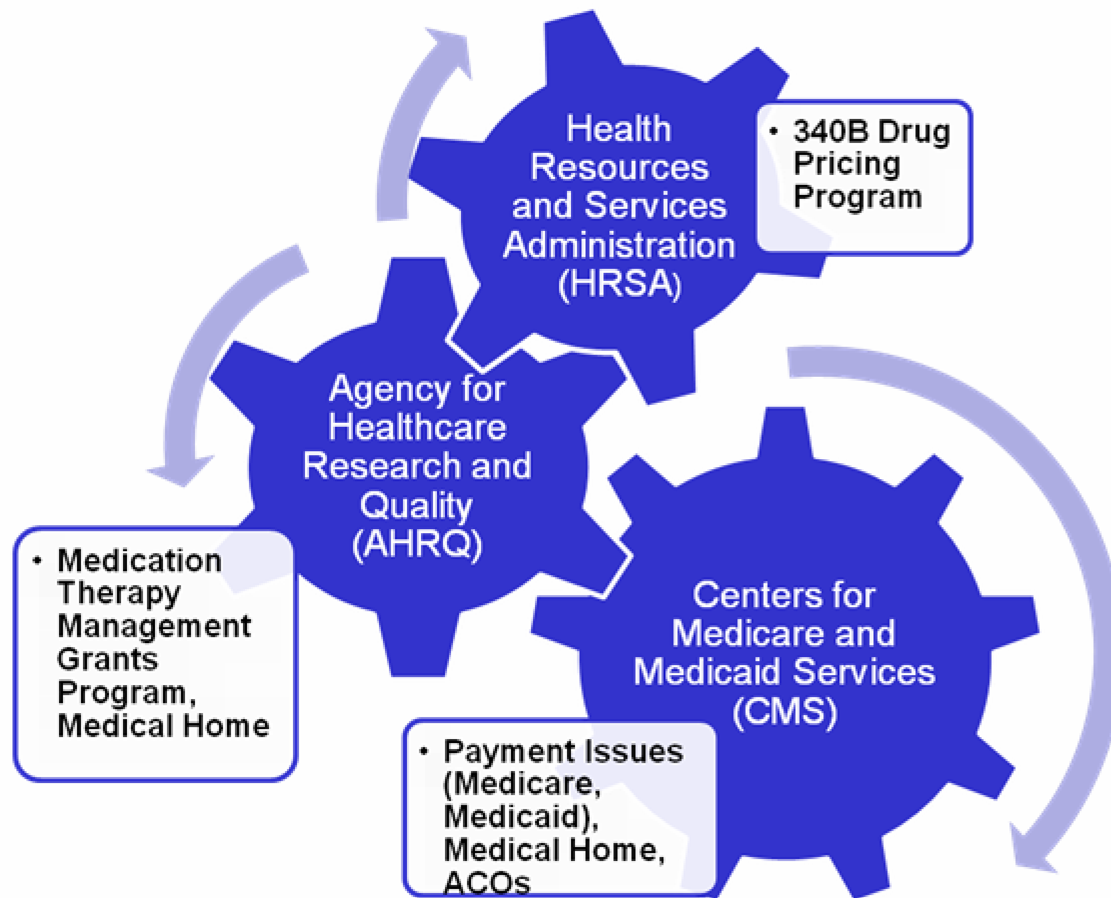
Recap of 2009/2010

- ASHP submitted testimony to House and Senate hearings, policy statements to Senate Finance Committee
- Focus: Access, Cost & Quality
- Held numerous Hill meetings
- Conducted ASHP's legislative day
- Grassroots action alerts (over 3k letters)
- Worked with a larger pharmacy coalition (presented a unified front) on Medication Therapy Management issues

What's Next?

- Under Health Care Reform, Pharmacists have numerous opportunities to become involved, but HOW will they be involved?
  - Up to the agencies
  - Up to ASHP/Pharmacists
  - Up to You: Other Healthcare providers/Educators/Consumers

What will the Changes Mean at the Practice Level?



Post Health Care Reform – Focus Points

- Delivery Systems Reform
  - Medication Therapy Management (MTM) Grants Program
  - Medical Home Model
  - Accountable Care Organizations
- Payment Reform and Quality
- Comparative Effectiveness Research
- Workforce
- 340B Drug Pricing Program

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Medication Therapy Management

- MTM grant program
  - Open to all practice settings
  - Defines MTM using pharmacy's definition
  - Is not specific to Part D or any single plan
  - Will be done in accordance with state practice acts
  - Agency for Healthcare Research and Quality (AHRQ) will provide oversight

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Our Focus

- **Medication Therapy Management (MTM) Grants Program**
  - Get funding, then get involved!
- **Medical Home Model**
  - Pharmacists: Become members of the health care team

AND…..

- **Accountable Care Organizations (ACOs)**
  - Talk to your C-Suites

How the MTM Program Works

- Entities (pharmacies or settings where MTM can be conducted) will apply to AHRQ for grants
- Targeted individuals for MTM:
  - Take 4 or more medications; or
  - Take any high risk medications; or
  - Have 2 or more chronic diseases

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MTM Grants

- MTM grants program
  - Good example of what happens when no money is available
  - May 1, 2010 – Implementation date
  - Law is not implemented (yet)
  - ASHP is working to obtain appropriations so AHRQ can begin providing grants to eligible entities to implement MTM services

Why is MTM program important?

- Statutory definition of MTM—pharmacist-defined
- MTM provided by pharmacists-pharmacist-driven
- Produce measureable results—addresses traditional barriers (CBO scoring) to provider status
- <u>The ultimate goal—provider status</u>

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Our Focus

- Medication Therapy Management (MTM) Grants Program
  - Get funding, then get involved!
- Medical Home Model
  - Pharmacists are included as members of the health care team

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Medical Home

- What is a medical home?
  - A physician-led team
  - Of patient care providers
  - Working in an integrated, collaborative fashion
  - With a focus on care coordination to optimize outcomes

Figure 2. Percentage of the Population of Each State Served by Community Health Centers, 2008.

Data on total numbers of CHC patients in each state are from the National Association of Community Health Centers, which based these numbers on the 2008 Uniform Data System, Bureau of Primary Health Care, Health Resources and Services Administration, Department of Health and Human Services; data on the population in each state are from the U.S. Census Bureau.

Medical Home AHRQ Grants

- **AHRQ will establish grants**
  - For entities to create community-based, interdisciplinary, inter professional health teams
  - To support primary care practices
  - An “entity” is:
    - A State or State-designated entity or
    - An Indian tribe or tribal organization

- **Health teams must agree to provide services to individuals with chronic conditions**
- Health teams may include pharmacists
- Must provide support for primary care providers to provide access to pharmacist-delivered medication management services, including medication reconciliation

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Medical Homes Under Medicaid

- Starting January 1, 2011, states may provide coordinated care through a health home for Medicaid beneficiaries with chronic conditions
- Medicaid beneficiaries with chronic conditions can select a designated provider, team of health care professionals operating with such a provider, or a health team as the individual's health home
  - A "health team" may include a pharmacist
  - "Team of health care professionals" can be based at a hospital

What is an ACO?

- Accountable Care Organizations (ACOs) are:
  - Organizations of health care providers
  - That agree to be accountable for the quality, cost, and overall care of Medicare beneficiaries
  - Who are enrolled in the traditional fee-for-service program and assigned to the ACO
- ACOs will operate through a Medicare shared savings program that will be established by January 1, 2012
- Groups of providers of services and suppliers will manage and coordinate care
  - For Medicare Fee-For-Service beneficiaries
  - Through an ACO

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ACO Requirements

- Hospitals that employ physicians/ACO professionals that meet specified criteria can become ACOs
  - Must become accountable for quality, cost, and overall care of assigned Medicare fee-for-service beneficiaries
  - Must have a formal legal structure to receive and distribute payments for the shared savings
  - Must have 5,000 or more assigned beneficiaries
  - Agree to participate in the program for no less than 3 years

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ACO Requirements (cont.)

- An ACO must:
  - Define processes to promote evidence-based medicine and patient engagement
  - Report on quality and cost measures
  - Coordinate care (e.g. through the use of telehealth, remote patient monitoring, etc.)
  - Show that it meets patient-centeredness criteria, (e.g., patient and caregiver assessments or use of individualized care plans)
- An ACO that meets specified quality performance standards will receive a share of the savings achieved through the program

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Why will hospitals or health systems be motivated to be the center of an ACO?

- Creating an ACO will allow a hospital or health system to bring together various innovations such as pay-for-performance, medical homes, and health information technology improvements and share in the savings generated by those initiatives that could finance further improvements

What are the specific financial incentives in the law?

- Financial incentives will be determined for each ACO if the ACO reaches the estimated average per capital Medicare expenditures for fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics.

- The benchmark set for each ACO will be based on the most recent three-years of per-beneficiary expenditures for parts A and B services for assigned beneficiaries, adjusted for beneficiary characteristics and other factors.

- The ACO incentive payment is a percentage of the savings generated by the ACO.

Pharmacy's Role in an ACO

- Participate in early discussions of health systems planning for ACOs
- Compile research at the hospital/health system level that shows pharmacists' value at improving patient care and reducing costs.
- Collect examples of published research that shows the clinical and economic value of pharmacists to share with hospital leadership.
- Use ASHP Health Policy Alerts Archive. http://www.ashp.org/Import/ADVOCACY/PolicyAlertsArchive.aspx

Published Research-Pharmacist Value

- American Journal of Health-System Pharmacy, Vol. 67, Issue 19, 1624-1634; Sept. 2010 Economic effects of pharmacists on health outcomes in the United States: A systematic review
- Marie A. Chisholm-Burns, Joshua S. Graff Zivin, Jeannie Kim Lee, Christina A. Spivey, Marion Slack, Richard N. Herrier, Elizabeth Hall-Lipsy, Ivo Abraham and John Palmer

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The Patient Protection and Affordable Care Act of 2010:
Impacts on Rural People, Places, and Providers: A First Look

Prepared by the
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About the Rural Policy Research Institute

The Rural Policy Research Institute (RUPRI) provides unbiased analysis and information on the challenges, needs, and opportunities facing rural America. RUPRI's aim is to spur public dialogue and help policymakers understand the rural impacts of public policies and programs. RUPRI is housed within the Harry S. Truman School of Public Affairs at the University of Missouri-Columbia. RUPRI's reach is national and international and it is one of the world's preeminent sources of expertise and perspective on policies impacting rural places and people. Read more at www.rupri.org.

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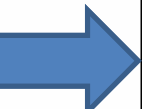
Appendix: Detailed Tables with Commentary on Rural Relevant Provisions from the ACA

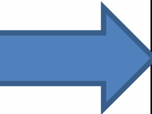
Section	Rural Implementation/Impact
Health Insurance Coverage	
1001-2711: A group plan and health insurance issuer of group and individual plans may not establish lifetime limits on the dollar value of benefits.	Rural people are more likely to be in plans with limits on b change will be especially important. Standardization may create fairness between and across urban and rural areas
1001 – 2714: Persons up to age 26 can stay in parent's plan.	This provision is beneficial to rural dependents, since in ru age 18-26 are more likely not to be enrolled full time in an system that would have them in dependent status.
1002-2793: Grants will be made to States or Exchanges in States for consumer assistance programs, including assistance with enrollment in a group health plan or health insurance coverage by providing information, referral, and assistance.	A set aside or directive to address rural circumstances ma
1101: A temporary high-risk pool program will be established for persons with pre-existing conditions precluding access to insurance coverage. Existing state programs must maintain current levels of support.	This provision is beneficial to rural persons—although the people affected is small, it is very important to them. Cor should be given to making sure plans are affordable to rur
1102: Re-insurance for early retirees	This provision is particularly beneficial to early retirees in
1103: An Internet portal will be established to provide information on coverage options. A direct appropriation of $250 million for state grants to create information for consumers.	While this is important and crucial for the functioning of h exchanges (HIEs), consideration should be given to make s accessible to rural residents since rural persons are less lik access to Internet services. The accessibility of informatio monitored for its impact in rural areas with respect to ava affordable health plans.
1311: A grant program will be created to help states establish exchanges. The minimum criteria to be certified as a health plan include network adequacy, the inclusion of essential community providers, and accreditation with respect to local performance on clinical quality measures. This section allows for regional or other interstate exchanges.	In general, HIEs have the potential to expand the availabil to rural persons. However, it will be crucial to monitor se HIE. In particular, the following should be monitored: out how risk rating and selection is handled, whether there is number of affordable choices of plans available for rural p the whole region, how subsidies are coordinated with the network adequacy standards include usual patterns of car governance is handled in the HIE (that is, does it include r

Section	Rural Implementation/Impact
1421: Small businesses will receive tax credits equal to 50% (35% for tax-exempt eligible small employers) of the lesser of (1) non-elective contributions for premiums or (2) the aggregate amount of contributions that the employer would have made if each employee had enrolled. Eligible employers are those with no more than 25 full-time equivalent employees with average annual incomes of less than $50,000.	This provision is critical for rural employers and employees disproportionate share of rural persons are employed in sm with lower wage rates. It will be very important to monito of the tax credits, and whether small employers become a availability of this program, and take it up.
2001: Medicaid eligibility will be expanded to include all persons under age 65 in low income households who are not enrolled in Medicare. *As amended by Reconciliation:* The federal government will fund 100% of the cost of newly eligible persons from 2014 through 2016, 95% in 2017, 94% in 2018, 93% in 2019, and 90% thereafter. States can initiate this provision sooner, if desired.	This expansion of coverage will have a significant positive i persons because of the disproportionately higher percenta persons with low incomes. It will be important to monitor outreach is done to rural areas to enroll eligible persons.
9022: Eligible employers are those with an average of 100 or fewer employees during either of the 2 preceding years. Employers are required to contribute. Employees are required to have at least 1,000 hours of service for the preceding year.	Given the disproportionately higher percentage of rural pe businesses, this provision will have an important impact or It is not clear how many rural employers will be able to aff implement these plans, however.
10105 and 1416 (GAO Study): The objective of this study is to recommend new applications of the federal poverty rate, adjusted for geographic differences. Collection of the data will be extremely difficult, casting doubt on the validity of measure for small places (pending definition of "region").	This study could have important implications for rural area important to monitor this work. The definition of region a area will be important, as this definition has variable impa across geography.
10203 Funding for the Children's Health Insurance Program is extended through the end of 2015.	This is an important provision for rural persons given the h rates for the Children's Health Insurance Program in rural a
10329: The Secretary must develop methodology to measure health plan value that takes into consideration, where applicable, (a) overall cost to enrollees under the plan, (b) quality of the care provided for under the plan, (c) relative risk of the plan's enrollees as compared to other plans, (d) actuarial value or other comparative measure of the benefits covered under the plan, and (e) other factors as determined by the Secretary.	The impact of risk selection may be particularly important where populations are small, and rural persons are known higher risk profile. Therefore, how health plans handle risl how the regulations are set to monitor this can be crucial f persons, affordability, and the accessibility of plans.
Medicare and Medicaid Payment	
2503: The upper payment limit for pharmaceuticals will be calculated as no less than 175% of the weighted average of the most recently reported	Although this provision improves upon those of the Medic Drug, Improvement, and Modernization Act of 2003, reiml

Section	Rural Implementation/Impact
3201: Medicare Advantage payment reductions begin in 2012 to align Medicare Advantage payments with Medicare fee-for-service payments.	Insurance industry response to the payment reductions i due to complex market conditions. The provision require ensure that rural disparities in health plan access and be do not develop or worsen.
3401: A productivity adjustment to market basket updates for prospective payment system hospitals will be equal to a 10-year average of changes in economy-wide private nonfarm business. This adjustment may result in a lower payment than the previous year. The Secretary will reduce any increases by 0.25% in FYs 2010 and 2011 and reduce any increases by 0.2% in FYs 2012 through 2019. However, the reduction will be 0.0% if the percentage of the non-elderly insured population for the preceding fiscal year is at least 5% less than projected.	Scheduled reductions listed in the section should be cons context of all ACA changes impacting hospital revenue, s delivery models, system affiliations, and efficiency impro cumulative impact on revenue may not be negative for r However, monitoring will be required to ensure rural acc care is maintained.
3403: The ACA establishes the Independent Payment Advisory Board (IPAB), an independent panel of medical experts tasked with devising changes to Medicare's payment system. Beginning in January 2014, each year that Medicare's per capita costs exceed a certain threshold, the IPAB will develop and propose policies for reducing this inflation. The Secretary must institute the policies unless Congress enacts alternative policies leading to equivalent savings.	The IPAB requires rural membership representation. Ru should monitor board reports for geographic bias.
5501: Primary care providers will be paid an additional 10% for primary care services (defined by certain CPT codes) if primary care represents 60% or greater of the practice. This payment will be in addition to the 10% Health Professional Shortage Area bonus.	Because rural physicians often provide more procedures, meet the primary care percentage threshold and thus wo eligible for the primary care bonus. Thus, further study is determine if this provision will benefit primary care pract areas.
10101: Medical reimbursement data centers shall develop fee schedules and other database tools that fairly and accurately reflect market rates for medical services and the geographic differences in those rates, use the best available statistical methods and data processing technology to develop such fee schedules and other database tools, and regularly update such fee schedules and other database tools to reflect changes in charges for medical services.	Since the data centers will develop fee schedules that ref differences in market rates, monitoring is required to ens geographic distribution of medical reimbursements.
10503: A Community Health Center (CHC) fund is established to expand and sustain federal investments in CHCs by appropriating an additional	CHCs are not the only rural safety-net provider. This signi funding influx should be balanced with the needs of rural

Section	Rural Implementation/Impact
1109 (Reconciliation Bill): $400 million is made available for prospective payment system hospitals located in the lowest Medicare-expenditure counties.	Rural impact will depend on county characteristics, n underserved location. Rural hospitals should not be program ineligibility for economic and other factors b
Quality, Financing, and Delivery System Reform	
2602: A Federal Coordinated Healthcare Office will be established to improve coordination between the federal government and states for dually eligible individuals to simplify the process to access services, improve the quality of health care and long-term services, improve care continuity, and improve the quality of performance of providers of services and suppliers under Medicare and Medicaid programs.	Rural expertise is necessary in the new Federal Coord Office to assure rural dually enrolled needs are met a opportunities realized.
3011: A national strategy will be established for improving the delivery of healthcare services, patient health outcomes, and population health.	The national strategy should be comprehensive and include a strong rural component that recognizes the opportunities of rural communities, patients, and pro
3014: A multi-stakeholder group will provide input into the selection of quality measures to the National Quality Forum and then to the Secretary.	The multi-stakeholder group should include meaning representation.
3501: The Center for Quality Improvement and Patient Safety at the Agency for Healthcare Research and Quality will have new responsibilities to conduct healthcare delivery system research and quality improvement technical assistance.	The Agency for Healthcare Research and Quality Cen Improvement and Patient Safety efforts should expli research and quality improvement technical assistan
Cost Measures	For the cost and quality measures listed here, the me and publicly reported should include measures of rur relevant measures should assess performance based type of services appropriately delivered in rural comm providers should not be disadvantaged by measurem associated incentive or payment systems) that by the clinical service, numerator/denominator size, inclusio it impossible for a rural provider to perform well, or i all.
1001–2719a: Healthcare cost information will be made available to the public through an Internet website that allows consumers to understand the amounts that healthcare providers in their area charge for particular medical services.	
1001-2718: Hospitals must make public a list of standard charges, including for diagnosis-related groups.	
1001-2718: Insurers must report the percentage of premiums used for clinical services, quality improvement, and all other non-claims costs.	
 6005: A health plan that provides pharmacy benefits management services on behalf of a health benefits plan in an exchange or through Medicare must report four new measures.	

Section	Rural Implementation/Impact
Quality Measures	
2701: The Secretary shall publish a recommended core set of adult health quality measures for Medicaid eligible adults, with an initial set reported by January 1, 2012.	
3013: The Secretary shall lead a national quality measurement development effort focused on health outcomes, care transitions, health information technology, efficiency, equity, and patient experience.	
3015: The Secretary shall collect and aggregate data on quality and resource use measures from information systems used to support healthcare delivery and may award grants for this purpose.	
10303: The Secretary shall develop and periodically update (at least every 3 years) provider-level outcome measures for hospitals and physicians, as well as other providers as determined appropriate by the Secretary.	
10331: By January 1, 2011, the Secretary shall develop a Physician Compare Internet website with information on physicians and other professionals who participate in the Physician Quality Reporting Initiative, and implement a plan to make information on physician performance public through Physician Compare.	
Delivery System Reform	
2703: State planning grants will be available to provide medical assistance to individuals with chronic conditions who designate a provider or a team of professionals as their health home; hospital readmission and savings data will be measured.	Ensure that the readmissions and savings data requ for evaluation purposes do not bias against the part providers.
2705: A 5-state demonstration project will be established under which payments to "large" safety net hospital systems or networks are adjusted from a fee-for-service structure to a global capitated payment model.	At least one of the sites in each of the 5 state demo include a rural network to test the efficacy of a glob model in rural communities. CAHs should be includ networks.
3021: The Center for Medicare and Medicaid Innovation will be established in the Centers for Medicare and Medicaid Services to test a list of 12 specified payment and service delivery models, including such approaches as patient-centered medical homes, geriatric assessments and	Ensure that the new Center for Medicare and Medi payment and delivery models tested include an em relevant to rural providers and patients.

Section	Rural Implementation/Impact
3022: ACOs will become a permanent part of the Medicare program, and become models based on shared savings.	In implementation, the governance and payment m should not preclude rural participation.
3023: A national pilot program will be established on payment bundling specific to 8 conditions.	Include conditions and sites relevant to rural.
3026: A community-based care transitions program will be established that provides funding for improved care transition services to high-risk Medicare beneficiaries by working across the continuum of care through arrangements with hospitals.	Include CAHs in the program.
3126: This section improves the demonstration project on community health integration models in certain rural counties.	A requirement that CAHs must provide rural health removed, allowing for more CAH participation.
3140: The Medicare Hospice Concurrent Care demonstration program shall be conducted for 3 years in not more than 15 hospice programs, including urban and rural programs.	This may create a greater probability of developing healthcare services.
3501: A Quality Improvement Network Research Program may be established to test, scale, and disseminate interventions to improve quality and efficiency in health care. Quality improvement technical assistance grants or contracts will be available to support institutions that deliver health care and to healthcare providers, including rural and urban providers.	Technical assistance grants could be beneficial to sm practices and hospitals, and to small networks.
3502: Community health teams will be established to support patient-centered medical homes in primary care practices within hospital service areas served by them.	Include rural primary care practices in CAH service a
 3503: A new Patient Safety Research Center provides grants or contracts to entities to implement medication management services provided by licensed pharmacists.	Include a representative proportion of rural pharma medication management program.
3504: At least 4 multi-year contracts or grants will be made to support pilot projects to design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems. Priority will be given to an entity that serves a population in a medically underserved area.	Implement at least one of the 4 grants in a predomi
3505: Grants will be made to trauma centers to further core missions,	In implementation, support rural access to and parti

Value Based Purchasing & Pay for Performance

- Readmissions
  - Heart attack
  - Heart failure
  - Pneumonia
  - Surgery
  - Health care related infections

- "No-Pay" conditions
  - Stage III, IV Pressure Ulcers
  - Catheter associated UTI
  - Vascular catheter-associated infection
  - Blood incompatibility
  - Foreign objects after surgery
  - Certain surgical site infections
  - Air embolism
  - Fall or trauma resulting in serious injury
  - Certain DVT or PE
  - Certain manifestations of poor blood sugar control

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340B Under Healthcare Reform

- **340B program was expanded under healthcare reform, (but not to inpatient)**
  - **Children's hospitals and Free-standing cancer hospitals**
    - Hospital must meet the disproportionate share (DSH) adjustment percentage of 11.75% if it was otherwise reimbursed under the prospective payment system to participate in 340B
  - **Critical access hospitals**
    - No DSH adjustment percentage requirement
  - **Rural referral centers and sole community hospitals**
    - DSH adjustment percentage equal to or greater than 8%

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What does this all mean for health system pharmacy practitioners?

- Health system leaders will be looking for services that manage total patient care and reduce over all cost.
- Revenue and profitability paradigms will change over the next 3-5 years.
- Keeping informed of health systems strategic planning will be critical
- Transitions of care will be a new focal point for many health system pharmacists

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Health Care Reform Wrap-Up

- Medication Therapy Management (MTM) Grants Program
  - Get funding, then get involved!
- Medical Home Model
  - Pharmacists: Become members of the health care team
- Accountable Care Organizations (ACOs)
  - Talk to your C-Suites about your hospital participating in an ACO & the need to incorporate pharmacists' medication and chronic disease management skills within the ACO

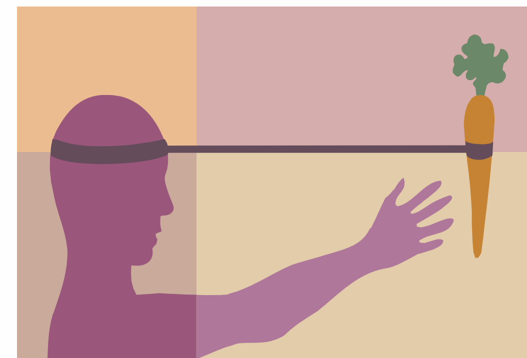
Regulatory Issues

- Electronic Health Records Incentive Program
- Risk Evaluation and Mitigation Strategies (REMS)
- FDA Safe Use Initiative

Meaningful Use

- American Recovery and Reinvestment Act of 2009 contained the Health Information Technology Act (Health IT Act)
  - Includes Medicare and Medicaid incentives to assist providers in adopting electronic health records (EHRs)

- CMS will provide these incentives to physicians and hospital providers who are "meaningful users" of electronic health records



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Meaningful Use (cont.)

- The Key: The definition of "Meaningful Use"
- Incentive payments for "meaningful users" of EHRs begin in 2011 and gradually phase down

Meaningful Use (cont.)

- In 2015, hospitals that are not meaningful EHR users will be penalized
- In FY 2015 hospitals that are not meaningful EHR users would receive a net reduction of the market basket update as follows:
  - FY 2015 – 25%
  - FY 2016 – 50%
  - FY 2017 and beyond – 75%
- For critical access hospitals, payment (currently paid at 101% of the CAH's Medicare allowed costs) is reduced to
  - FY 2015 - 100.66% of cost
  - FY 2016 - 100.33% of cost
  - FY 2017 and beyond - 100% of cost

Meaningful Use Final Rule

- **July 28, 2010, CMS published Final Rule on Meaningful Use**
  - **Stage 1 proposal for Meaningful Use**
  - **Final Rule includes 24 objectives for eligible hospitals that must be met in order for these entities to be deemed meaningful EHR users.**
  - **Some of the objectives for hospitals included:**
    - Use CPOE
    - Implement drug-drug, drug-allergy interaction checks
    - Maintain up-to-date problem list of current and active diagnoses
    - Maintain active medication lists

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Stage 1 Meaningful Use Objectives for Hospitals

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Proposed Stages of Meaningful Use Criteria by Payment Year

First Payment Year	Payment Year				
	2011	2012	2013	2014	2015
2011	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3
2012		Stage 1	Stage 1	Stage 2	Stage 3
2013			Stage 1	Stage 2	Stage 3
2014				Stage 1	Stage 3
2015					Stage 3

Final Stages of Meaningful Use Criteria by Payment Year

First Payment Year	Payment Year				
	2011	2012	2013	2014	2015
2011	Stage 1	Stage 1	Stage 2	Stage 2	TBD
2012		Stage 1	Stage 1	Stage 2	TBD
2013			Stage 1	Stage 1	TBD
2014				Stage 1	TBD
2015	---------	---------	---------	---------	---------

What is a REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a requirement that a drug is dispensed with certain safety measures in place
- FDA can require a REMS when the agency determines it necessary to ensure the benefits of a drug outweigh its risks
- A REMS may include:
  - Medication Guide and/or patient package insert
  - Communication plan to health care providers and/or
  - Elements to assure save use (e.g. certification requirements for healthcare providers, pharmacies, patient monitoring requirements, restricted distribution requirements).

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Where Did REMS Come From?

- **How were REMS created?**
  - **Before REMS there were Risk Minimization Action Plans (RiskMAPS)**
    - Developed during the drug approval process
    - For products that required additional risk management strategies beyond standard product labeling (e.g. lab test requirements for patients, restricted distribution systems)
    - FDA did not have the enforcement authority that the agency now has with REMS

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Where Did REMS Come From? (cont.)

- Prescription Drug User Fee Act (PDUFA) came up for reauthorization in 2007
  - PDUFA was first passed in 1992
  - Sunsets every 5 years
  - Allows FDA to collect fees from industry for new drug applications
- Food and Drug Administration Amendments Act of 2007 (FDAAA)
  - Became the vehicle to reauthorize PDUFA
- Through FDAAA, FDA obtained the statutory authority to require REMS

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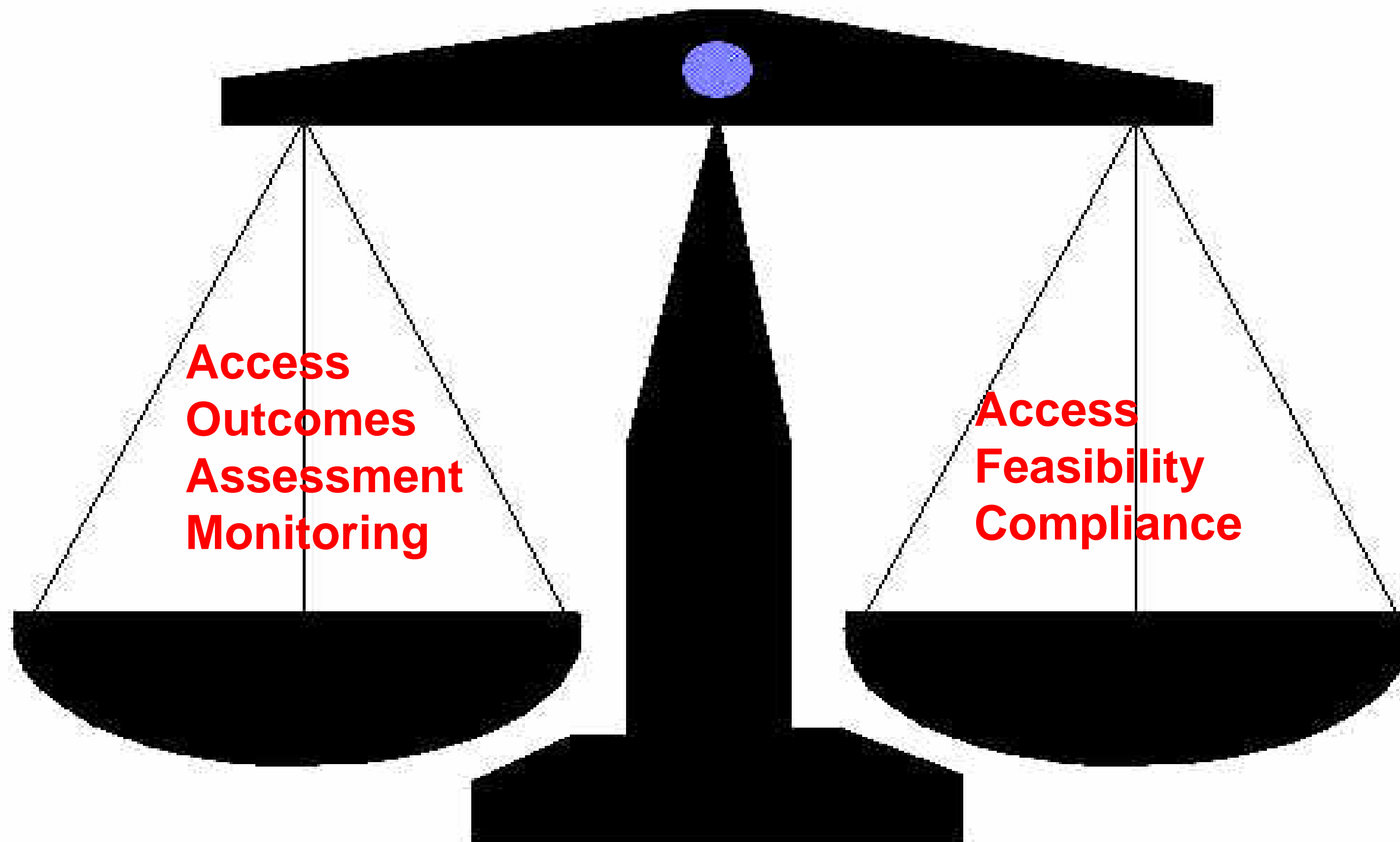
Balancing Medication Safety and Access for All Patients



What's Next?

- **There are well over 100 drugs with REMS in place**
  - **Medication Guide is most common, but also REMS containing elements to assure safe use**
  - **FDA seems to be moving toward requiring class-wide REMS**
    - REMS for long acting and extended release opioids is under development at FDA
    - FDA REMS for ESAs
    - FDA announcement of REMS for rosiglitazone

REMS Issues

- **ASHP has been very involved in advocating to FDA:**
  - **Need for standardization**
    - Currently, duplication of REMS requirements in health care systems
    - No centralized, standardized methodology for implementing REMS
    - Results in significant burdens to the healthcare delivery system
    - Increased workload, potentially resulting in providers and/or patients not initiating a REMS drug
    - Standardization would make monitoring and assessment of REMS more generalizable to future REMS

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REMS Issues (cont.)

- Need to evaluate the effectiveness of REMS
- Need continued verification and validation that patient knowledge and receipt of information improves outcomes
  - Patient adherence
  - Safety & efficacy
- Need for meaningful metrics to determine effectiveness of REMS
  - Measure impact on medication use
  - Measure unintended consequences
- Examine workload impact of REMS, including financial impact

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Resources For Practitioners

http://www.ashp.org/rems

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PRACTICE AND POLICY

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  - Influenza
  - Investigational Drug Services
  - Patient Safety
  - Patient Assistance Programs
  - Public Relations Network Resource Center
  - Quality Improvement Initiative (QII)
  - Risk Evaluation and Mitigation Strategies Resource Center
  - Small and Rural Hospital
  - Tobacco Cessation

Risk Evaluation and Mitigation Strategies Resource Center

The Risk Evaluation and Mitigation Strategies, REMS, were created by the FDA to serve as a post-marketing surveillance process that ensures medication safety. This resource center contains basic information for pharmacists, patients and other healthcare professionals about REMS, as well as other medications that are managed through other medication risk management programs or RDDS outside of the REMS processes.

Access the REMS Database

ASHP's easy to use database containing basic information about each medication along with a risk management program. Links to useful websites are located throughout. Use the alpha list on the right to select from the generic drug name.

- A to G - drug listed by generic name
- I to P - drug listed by generic name
- Q to Z - drug listed by generic name

What are REMS & RDDS?

REMS are post-marketing surveillance processes created by the FDA to ensure drug safety. Previous risk management programs were classified as Risk Minimization Action Plans and Restricted Drug Distribution Systems (RDDS). Read more

Even More Information

Updates on all medications can be found in the FDA's Drug Database or on the manufacturer's website.

FDA Safe Use Initiative

- The mission of the *Safe Use Initiative is to create and facilitate public and private collaborations within the healthcare community. The goal of the Safe Use Initiative is to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing and evaluating cross-sector interventions with partners who are committed to safe medication use.*
- Potential partners in Safe Use include:
  - Federal agencies
  - Healthcare professionals and professional societies
  - Pharmacies, hospitals, and other health care entities
  - Patients, caregivers, consumers, and their representative organizations
- Through coordinated efforts, we can make significant improvements in the safe use of medications and reduce preventable harm from medication misuse, abuse, and errors.

(Reference FDA website accessed 09-24-2010)

What do REMS and Other Safe Use Initiatives Mean to Practitioners?

- Utilize resources to understand regulations
- Examine impact on your pharmacy and health system
- Develop interdisciplinary teams to develop best course of action
- Participate in advocacy to ensure regulators understand impact on health care practices

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Change is here….

- With health care reform, change is on the horizon
- With REMS and 340B, change is here
- ASHP will continue to advocate on the Hill and to the agencies to ensure pharmacists have the opportunity to be involved in all of these issues, and have their voices heard
- But it's also up to you to collaborate with your pharmacists and stay involved in the healthcare discussion and its continual evolution

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New Opportunities and Research
•MTM Grants
•Medical Homes

Pay for Performance

Hospital Re-Admissions

CMS Hospital Compare Report

Hospital Strategies for Mergers

Hospital Status on Meaningful Use

Hospital Strategies for Acquisitions

Hospital Payment Risk for Missed Targets

Compliance with Current Regulations and Drug Reimbursement

ACT NOW

Accountable Care Organizations - 2012

- Health Systems will engage
- Integrates ALL of CMS's payment reforms
- Will be driven by desire to maintain competitive advantage and market share

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