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Sen. Patricia Miller, Chairperson  
Sen. Ryan Mishler  
Sen. Vaneta Becker  
Sen. Ed Charbonneau  
Sen. Beverly Gard  
Sen. Ron Grooms  
Sen. Jean Leising  
Sen. Jean Breaux  
Sen. Earline Rogers  
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Rep. Donald Lehe  
Rep. Eric Turner  
Rep. Charlie Brown  
Rep. John Day  
Rep. Craig Fry  
Rep. Scott Reske  
Rep. Peggy Welch



# HEALTH FINANCE COMMISSION

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**LSA Staff:**

Casey Kline, Attorney for the Commission  
Kathy Norris, Fiscal Analyst for the Commission

Authority: IC 2-5-23

## MEETING MINUTES<sup>1</sup>

Meeting Date: September 28, 2011  
Meeting Time: 10:00 A.M.  
Meeting Place: State House, 200 W. Washington St.,  
Room 404  
Meeting City: Indianapolis, Indiana  
Meeting Number: 3

**Members Present:** Sen. Patricia Miller, Chairperson; Sen. Ryan Mishler; Sen. Vaneta Becker; Sen. Beverly Gard; Sen. Ron Grooms; Sen. Jean Leising; Sen. Jean Breaux; Sen. Earline Rogers; Rep. Steven Davisson; Rep. Suzanne Crouch; Rep. Richard Dodge; Rep. David Frizzell; Rep. Donald Lehe; Rep. Eric Turner; Rep. John Day; Rep. Craig Fry; Rep. Scott Reske; Rep. Peggy Welch.

**Members Absent:** Sen. Ed Charbonneau; Sen. Vi Simpson; Rep. Timothy Brown, Vice-Chairperson; Rep. Ronald Bacon; Rep. Charlie Brown.

Chairperson Patricia Miller called the meeting to order at 10:10 a.m. The Commission discussed the next meeting date, deciding that the last Commission meeting would be held on October 18, 2011 at 10:00 a.m.

### Generic Drug Competitive Bidding

Senator Beverly Gard stated that the issue of generic drug competitive bidding

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<sup>1</sup> These minutes, exhibits, and other materials referenced in the minutes can be viewed electronically at <http://www.in.gov/legislative>. Hard copies can be obtained in the Legislative Information Center in Room 230 of the State House in Indianapolis, Indiana. Requests for hard copies may be mailed to the Legislative Information Center, Legislative Services Agency, West Washington Street, Indianapolis, IN 46204-2789. A fee of \$0.15 per page and mailing costs will be charged for hard copies.

arose during the last legislative session. Mr. Michael O'Connor, Eli Lilly and Co., introduced Professor Mick Kolassa, MME, LLC, who provided the results of a study he conducted concerning potential Medicaid savings through generic bidding. See Exhibit 1. Mr. O'Connor also provided information from the United States Department of Health and Human Services concerning generic drug price increases. See Exhibit 2. Professor Kolassa provided some general information about generic drugs and stated that his study consisted of two steps: (1) determining whether actual savings could occur if the Medicaid program used a bidding process for its generic drug business; and (2) defining the administrative system in a manner that would not be overly burdensome or offset the savings determined in the first step.

Professor Kolassa informed the Commission that a generic drug bidding program could lower state prescription drug costs by requiring aggressive generic substitution programs and including supplemental generic drug rebate agreements. Professor Kolassa discussed the current Indiana Medicaid prescription drug program that utilizes Maximum Allowable Cost (MAC) of drugs. Professor Kolassa stated that the MAC program still results in the state reimbursing too much for generic drugs because the MAC rates tend to be changed slowly and are based on an average price. Professor Kolassa described a generic drug bidding program and stated that there are still several issues that would need to be addressed in the development of such a program.

Professor Kolassa provided an analysis of the top 30 generic drug classifications and the possible savings that would result from implementing a generic drug bidding program. See Exhibit 1, pages 5 through 7. Professor Kolassa described the next steps in developing such a program, including: (1) identifying the drugs and manufacturers to include in the program; (2) identifying incentives that would be provided to pharmacies for stocking the preferred generic drug; (3) identifying disincentives for non-preferred generic drugs; and (4) determining the cost of implementation of the program. Commission members expressed concerns with the increase in inventory that pharmacies would have, the role of wholesalers, the result of less competition, and possible drug shortages.

Ms. Brynna Clark, Generic Pharmaceutical Association, stated that the generic drug manufacturers have some concerns with potential unintended consequences of the proposal, including monopolies, decreasing competition, drug shortages, and the administrative burden of the proposal. Ms. Clark stated that the current prescription drug program used by Indiana Medicaid works.

Ms. Sarah Jagger, Office of Medicaid Policy and Planning (OMPP), informed the Commission that current state law limits what OMPP can competitively bid, so legislative action would be required to allow for this proposal. Ms. Jagger stated that 82% of Indiana's Medicaid prescription drug claims are for generic drugs whereas the national average is 78%. Indiana's current pharmacy reimbursement is at the lowest of the following: (1) the Estimated Acquisition Cost of the drug (which is the Average Wholesale Price less 16%); (2) MAC; or (3) the provider submitted charge. Ms. Jagger said that Indiana is aggressive in managing its MAC program and uses a contractor to assist in establishing and altering the MAC rate. Ms. Jagger reported that in State Fiscal Year 2010, Indiana's MAC program saved the state \$88.5 million. Ms. Jagger stated that OMPP still has some concerns and questions concerning Professor Kolassa's proposal, and indicated that the savings reported by Professor Kolassa of \$5 million includes both federal and state dollars.

Mr. Grant Monahan, Indiana Retail Council, provided a document expressing concerns with the generic drug competitive bidding proposal. See Exhibit 4. Mr. Monahan stated that the current MAC program is competitive.

Mr. Robert Spolyar, CVS/Caremark, stated that he opposes the competitive bidding proposal concept and indicated that no other state has such a program. Mr. Spolyar expressed concerns with a contracted drug reimbursement rate when the prices of drugs often fluctuate.

### **Hospital Employee Immunization Reporting**

Ms. Sarah Strawbridge, Indiana Immunization Coalition, testified that vaccines are an important tool to assist in preventing the spread of diseases. Ms. Strawbridge stated that an individual can have influenza up to a day before symptoms present and can last for five to seven days, during which time influenza can be transmitted to others. Ms. Strawbridge said that an 80% immunization rate for a community is needed to protect a community and that where hospital vaccination programs have been voluntary, the employee immunization rate was only around 70%. Ms. Strawbridge further stated that where companies have had mandatory influenza vaccination programs, the compliance rate was around 88% to 99%.

Ms. Strawbridge testified that all hospital personnel, including students and medical staff, should be required to get the influenza vaccine and should be recorded in the Children and Hoosiers Immunization Registry Program (CHIRP) database. Ms. Strawbridge stated that reporting the immunizations will provide the state with a baseline to measure where the state is. In response to a question concerning the make-up of her Coalition's board, Ms. Strawbridge said that the Coalition consists of providers, health departments, and consumers, and while pharmaceutical manufacturers may belong to the Coalition, they are not members of the board. The Commission discussed concerns with mandating influenza vaccinations for hospital employees and what happens if there is a vaccine shortage.

Mr. Paul Chase, AARP of Indiana, stated that he supports mandatory reporting of hospital employee immunization rates to improve compliance rates and protect the community. Mr. Chase further commented that the law requiring nursing home employees to receive the flu vaccine allows for an exemption when supply is not available.

Dr. Charlotte Graves, Indiana Chapter of the American Academy of Pediatrics, disclosed that she is also a scientific speaker for GlaxoSmithKline. Dr. Graves stated that the governmental Healthy People 2020 goal for hospital employee influenza vaccination rate has been set at 90%. Dr. Graves reported that there is no Indiana hospital employee vaccination rate data currently reported. Dr. Graves testified that hospitals are familiar with using CHIRP and could report employee immunization rates using this existing system.

Mr. Tim Kennedy, Indiana Hospital Association, stated that there are two issues; (1) whether to mandate reporting of hospital employee immunizations; and (2) whether to mandate hospital employees to receive the influenza immunization. See Exhibit 5. Mr. Kennedy informed the Commission of a federal law that goes into effect in 2013 that will require hospitals to report employee flu immunization rates to the federal government. Mr. Kennedy stated that a state reporting requirement is unnecessary and would be redundant. Mr. Kennedy discussed the federal requirements and stated that the information reported to the federal government could be made accessible to the State Department of Health. Mr. Kennedy stated that, with regards to requiring the immunization, he does not favor a legislative mandate at this time since hospitals are voluntarily developing programs on their own.

Mr. Brian Carnes, Indiana State Department of Health (DOH), stated that he finds

little value in reporting the hospital employee influenza immunization rates to DOH, but that if legislation does require this reporting, DOH would like the hospitals use CHIRP. Dr. Joan Duwve, DOH, gave the Commission a demonstration on using the CHIRP database.

### **Agency Updates from Last Meeting**

Ms. Julia Holloway, FSSA, reported to the Commission on multiple FSSA employment initiatives that FSSA has implemented to assist individuals with disabilities in finding employment. See Exhibit 6. Mr. Michael Duvalle, Indiana Department of Administration (IDOA), also testified concerning IDOA's work in increasing employment opportunities for individuals with disabilities. See Exhibit 7. Mr. Duvalle stated that he would continue to partner with the Indiana Association of Rehabilitation Facilities (INARF) and work centers to assist in promoting employment of individuals with disabilities.

### **Pharmacy Drug Substitution and Notification of Providers**

Dr. Steven Maynard, Terre Haute, IN, informed the Commission that generic drugs are not the same thing as brand name drugs. See Exhibit 8. Dr. Maynard stated that seizure medications are only effective under a narrow therapeutic range and that changes in the drug given to a patient with epilepsy impact the individual's care. Dr. Maynard further stated that two-thirds of neurologists have reported a patient experiencing a breakthrough seizure after switching a patient from a brand name epilepsy drug to a generic drug. Dr. Maynard testified that brand-name seizure medications are cost effective because of the hospitalization risks that could occur when switching the patient to a generic epilepsy drug. Dr. Maynard commented that there are litigation liability issues involved with changing the medication as well. Dr. Maynard provided the Commission with some examples of problems he has experienced with his patients when substituting a generic epilepsy drug for a brand name drug. See Exhibit 8.

Dr. Thomas Vidic, Elkhart, IN, informed the Commission that the American Academy of Neurology opposes generic substitution of anti-convulsant drugs for treatment of epilepsy without the attending physician's approval. See Exhibit 9. Dr. Vidic cited the loss of jobs, vehicle accidents, and hospital costs that occur when switching a patient from a brand name epilepsy drug to a generic drug. Dr. Vidic stated that switching between generic epilepsy drugs is a problem as well. Dr. Vidic referred to a bill that was introduced in Connecticut prohibiting the substitution of anti-epileptic drugs. Dr. Vidic stated that the problem was more with insurance companies than pharmacies. Dr. Vidic commented that Indiana Medicaid had just informed him that the prior authorization process for Medicaid was going to be streamlined and that this may help.

Ms. Brynna Clark, Indiana Generic Pharmaceutical Association, stated that the Federal Drug Administration (FDA) has reported the efficacy of generic drugs and that the variance in absorption between a brand name drug and a generic drug is less than 3.5%, and not different than separate batches of the same brand name drug. Mr. Dave Dederichs, Express Scripts, stated that the existing law prohibiting substitution when the prescription specifies to "dispense as written" is sufficient.

Mr. Grant Monahan, Indiana Retail Council, testified that substitution of FDA-approved generic drugs for brand name drugs is a safe and well-established practice. See Exhibit 4. Mr. Monahan stated that pharmacists do not substitute if the prescription specifies to "dispense as written".

Mr. Robert Spolyar, CVS/Caremark, stated that the "dispense as written" law is sufficient and stated that the problem resides with pharmacy benefit managers and the

FDA.

Ms. Michelle Rice, National Hemophilia Foundation, stated there is a drug substitution issue for hemophilia drugs as well. Ms. Rice relayed stories about her sons who have hemophilia and her problems in obtaining the medication they need. Ms. Rice commented that the high cost shares insurers require in obtaining the drugs are also an issue, stating that insurance companies have created specialty tier drugs that require higher co-payments.

Mr. Charlie Hiltunen, Indiana Minority Health Coalition, stated that substitution of generic drugs is only part of the issue, referring to the higher tier co-payment requirements for drugs.

### **Pharmacy dispensing drugs with labels accessible for the visually impaired**

Rep. Craig Fry informed the Commission that a friend made him aware of the problem the visually impaired have in reading prescription drug labels and stated that his local pharmacy purchased at a low cost the equipment necessary to make the labels accessible for the visually impaired.

Ms. Susan Jones informed the Commission that she has been blind since birth. Ms. Jones stated that technology is available to assist a blind individual in identifying each medicine. Ms. Jones testified that her friend who has state-funded healthcare has to have a nurse come in weekly to separate her drugs and that this cost would be unnecessary with the technology.

Mr. Lee Martin stated that he is a veteran and that the Veteran's Administration uses technology to make drug labels accessible for the visually impaired. Mr. Martin stated that he wants pharmacies to make the technology available to everyone.

Mr. Mark Richert, American Foundation for the Blind, stated that many issues face the blind and that providing access to effective communication will allow for the blind to safely take their medication. Mr. Richert referred to the legislation introduced last session that did not pass, saying that it was time for Indiana to commit to this legislation and that the language should not specify the technology to be used.

Mr. John Huffman, American Council of the Blind of Indiana, told the Commission that blind individuals are managing multiple prescriptions by distinguishing a drug by the size of bottles or by tying rubber bands, ribbons or other items to containers. Mr. Huffman stated that this issue could become a liability issue or result in a claim under the federal American with Disabilities Act, which requires access to the same materials as non-disabled individuals.

Mr. Grant Monahan, Indiana Retail Council, made comments concerning the language contained in legislation from last year, stating that requiring specific labeling or requirements is problematic. Mr. Monahan gave the example of having the label in braille, and the fact that not all blind people can read braille, and also noted that the pharmacist would have a hard time confirming that the label's language was correct. Mr. Monahan stated that his members are reviewing the various technologies available for reliability and cost. See Exhibit 4.

Mr. Robert Spolyar, CVS/Caremark, questioned whether a problem even exists and needs to be addressed.

## Midwifery

Dr. Joseph LaRosa testified that the Indiana Section of the American Congress of Obstetricians and Gynecologists (ACOG) does not support lay midwifery. Dr. LaRosa stated that he is concerned for the safety of the patients and that the person delivering a newborn must have the proper training.

Ms. Mary Ann Griffin, Certified Professional Midwife (CPM), informed the Commission that she has been a midwife for 29 years, delivered over 2,000 babies, and is certified. Ms. Griffin testified that the Indiana Midwives Task Force was founded to promote and support legal home birth options and set forth regulations for midwives. See Exhibit 10. Ms. Griffin stated that over 900 births a year in Indiana occur at home. Ms. Griffin testified that CPMs are licensed, certified, or registered in 28 states, and that Indiana is one of nine states that prohibit this type of midwifery. Ms. Griffin stated that home birth is safe and referred to the CPM 2000 study which found that home birth for low risk women is just as safe as hospital birth. Ms. Griffin discussed the education needed to become a CPM. See Exhibit 10.

Dr. John Labban stated that he enters into a home birth agreement with patients that compares to a hospital birth agreement. Dr. Labban testified that he sees a patient who is going to use a midwife and have a home birth three times during her pregnancy and provides an outlet for information for the midwife or patient. Dr. Labban stated that since home births are going to happen, they need to be legalized and standards need to be defined.

Ms. Linda Barton-Kirch, RN, Certified Nurse Midwife (CNM), stated that there is a fundamental right for a woman to choose where she wants to deliver her baby and that home births need to be regulated to ensure that trained individuals are providing this service. Ms. Barton-Kirch stated that collaborative care does not currently exist because of the prohibition in Indiana law and that regulation is needed to protect the consumer.

Ms. Georg'ann Cattelona, Director of Bloomington Area Birth Services and consumer, stated that she performed a lot of research before determining that a home birth was best for her. Ms. Shannon Frieka, consumer, stated that she had difficulty in researching the qualifications of midwives in Indiana because of Indiana law. Ms. Frieka stated that licensure would help protect consumers and that she is studying to become a CPM.

Dr. Rhonda Sharp, representing the Indiana State Medical Association (ISMA), discussed the differences in the levels of education among midwives and physicians. Dr. Sharp referred to the lack of data concerning mortality rates of home births, commenting that current data is skewed because some hospital births started off in the home. Dr. Sharp gave the Commission examples of problematic home births in the last six months that she had been involved with afterwards at the hospital. Dr. Maria Del Rio Hoover, representing ISMA, stated that she has experienced similar stories to those described by Dr. Sharp and agreed that there was insufficient data available concerning mortality rates. Dr. Hoover stated that legalizing midwives performing home births would place outcomes at risk.

Ms. Heidi Curtis told the Commission about her experience with a home birth in which her baby died. Ms. Curtis stated that she had conducted as much research as she could and had received recommendations for the midwife that she used. Ms. Curtis stated that she has concerns with home births and accountability, stating that her midwife left the state and is now practicing in another state with no action taken against her certification.

Ms. Glenna Shelby, representing the Indiana State Nurses' Association (ISNA), stated that ISNA neither supports nor opposes this proposal but has some concerns with the similarity in name of CPM and CNM, which require different education levels. Ms. Shelby also stated that if the CPMs were licensed, then the CNMs would want current statutory restrictions on their practice concerning home births to be adjusted as well.

### **Adult day services licensure**

Ms. Kim Smith and Ms. Tina McIntosh, Indiana Association of Adult Day Services, informed the Commission that their Association has been discussing the need for licensure the last three years. Ms. McIntosh stated that adult services are provided to individuals over 18 years old and that this industry has increased by 35% nationwide over the last 8 years. Ms. McIntosh stated that, since the industry is not regulated, she does not even know how many adult day services facilities exist in Indiana unless the facility participates in the Medicaid program. Ms. McIntosh expressed the need for minimum standard of care requirements for an adult day services facility.

Mr. Dennis Neary, Indiana Health Care Association, stated that his Association supports the concept of licensure but has not seen any language specifying the standards that would be established. Mr. Jim Leich, Indiana Association of Homes & Services for the Aging, stated that some of his members provide adult day services and that licensure would be an important step for this service to be included as part of long term care and would assist in ensuring quality care.

The Commission discussed who the proper agency would be to provide this licensure. Ms. McIntosh expressed an interest in having the Division of Aging operate the licensure since the Division already regulates those who participate in the Medicaid program. Commission members discussed whether the issue of licensure was still in the development stage and may need more time before legislation is considered.

See Exhibit 11 for the following documents that were distributed to Commission members:

-Letter from the American Lung Association expressing support for hospital reporting of employee influenza vaccination rates

-Memorandum from Diane Graves concerning accessibility to prescription drug labels by the blind

-Letter from Dr. Ardesha concerning anti-epileptic drug substitution

The Commission adjourned at 3:45 p.m.

**MMIE**

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# Potential Medicaid Savings Through Generic Bidding



# CMS Best Practices Report, 2004

## 4 Proven Approaches to Cost Savings

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### **Safe and Effective Approaches to Lowering State Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs (9/9/04)**

1. Aggressive Generic Substitution Policies
2. Supplemental Rebate Agreements
3. Successful Disease Management Programs in Medicaid
4. Electronic Transmission of Prescriptions (E-Prescribing)

Generic Bidding combines the first two approaches

# Potential Medicaid Savings

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- ▶ Generic drugs make up the majority of prescriptions reimbursed by State programs, but there are few efforts to gain competitive prices for these products
- ▶ The market for generic drugs is highly competitive, with prices constantly dropping
- ▶ State Medicaid programs tend to pay prices well above market prices when they reimburse for generic drugs, even with MACs, mainly because the reimbursement rates tend to change very slowly and MAC prices are often based on “Averages” not on specific prices.
- ▶ By contracting with individual generic firms to provide Medicaid with “exclusive” generic drugs, substantial savings can be realized
  - Generic firms will gladly contract with the State, guaranteeing their lowest price in exchange for placement as the exclusive generic for the program
    - All firms are likely to compete for part of this business, guaranteeing their lowest prices

# How would bidding work?

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- ▶ The State would issue a request for bids for the most commonly prescribed generic drugs within the Medicaid program.
- ▶ The lowest bidder(s) would be awarded the contract for the State programs, which would require that retailers stock and dispense only those manufactures' product for Medicaid.
- ▶ Winners would provide their products to retail pharmacies at the contract price, pharmacies would be reimbursed at a MAC plus a fee.
  - Some disincentive would be needed to prevent use of non preferred generics
- ▶ Manufacturers would provide a rebate to the State for the use of their products
- ▶ Supplemental rebates will facilitate the contract pricing and rebates
  - Upon completion of this phase we will provide specific guidance on the operations of such a program.
  - Our work to date has focused on determining the potential for savings, not in the details of implementation

# Potential Savings Analysis

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- ▶ To determine the potential savings to a state, we undertook an analysis using commercially and publicly available data to estimate the potential savings to the State with competitive bidding. To do this we used:
  - The prices at which the State reimbursed retail pharmacies for several widely used generic drugs (from IMS and other sources – including the states themselves)
  - The prices for the same generics charged by a large national wholesaler
  - The prices for the same generics available through the Federal Supply Schedule
- ▶ We then took the lowest of the two prices (Wholesaler or FSS) and compared them with the prices actually paid by the State
- ▶ We believe this analysis is conservative because we are confident that prices lower than the wholesale and FSS prices can be achieved through competitive bidding.

# Indiana Potential Savings Analysis (using State provided data)

NDC Description	Average MAC rate per unit	FSS prices	Whlsr Web	Total Spending	Ingredient Spending	Maximum Savings
HYDROCODON-ACETAMINOPHEN 5-500	\$0.03641	\$0.0340	\$0.0325	\$841,959.65	\$291,851.35	(\$31,196.60)
OMEPRAZOLE DR 20 MG CAPSULE	\$0.15835	\$0.1048	\$0.4853	\$1,393,608.15	\$955,404.09	(\$319,262.96)
AMOXICILLIN 400 MG/5 ML SUSP	\$0.03860	\$0.0224	\$0.0278	\$1,227,887.73	\$703,279.35	(\$295,605.42)
TRAMADOL HCL 50 MG TABLET	\$0.02521	\$0.0286	\$0.0259	\$464,247.00	\$209,426.98	\$5,694.76
ALPRAZOLAM 1 MG TABLET	\$0.03542	\$0.0162	\$0.0290	\$482,120.31	\$285,587.19	(\$155,422.90)
ALBUTEROL 0.083% INHAL SOLN	\$0.05612	\$0.0430	\$0.0772	\$1,397,662.22	\$1,083,602.74	(\$253,369.92)
CYCLOBENZAPRINE 10 MG TABLET	\$0.03545	\$0.0161	\$0.0554	\$390,107.28	\$164,439.84	(\$89,702.81)
AZITHROMYCIN 250 MG TABLET	\$0.74810	\$0.7790	\$1.5233	\$640,897.53	\$374,344.32	\$15,491.84
CLONAZEPAM 1 MG TABLET	\$0.02873	\$0.0284	\$0.0270	\$324,997.80	\$148,018.80	(\$8,906.87)
HYDROCODON-ACETAMINOPH 7.5-500	\$0.04847	\$0.0310	\$0.0310	\$432,751.20	\$237,240.39	(\$85,051.84)
ALPRAZOLAM 0.5 MG TABLET	\$0.03119	\$0.0110	\$0.0266	\$325,349.34	\$157,277.88	(\$101,178.25)
AMOXICILLIN 250 MG/5 ML SUSP	\$0.02767	\$0.0099	\$0.0267	\$658,622.40	\$337,735.44	(\$216,382.73)
CLONAZEPAM 0.5 MG TABLET	\$0.01766	\$0.0139	\$0.0154	\$262,852.60	\$70,143.25	(\$14,991.46)
AMOXICILLIN 500 MG CAPSULE	\$0.11606	\$0.0090	\$0.1040	\$426,846.40	\$230,974.45	(\$210,412.81)
HYDROCODON-ACETAMINOPH 7.5-750	\$0.04259	\$0.1589	\$0.0410	\$360,836.88	\$194,879.46	(\$7,335.87)
CEPHALEXIN 500 MG CAPSULE	\$0.16896	\$0.0975	\$0.3578	\$491,796.00	\$336,743.65	(\$141,551.18)
HYDROCODON-ACETAMINOPHEN 5-325	\$0.22297	\$0.1590	\$0.1436	\$778,206.69	\$643,478.40	(\$228,763.94)
FLUTICASONE PROP 50 MCG SPRAY	\$2.82064	\$0.8968	\$1.2425	\$3,125,070.60	\$3,097,634.22	(\$2,059,832.40)

# Indiana Potential Savings Analysis (using State provided data)

NDC Description	Average MAC rate per unit	FSS prices	Whlsr Web	Total Spending	Ingredient Spending	Maximum Savings
IBUPROFEN 800 MG TABLET	\$0.04604	\$0.0235	\$0.0578	\$312,902.60	\$155,835.35	(\$76,359.32)
HYDROCODON-ACETAMINOPHN 10-500	\$0.11702	\$0.0706	\$0.1072	\$795,002.88	\$666,643.04	(\$263,600.24)
HYDROCODON-ACETAMINOPHN 10-325	\$0.14486	\$0.0950	\$0.1480	\$1,012,954.80	\$889,582.10	(\$306,096.52)
IBUPROFEN 100 MG/5 ML SUSP	\$0.02824	\$0.0083	\$0.0323	\$561,645.32	\$307,594.80	(\$216,615.66)
SULFAMETHOXAZOLE-TMP DS TABLET	\$0.07387	\$0.0976	\$0.1965	\$242,779.39	\$84,148.36	\$26,984.33
CLONIDINE HCL 0.1 MG TABLET	\$0.03579	\$0.0343	\$0.0569	\$333,468.00	\$96,084.00	(\$3,958.10)
POLYETHYLENE GLYCOL 3350 POWD	\$0.03698	\$0.0319	\$0.0464	\$1,143,410.00	\$964,650.00	(\$132,339.08)
AZITHROMYCIN 200 MG/5 ML SUSP	\$0.75107	\$0.4586	\$0.6460	\$1,148,806.08	\$943,719.36	(\$374,885.71)
PROMETHAZINE 25 MG TABLET	\$0.13185	\$0.1310	\$0.0916	\$351,408.30	\$222,383.76	(\$67,554.31)
LORAZEPAM 0.5 MG TABLET	\$0.03126	\$0.0233	\$0.0274	\$233,512.24	\$73,876.66	(\$18,916.56)
FOLIC ACID 1 MG TABLET	\$0.02189	\$0.0180	\$0.0712	\$194,224.80	\$42,880.80	(\$7,653.47)
SERTRALINE HCL 100 MG TABLET	\$0.07825	\$0.0433	\$0.1030	\$304,316.16	\$160,166.40	(\$71,722.01)
ZOLPIDEM TARTRATE 10 MG TABLET	\$0.03263	\$0.0268	\$0.0410	\$177,995.40	\$45,728.10	(\$8,313.17)
NAPROXEN 500 MG TABLET	\$0.04182	\$0.0408	\$0.0922	\$216,629.64	\$96,751.80	(\$2,358.86)
METFORMIN HCL 500 MG TABLET	\$0.02485	\$0.0541	\$0.0275	\$205,483.95	\$89,462.40	\$9,507.71
				\$21,260,359.34	\$14,361,568.73	(\$5,711,662.33)
			<b>SAVINGS</b>	<b>-27%</b>	<b>-40%</b>	

# Potential Details

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- ▶ Provide sufficient advanced notice to allow retail pharmacies to acquire inventory
- ▶ Award bid to two suppliers for each drug chosen
  - Only award in cases where savings are significant relative to current MAC
  - Include penalties if awardees run out of inventory or cause similar disruptions
- ▶ Manage through current MAC and PDL programs
  - MAC to establish reimbursement
  - PDL to determine and receive rebate

# Unanswered Questions/Next Steps

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- ▶ Which drugs to target
- ▶ Establish management parameters with current PDL and MAC systems
- ▶ Identify all manufacturers willing to participate
- ▶ Identify any manufacturers with whom retail pharmacies would be unwilling to do business
- ▶ Identify and quantify the appropriate incentives to encourage stocking and dispensing of preferred generics and disincentives for doing otherwise
- ▶ Calculate costs of implementation
- ▶ Calculate net savings



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

~~OCT 24 2007~~

**TO:** Kerry Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services

**FROM:** Daniel R. Levinson *Daniel R. Levinson*  
Inspector General

**SUBJECT:** Review of Generic Drug Price Increases (A-06-07-00042)

Attached is our final report on generic drug price increases. Our objective was to determine the extent to which generic drug price increases have exceeded the specified statutory inflation factor used to calculate the inflation-based rebate for brand-name drugs.

Section 1927 of the Social Security Act (the Act) requires manufacturers to pay additional rebates for brand-name drugs when the average manufacturer prices (AMP) for those drugs increase more than a specified inflation factor. The Act does not include a similar inflation-based rebate provision for generic drugs.

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. By applying the method in the Act for calculating additional rebates on brand-name drugs to generic drugs, we calculated that the Medicaid program would have received a total of \$966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

We recommend that the Centers for Medicare & Medicaid Services (CMS) consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

In its comments on our draft report, CMS said that the report provides evidence that additional rebates would be payable if the inflation-based rebate provision were applied to generic drugs. However, CMS said that it cannot commit to pursuing the legislative change we recommended at this time because it has not yet had sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the Deficit Reduction Act of 2005. CMS agreed to consider our recommendation when it considers future legislative proposals.

Page 2 – Kerry Weems

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at [George.Reeb@oig.hhs.gov](mailto:George.Reeb@oig.hhs.gov). Please refer to report number A-06-07-00042 in all correspondence.

Attachment

Department of Health and Human Services



**REVIEW OF GENERIC DRUG  
PRICE INCREASES**



**Daniel R. Levinson**  
Inspector General

October 2007  
A-06-07-00042

# *Office of Inspector General*

<http://oig.hhs.gov>

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## **OAS FINDINGS AND OPINIONS**

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.



## **EXECUTIVE SUMMARY**

### **BACKGROUND**

#### **Medicaid Drug Rebate Program**

The Medicaid drug rebate program became effective on January 1, 1991, pursuant to section 1927 of the Social Security Act (the Act). For a covered outpatient drug to be eligible for Federal Medicaid funding, the manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. During the period covered by our review, section 1927(b)(3) of the Act required a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) and, if applicable, the best price for each covered outpatient drug.

The Act requires the payment of additional rebates for single source and innovator multiple source drugs (collectively, “brand-name drugs”) under certain situations. Section 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases more than a specified inflation factor. Generally, the amount of the additional rebate is based on the amount that the drug’s reported AMP exceeds its inflation-adjusted baseline AMP, and manufacturers pay the additional rebate for each unit of the drug reimbursed by Medicaid. The Act does not include a similar inflation-based rebate provision for noninnovator (generic) drugs.

#### **Objective**

Our objective was to determine the extent to which generic drug price increases have exceeded the specified statutory inflation factor.

### **FINDINGS AND RECOMMENDATION**

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. By applying the method in the Act for calculating additional rebates on brand-name drugs to generic drugs, we calculated that the Medicaid program would have received a total of \$966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

We recommend that CMS consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

### **CENTERS FOR MEDICARE & MEDICAID SERVICES’S COMMENTS**

In its comments on our draft report, CMS agreed to consider our recommendation as it considers future legislative proposals. The full text of CMS’s comments is included as the Appendix.

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## INTRODUCTION

### BACKGROUND

#### Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective on January 1, 1991, pursuant to section 1927 of the Social Security Act (the Act). For a covered outpatient drug to be eligible for Federal Medicaid funding, the manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. During the period covered by our review, section 1927(b)(3) of the Act required a participating manufacturer to report quarterly to CMS the average manufacturer price (AMP) and, if applicable, the best price for each covered outpatient drug.

CMS uses the AMP and, in some cases, the best price to calculate a unit rebate amount (URA) for each drug. Section 1927(c)(1) defines a basic rebate amount for single source and innovator multiple source drugs (collectively, "brand-name drugs") as the greater of the difference between the AMP and the best price or a specified percentage of the AMP, which has been 15.1 percent since January 1, 1996. Section 1927(c)(3) defines the URA for noninnovator (generic) drugs as 11 percent of the AMP.

Section 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases more than a specified inflation factor. Generally, the amount of the additional rebate is based on the amount that the drug's reported AMP exceeds its inflation-adjusted baseline AMP, and manufacturers pay the additional rebate based on utilization (i.e., units of the drug reimbursed by Medicaid).

The baseline AMP for a brand-name drug that was on the market when the Act was passed was the AMP for the quarter ending September 30, 1990. The baseline AMP for a drug that entered the market after 1990 was generally the AMP in effect for the quarter after it entered the market. The baseline AMP for each drug was indexed to the consumer price index for urban consumers for the appropriate quarter. The Act does not include a similar inflation-based rebate provision for generic drugs.

#### President's Budgetary Proposal for Fiscal Year 2001

The President's budget request for fiscal year 2001 contained a proposal that would have extended the additional rebate provision to generic drugs. The Congressional Budget Office estimated that the proposal would have saved \$800 million over 10 years. The proposal was not implemented.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine the extent to which generic drug price increases have exceeded the specified statutory inflation factor.

### **Scope**

We obtained and reviewed a list of the top 200 generic drugs (top 200 generics), ranked by Medicaid reimbursement, for each year from 1991 through 2004.<sup>1</sup> Our objective did not require that we identify and review any internal control systems.

### **Methodology**

To accomplish our objective, we:

- reviewed section 1927 of the Act;
- reviewed CMS guidance on the URA calculation;
- obtained from CMS a list of the top 200 generics, in terms of Medicaid reimbursements, for each year from 1991 through 2004;
- obtained market date, AMP, best price, URA, consumer price index for urban consumers values, and utilization from CMS for the top 200 generics for each year;
- assigned a baseline AMP to each generic drug in our review based on the AMP for the second quarter the drug was on the market;
- compared each quarterly AMP to the inflation-adjusted baseline AMP;
- calculated an additional rebate amount for the top 200 generics, using steps similar to the additional rebate calculation for brand-name drugs, for each quarter that the quarterly AMPs exceeded the inflation-factored baseline AMPs; and
- applied the additional rebate amount for each of the top 200 generics to the utilization of the drug to determine a total dollar amount of additional rebates for generic drugs.

We performed our review in accordance with generally accepted government auditing standards.

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<sup>1</sup>We obtained this list from CMS. A total of 772 drugs were in the top 200 generics at least once during the 14 years.

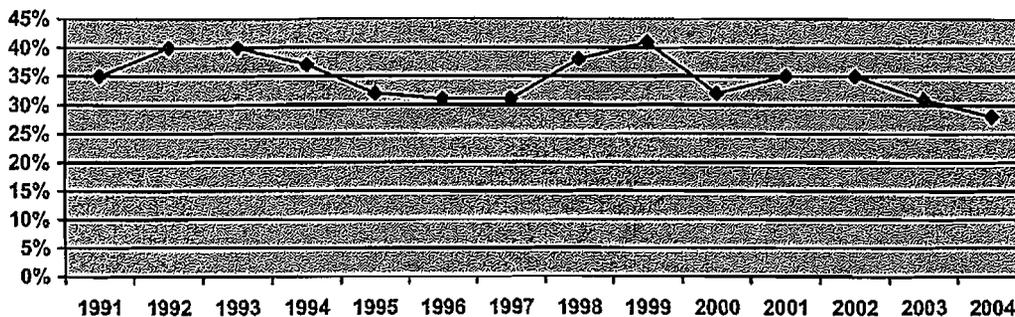
## FINDINGS AND RECOMMENDATION

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. By applying the method in the Act for calculating additional rebates on brand-name drugs to generic drugs, we calculated that the Medicaid program would have received a total of \$966 million in additional rebates for the top 200 generics, ranked by Medicaid reimbursement, from 1991 through 2004.

### GENERIC PRICE INCREASES

For the top 200 generics, 35 percent of the quarterly AMPs exceeded their inflation-adjusted baseline AMPs.<sup>2</sup> For 523 of the 772 drugs we reviewed, there was at least one quarter in which the drugs' quarterly AMPs exceeded the inflation-adjusted baseline AMPs. We also noted that 100 drugs had quarterly AMPs exceeding their inflation-adjusted baseline AMPs for every quarter that the drugs were included in the review. The graph below shows the percent of quarterly AMPs that exceeded their inflation-adjusted baseline AMPs each year from 1991 to 2004.

**Percent of Quarterly Average Manufacturer Prices Greater Than Inflation-Adjusted Average Manufacturer Prices**



The AMP increases exceeding the specified statutory inflation factor were frequent and significant for some drugs. For example, one drug had quarterly AMPs that exceeded the inflation-adjusted AMPs by an average of 40 percent for all 54 of the quarters in our review.<sup>3</sup> In another example, one drug had quarterly AMPs that exceeded the inflation-adjusted AMPs by an average of 53 percent for all 22 of the quarters that the drug was in the top 200 generics.

<sup>2</sup>CMS determines Medicaid drug rebates quarterly. We reviewed information on the top 200 generics for all four quarters of each year; however, not all 200 had utilization or Medicaid drug rebate information for all four quarters of each year.

<sup>3</sup>We determined baseline information based on the second quarter a drug was on the market. For drugs on the market when the rebate program began, we began our review for the second quarter of 1991 and looked at a total of 54 quarters from the third quarter of 1991 through the fourth quarter of 2004.

## ADDITIONAL REBATES

Using the method in the Act for calculating the additional rebate on brand-name drugs, we calculated additional rebates for the yearly top 200 generics in our review. The additional rebates totaled \$966 million from 1991 through 2004. The additional rebates for the top 200 generics increased most years, from more than \$4 million in 1991 to more than \$151 million in 2004. The table below shows the annual amount of additional rebates, actual rebates, and percentage increases in rebates for the top 200 generics.

**Calculated Additional Rebates and Actual Rebates for the Top 200 Generic Drugs  
1991–2004**

Year	Calculated Additional Rebates	Actual Rebates	Percentage Increase in Rebates
1991	\$4,121,324	\$21,766,915	19%
1992	16,589,099	27,813,999	60%
1993	29,470,249	34,476,275	85%
1994	40,643,737	39,279,335	103%
1995	47,805,812	44,482,024	107%
1996	62,452,669	44,029,230	142%
1997	65,504,220	47,121,700	139%
1998	93,019,527	48,885,496	190%
1999	85,501,693	48,007,739	178%
2000	65,424,060	49,847,262	131%
2001	95,784,852	71,888,361	133%
2002	106,853,451	83,665,873	128%
2003	101,571,893	85,383,928	119%
2004	151,077,044	100,891,678	150%
<b>Total</b>	<b>\$965,819,630</b>	<b>\$747,539,815</b>	<b>129%</b>

## RECOMMENDATION

We recommend that CMS consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

## CENTERS FOR MEDICARE & MEDICAID SERVICES'S COMMENTS

In its comments on our draft report, CMS said that the report provides evidence that additional rebates would be payable if the inflation-based rebate provision were applied to generic drugs. However, CMS said that it cannot commit to pursuing the legislative change we recommended at this time because it has not yet had sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the Deficit Reduction Act of 2005. CMS agreed to consider our recommendation when it considers future legislative proposals.

The full text of CMS's comments is included as the Appendix.

# **APPENDIX**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator  
Washington, DC, 20201

DATE: SEP 10 2007  
TO: Daniel R. Levinson  
Inspector General  
FROM: Kerry Weems, *Kerry Weems*  
Acting Administrator  
SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Generic Drug Price Increases" (A-06-07-00042)

RECEIVED  
2007 SEP 11 AM 9:46  
OFFICE OF INSPECTOR GENERAL

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled "Review of Generic Drug Price Increases." This report provides evidence that additional rebates would be payable if the inflation-based rebate provision is applied to generic drugs. Legislation would be needed to extend the inflation-based rebate provisions to generic drugs.

In light of recent changes implemented by the Deficit Reduction Act of 2005 (DRA), the Centers for Medicare & Medicaid Services (CMS) cannot commit to pursuing the legislative change recommended by OIG at this time. CMS will consider OIG's recommendation as we consider legislative proposals in the future.

The OIG findings and recommendations and the CMS responses are as follows:

**OIG Findings**

Overall, prices for generic drugs exceeded increases in the CPI-U for 35 percent of the generic drugs reviewed by the OIG. If the additional rebate had been applied to generic drugs, the Medicaid program would have received additional rebates of \$966 million for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

For 532 of the 772 drugs reviewed, the quarterly AMPs exceeded the inflation-adjusted baseline AMP in at least one quarter. One hundred drugs had quarterly AMPs exceeding their inflation-adjusted baseline AMPs for every quarter of the review. The AMP increases exceeding the specified statutory inflation factor were frequent and significant for some drugs. For example, one drug had quarterly AMPs that exceeded the inflation-adjusted AMP by an average of 40 percent for every quarter of the 14 years reviewed. In another example, one drug had quarterly AMPs that exceeded the inflation-adjusted AMPs by an average of 53 percent for all 22 of the quarters that the drug was in the top 200 generic drugs, ranked by Medicaid reimbursement.

Page 2-Daniel R. Levinson

Using the method for calculating the additional rebates for brand name drugs, the OIG calculated that the additional rebates that would have been due for the top 200 generics increased most years, from more than \$4 million in 1991 to more than \$151 million in 2004.

**OIG Recommendation**

CMS should consider seeking legislation to extend the additional rebate provision to generic drugs.

**CMS Response**

The CMS will consider OIG's recommendation as we consider legislative proposals in the future. The DRA included major changes to the Medicaid prescription drug program. The final rule implementing these changes was published in the Federal Register on July 17, 2007. We have not yet had sufficient time to assess the impact of these changes and need to do so before seeking additional changes to the program.

Again we thank you for the opportunity to review and comment on the subject draft report.



# MEDICAID GENERIC DRUG REIMBURSEMENT PROGRAM

September 28, 2011  
Health Finance Commission

Office of Medicaid Policy and Planning





## Senate Resolution ~~2527~~<sup>71</sup>

- “Study whether the Family and Social Services Administration shall require all generic drug manufacturers...to compete in a competitive bidding process created by the agency...”



## IC 12-15-11-7

- **Competitive bids; services and items for which bids may be sought**

Sec. 7. The office may seek competitive bids for the following items or services provided under Medicaid:

- (1) Prescribed drugs and services for state operated institutions.
- (2) Physical therapy and other therapeutic services.
- (3) Prescribed laboratory and x-ray services.
- (4) Eyeglasses and prosthetic devices.
- (5) Medical equipment and supplies.
- (6) Transportation services.



# Indiana Medicaid Pharmacy Program, SFY 2011

	Claim Volume	Expenditures
Brand Name	2,609,787 (18%)	\$558.9M (78%)
Generic	12,063,378 (82%)	\$157.3M (22%)
<b>Total</b>	<b>14,673,165</b>	<b>\$716.2M</b>

Indiana ranks in the **top 2-3** generic dispensing rates nationwide amongst State Medicaid programs.



# Pharmacy Reimbursement Methodology

In accordance with Indiana law (405 IAC 5-24-4), Indiana Medicaid reimburses pharmacy providers at the **lowest** of:

1. The estimated acquisition cost (EAC) of the drug, plus the Medicaid dispensing fee.
  - “Estimated acquisition cost” (EAC) is the agency’s best estimate of what providers pay for a drug. Indiana Medicaid currently uses Average Wholesale Price (AWP) minus 16% as “EAC”. AWP is provided by a national drug data base vendor, First DataBank.
2. The State maximum allowable cost (MAC) of the drug, plus the Medicaid dispensing fee.
  - “State maximum allowable cost” of a drug is determined by a Medicaid contractor, Myers & Stauffer, LC, based on invoice information they receive from Medicaid pharmacy providers.
3. The provider’s submitted charge, which is the provider’s usual and customary charge to the general public for the drug.



## Other Commonly Used Pharmacy Reimbursement Terms

- **Ingredient cost**-Medicaid reimbursement is comprised of the estimated acquisition cost (EAC) of the drug, essentially the “ingredient cost”, plus the Medicaid dispensing fee. “Ingredient cost” generally means the amount that Medicaid pays for the drug component, not including the dispensing fee.
- **Dispensing fee**-The amount paid by Medicaid to the provider for the provider’s dispensing of any given prescription.
- **Acquisition cost**-The amount the provider pays to acquire a drug, such as from a wholesaler. Also sometimes referred to as “actual acquisition cost”.
- **Average acquisition cost**-The average cost incurred by providers over a given area to acquire a given drug



## Indiana Medicaid State Maximum Allowable Cost (SMAC) program

- Generic drug ingredient reimbursement is aggressively managed under SMAC.
  - 80% of generic drug spend has SMAC rate.
  - Regular monitoring and monthly rate updates based on marketplace changes.
- SFY2010 SMAC Savings = \$88.5M
- Indiana Medicaid SMAC = Gold Standard
  - Administered by Myers and Stauffer LLC (M&S)
  - CMS contracted with M&S to replicate Indiana SMAC nationwide



# Competitive Bidding Administrative Requirements

- Process for obtaining and managing bids and setting pricing not developed.
  - No proven model to adopt from other states.
- Administrative requirements could be costly to the State.
  - Additional state or vendor staff to develop, implement and oversee.
- Unknown administrative costs could outweigh unknown savings.
- Efficiencies would be lost if required to pursue competitive bidding on some drugs and maintain SMAC.



## Access to Prescription Drugs

- Today's prescription drug marketplace requires payors, manufacturers and providers to be nimble.
- Any limitations have the potential of resulting in reduced access to providers and products.
- Reduced access will have negative consequences for Indiana Medicaid members in addition to limiting any potential savings the State may achieve.



- Indiana SMAC is an effective, cost efficient, administratively simplistic program.
- The program applies broadly across nearly all generic products and manufacturers.
- It produces significant savings to the State while ensuring our members have access to both providers and products.



NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

Statement of the National Association of Chain Drug Stores  
to the Indiana Health Finance Commission

September 28, 2011

On behalf of our members operating approximately 928 chain pharmacies in the state of Indiana, the National Association of Chain Drug Stores ("NACDS") thanks Indiana Health Finance Commission for considering our written testimony on several matters of importance that will be discussed at the September 28, 2011 hearing, including:

- Generic drug competitive bidding.
- Pharmacy drug substitution and notification of provider, and anti-epileptic drug substitution; and
- Pharmacy dispensing of drugs with labels accessible to the blind and visually impaired.

413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

The National Association of Chain Drug Stores represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States.

Generic Drug Competitive Bidding

SR 71 directed the Health Finance Committee to study the issue of a generic drug competitive bidding program for the Medicaid program. Such a program would require all generic drug manufacturers whose products are provided to Medicaid recipients to compete in a competitive bidding process. Chain pharmacy has serious concerns with this concept and believes that such a program would be unworkable.

One of the reasons why generic drugs are so inexpensive already (especially when compared to their brand counterparts) is that chain pharmacies, which buy products to stock multiple locations and have a large market share spanning the country, have

successfully negotiated down the cost of generic medications. A competitive bidding program for generic drugs would undermine this system, as the state of Indiana (not pharmacies) would set the price for a particular generic product based on whatever the lowest bid received by the state would be. In this scenario, there would be no guarantee that the lowest bid would be the best price. Moreover, competing generic manufacturers would then lose the incentive to negotiate lower prices with pharmacies in the state of Indiana, impacting healthcare costs for Medicaid as well as consumers, health insurers and other third party payors.

Since states don't purchase drugs, rather pharmacies do, it's unclear as to how a generic drug competitive bidding program could even work. Would all pharmacies be expected to buy special stock from the manufacturers who won the bid and keep that "Medicaid" stock separate and aside from their stock for other patients? What would happen if the winning manufacturer was unable to meet the demand of all of the pharmacies? Would pharmacies then be expected to fill the order with other generics they have on hand for their non-Medicaid patients, and then potentially be reimbursed at a lower rate than the rate at which they acquired the product? Considering the inadequate Medicaid dispensing fee of \$3.00, which is far less than the \$9.92<sup>1</sup> that a recent Medicaid study determined the cost of dispensing to be, putting pharmacy providers in the position of having to dispense products at a loss could threaten patient access to critical pharmacy services.

While we appreciate that state budget concerns amplify the need to explore new ways to control costs in the Medicaid program, we believe that implementing a generic drug competitive bidding program would be misguided. One of the biggest cost drivers in the Medicaid drug spend is the cost of brand drugs. Notably, brand prescriptions cost the Medicaid program an average of \$242.28 per prescription; by comparison, generic drugs cost the Medicaid program an average \$16.47. Clearly, significant savings could be achieved through encouraging a higher rate of generic dispensing. One of the ways the state could do this is to incentivize the dispensing of generic drugs. A generic drug

competitive bidding program would do the opposite. It would create a system that impedes pharmacies' ability to obtain the best price for generics and removes incentives to continue to drive down the price of generic medications. For this reason, we would strongly encourage the members of the Indiana Health Finance Commission not to recommend such a program.

### **Pharmacy Drug Substitution and Notification of Provider, and Anti-Epileptic Drug Substitution**

Pharmacist substitution of brand name drugs with FDA-approved, therapeutically equivalent ("generic") drugs is a safe, legal and well-established practice that saves money for patients, employers, insurance carriers, and other third party payors. Prescribers, when issuing prescriptions to patients, indicate whether a pharmacist may engage in generic substitution. The laws of Indiana ensure that prescribers retain the ultimate authority in this matter, only permitting substitution to occur when the prescriber has signed a prescription to expressly permit generic substitution<sup>2</sup>. Layering on additional, special requirements for generic substitution of certain classes of drugs, (including anti-epileptic drugs,) beyond the requirements already in existing law, would be redundant.

Special generic requirements for anti-epileptic drugs would be unwarranted considering the findings of experts on this matter. Through its rigorous approval process, FDA requires generic drugs to have the same quality and performance as their brand name drug counterparts, and only approves generic versions of brand drugs when the generic has the same active ingredient, strength, dosage form, and route of administration and meets the agency's criteria for bioequivalence. According to the FDA Office of Generic Drugs, "[t]he American public can be confident that when a generic drug product is approved, it has met the rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. Through review of data on proposed

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<sup>1</sup> Analysis of Pharmacy Dispensing Fees for the Indiana Medicaid Program. Prepared by Myers & Stauffer for the Indiana Office of Medicaid Policy and Planning, May 2011, p. 35

<sup>2</sup> Indiana Code 16-40-02-6

products; the Office of Generic Drugs assures that generic product will perform the same as their respective brand name reference products.<sup>3</sup>

FDA has also specifically addressed the therapeutic equivalence of drugs prescribed for epilepsy patients. In a 2008 letter from FDA, the Agency advises that they are "aware that certain individuals and groups have expressed particular concern about the switching of epilepsy drug products," and indicates that they have seen "no scientific evidence that demonstrates a particular problem with this group of products."<sup>4</sup> In fact, there are "frequently circumstances other than the switch that may cause untoward response." Furthermore, FDA's letter notes that their position continues to be that health care providers need not approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence by FDA.

Additionally, the American Medical Association (AMA) has made similar determinations regarding generic drugs, noting that studies support the conclusion that generic epilepsy drugs are equivalent to their brand-name counterparts. After thorough review of published scientific literature, the AMA Council on Scientific Affairs concluded that "generic NTI drugs [are] bioequivalent to their brand name innovator products in patients with diseases for which the drugs are indicated."<sup>5,6</sup> AMA also noted that the criteria used by FDA to ensure bioequivalence of products, or how a drug is absorbed in a patient's body, are widely misunderstood. Notably, these same criteria for bioequivalence of generic products are applied to brand name products when they undergo formulation changes, which occur often prior to marketing. Any differences in therapeutic equivalence of generic products are no greater than what would be expected if one lot of the innovator's product were substituted for another. Any statements suggesting otherwise are misleading.

In light of the determinations made by the experts regarding the efficacy of generic anti-epilepsy drugs, it would be imprudent to pursue any statutory changes that would

<sup>3</sup> [http://www.fda.gov/cder/ogd/welcome\\_to\\_ogd.htm](http://www.fda.gov/cder/ogd/welcome_to_ogd.htm)

<sup>4</sup> Gary Duchini, R.Ph., Director, Office of Generic Drugs, FDA, Letter to the Iowa Pharmacy Association, 11 January 2008.

<sup>5</sup> Council on Scientific Affairs Report 6 at the 2007 AMA Annual Meeting.

<sup>6</sup> Council on Science and Public Health Report 2 at the 2007 AMA Annual Meeting.

make the act of dispensing cost-effective generic drugs more challenging. Logistical challenges such as special prescriber notification requirements could result in pharmacists opting to dispense a brand product rather than go through the extra steps required to dispense the more cost-effective generic. As a result, healthcare costs would increase for patients, employers and other payors. Considering the national average price of a brand name drug (where a generic is available) is \$171.94 and the national average price of a generic drug is \$22.29, the cost impact could be substantial. Particularly in these trying economic times, it would be imprudent to pass legislation that could so drastically increase healthcare costs in this manner.

**Pharmacy dispensing of drugs with labels accessible to the blind and visually impaired**

Pharmacists are committed to ensuring that patients are appropriately counseled on proper medication use and are provided the information necessary to take their prescriptions as directed. Depending on individual patient needs, the way in which pharmacists accomplish this can vary. Some chain pharmacies serve visually impaired patients by providing written directions for proper medication use on separate paper in large, bold font if this is appropriate for a particular patient. Others spend extra time with patients and/or patient caregivers to come up with individualized ways of providing patients with the information necessary to take their medications safely and appropriately. We would caution the members of the Indiana Health Finance Commission from recommending any mandates as to how medication information is conveyed to visually impaired patients, as doing so would be ill-advised and could unintentionally hamper pharmacists' efforts in this regard.

In the past, legislation has been considered in Indiana that would have imposed special mandates for how prescriptions are to be labeled for blind and visually impaired individuals. While well-intentioned, legislation stipulating specific labeling and/or prescription vial requirements for prescriptions dispensed to visually impaired patients would be problematic considering the current technologies available.

**HEALTH FINANCE COMMISSION**

"Whether Hospitals Should Be Required  
To Report Employee Immunization Rates"

September 28, 2011

Issue: Whether hospitals should be required to report employee influenza immunization rates

IHA's Position: Effective January, 2013, federal law will require Indiana hospitals to report to the CDC (via the National Healthcare Safety Network) influenza vaccination rates for healthcare personnel.  
Layering a state reporting requirement on top of the federal reporting requirement would be redundant and unnecessarily burdensome and costly for hospitals and the state.

**Current and Proposed Quality Measures for Reporting in 2011 through 2015**

<b>INPATIENT Current and Proposed</b>					
<b>Measures Collected and Submitted by Hospital</b>					
<b>MEASURE</b>	<b>HIQRP</b>		<b>VBP</b>		<b>HITECH</b>
	<b>Reporting effective date</b>	<b>Affects APU</b>	<b>Reporting effective date</b>	<b>Affects Reimbursement</b>	<b>Required for Meaningful Use?</b>
<b>Acute Myocardial Infarction (AMI)</b>					
AMI-1 Aspirin at arrival	Suspend after 12/31/2011	Suspend after FY 2013			
AMI-2 Aspirin prescribed at discharge	Ongoing	Ongoing			
AMI-3 Angiotensin Converting Enzyme Inhibitor (ACE-I) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction	Suspend after 12/31/2011	Suspend after FY 2013			
AMI-4 Adult smoking cessation advice/counseling	End after 12/31/2011	Retire after FY 2013			
AMI-5 Beta blocker prescribed at discharge	Suspend after 12/31/2011	Suspend after FY 2013			
AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival	Ongoing	Ongoing	July 2011	FY 2013	
AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI)	Ongoing	Ongoing	July 2011	FY 2013	
AMI-10 Statin prescribed at discharge	Jan 2011	FY 2013			
<b>Emergency Department (ED)</b>					
ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department	Jan 2012	FY 2014			Stage 1
ED-2 Median time from admit decision time to time of departure from the emergency department for emergency department patients admitted to inpatient status	Jan 2012	FY 2014			Stage 1
<b>Global Immunizations</b>					
Immunization for Influenza	Jan 2012	FY 2014			
Immunization for Pneumonia	Jan 2012	FY 2014			
<b>Heart Failure (HF)</b>					
HF-1 Discharge instructions	Ongoing	Ongoing	July 2011	FY 2013	
HF-2 Left ventricular function assessment	Ongoing	Ongoing			

\*Red highlighted measures are proposed for the FY 2014 APU.  
TBA= To Be Announced

**Current and Proposed Quality Measures for Reporting in 2011 through 2015**

HF-3 Angiotensin Converting Enzyme Inhibitor (ACE-1) or Angiotensin II Receptor Blocker (ARB) for left ventricular systolic dysfunction	Ongoing	Ongoing			
HF-4 Adult smoking cessation advice/counseling	End after 12/31/2011	Retire after FY 2013			
<b><i>Pneumonia (PN)</i></b>					
PN-2 Pneumococcal vaccination status	End after 12/31/2011	Retire after FY 2013			
PN-3b Blood culture performed before first antibiotic received in hospital	Ongoing	Ongoing	July 2011	FY 2013	
PN-4 Adult smoking cessation advice/counseling	End after 12/31/2011	Retire after FY 2013			
PN-5c Timing of receipt of initial antibiotic following hospital arrival	End after 12/31/2011	Retire after FY 2013			
PN-6 Appropriate initial antibiotic selection	Ongoing	Ongoing	July 2011	FY 2013	
PN-7 Influenza vaccination status	End after 12/31/2011	Retire after FY 2013			
<b><i>Stroke</i></b>					
STK-1 Venous Thromboembolism (VTE) Prophylaxis for patients with ischemic or hemorrhagic stroke	Jan 2013	FY2015			
STK-2 Ischemic stroke patients discharged on antithrombotic therapy	Jan 2013	FY2015			Stage 1
STK-3 Anticoagulation therapy for atrial fibrillation/flutter	Jan 2013	FY2015			Stage 1
STK-4 Thrombolytic Therapy for Acute ischemic stroke patients	Jan 2013	FY2015			Stage 1
STK-5 Antithrombotic therapy by the end of hospital day two	Jan 2013	FY2015			Stage 1
STK-6 Discharged on statin medication	Jan 2013	FY2015			Stage 1
STK-8 Stroke education	Jan 2013	FY2015			Stage 1
STK-10 Assessed for rehabilitation services	Jan 2013	FY2015			Stage 1
<b><i>Surgical Care Improvement Project (SCIP)</i></b>					
SCIP-Infection-1 Prophylactic antibiotic received within 1 hour prior to surgical incision	Ongoing	Ongoing	July 2011	FY 2013	
SCIP-Infection-2 Prophylactic antibiotic selection for surgical patients	Ongoing	Ongoing	July 2011	FY 2013	
SCIP-Infection-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time	Ongoing	Ongoing	July 2011	FY 2013	
SCIP-Infection-4 Cardiac surgery patients with controlled 6AM postoperative serum glucose	Ongoing	Ongoing	July 2011	FY 2013	

## Current and Proposed Quality Measures for Reporting in 2011 through 2015

SCIP-Infection-6 Surgery patients with appropriate hair removal	Suspend after 12/31/2011	Suspend after FY 2013			
SCIP-Infection-9 Postoperative urinary catheter removal on post operative day 1 or 2	Ongoing	Ongoing	*April 2012	*FY2014	
SCIP-Infection-10 Perioperative temperature management	Ongoing	Ongoing			
SCIP-Cardiovascular-2 Surgery patients on a beta blocker prior to arrival who received a beta blocker during the perioperative period	Ongoing	Ongoing	July 2011	FY 2013	
SCIP-VTE-1 Venous thromboembolism (VTE) prophylaxis ordered for surgery patients	Ongoing	Ongoing	July 2011	FY 2013	
SCIP-VTE-2 VTE prophylaxis within 24 hours pre/post surgery	Ongoing	Ongoing	July 2011	FY 2013	
<b><i>Venous Thromboembolism (VTE)</i></b>					
VTE-1 Venous thromboembolism Prophylaxis	Jan 2013	FY2015			Stage 1
VTE-2 Intensive care unit venous thromboembolism prophylaxis	Jan 2013	FY2015			Stage 1
VTE-3 Venous thromboembolism patients with anticoagulation overlap therapy	Jan 2013	FY2015			Stage 1
VTE-4 Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol or nomogram	Jan 2013	FY2015			Stage 1
VTE-5 Venous thromboembolism discharge instructions	Jan 2013	FY2015			Stage 1
VTE-6 Incidence of potentially-preventable venous thromboembolism	Jan 2013	FY2015			Stage 1
<b><i>Healthcare Associated Infections Reported to NHSN</i></b>					
Central Line Associated Bloodstream Infection	Ongoing	Ongoing			
Surgical Site Infection	Jan 2012	FY 2014			
Catheter-Associated Urinary Tract Infection	Jan 2012	FY 2014			
MRSA Bacteremia	Jan 2013	FY2015			
Clostridium Difficile (C. Diff)	Jan 2013	FY2015			
Healthcare Personnel Influenza Vaccination	Jan 2013	FY2015			
<b><i>Structural Measures</i></b>					
Participation in a systematic database for cardiac surgery	Ongoing	Ongoing			
Participation in a systematic clinical database registry for stroke care	Ongoing	Ongoing			
Participation in a systematic clinical database registry for nursing sensitive care	Ongoing	Ongoing			

**Current and Proposed Quality Measures for Reporting in 2011 through 2015**

Participation in a systematic clinical database registry for general surgery	Jan-Dec 2012 Data Reported Apr-May 2013	FY 2014			
<b><i>Patients' Experience of Care</i></b>					
HCAHPS survey	Ongoing	Ongoing	July 2011	FY 2013	

**Current and Proposed Quality Measures for Reporting in 2011 through 2015**

<b>Claims Based Measures Calculated by GMS (Inpatient)</b>				
<b>MEASURE</b>	<b>HIQRP</b>		<b>VBP</b>	
	<b>Reporting effective date</b>	<b>Affects APU</b>	<b>Reporting effective date</b>	<b>Affects Reimbursement</b>
<b>Mortality Measures (Medicare Patients)</b>				
AMI 30-day mortality rate	Ongoing	Ongoing	7/1/11	2014
Heart Failure (HF) 30-day mortality rate	Ongoing	Ongoing	7/1/11	2014
Pneumonia (PN) 30-day mortality rate	Ongoing	Ongoing	7/1/11	2014
<b>Readmission Measures (Medicare Patients)</b>				
AMI 30-day risk standardized readmission	Ongoing	Ongoing		
Heart Failure (HF) 30-day risk standardized readmission	Ongoing	Ongoing		
Pneumonia (PN) 30-day risk standardized readmission	Ongoing	Ongoing		
<b>AHRQ Measures</b>				
PSI 06 Iatrogenic pneumothorax, adult	Ongoing	Ongoing		
PSI 11 Post operative respiratory failure	TBA	2012		
PSI 12 Post operative PE or DVT	TBA	2012		
PSI 14 Post operative wound dehiscence	Ongoing	Ongoing		
PSI 15 Accidental puncture or laceration	Ongoing	Ongoing		
IQI 11 Abdominal aortic aneurysm (AAA) mortality rate (with or without volume)	Ongoing	Ongoing		
IQI 19 Hip fracture mortality rate	Ongoing	Ongoing		
Complication/patient safety for selected indicators (composite)	Ongoing	Ongoing	3/3/12	2014
Mortality for selected medical conditions (composite)	Ongoing	Ongoing	3/3/12	2014
<b>AHRQ and Nursing Sensitive Care</b>				
Death among surgical inpatients with serious, treatable complications	Ongoing	Ongoing		
<b>Hospital Acquired Conditions</b>				
Foreign object retained after surgery	Ongoing	Ongoing	3/3/12	2014
Air embolism	Ongoing	Ongoing	3/3/12	2014
Blood incompatibility	Ongoing	Ongoing	3/3/12	2014
Pressure Ulcer stages III & IV	Ongoing	Ongoing	3/3/12	2014
Falls and Trauma (Includes: fracture, dislocation, intracranial injury, crushing injury, burn, electric shock)	Ongoing	Ongoing	3/3/12	2014
Vascular catheter-associated infection	Ongoing	Ongoing	3/3/12	2014
Catheter-associated urinary tract infection (UTI)	Ongoing	Ongoing	3/3/12	2014
Manifestations of poor glycemic control	Ongoing	Ongoing	3/3/12	2014
<b>Cost Efficiency</b>				
Medicare spending per beneficiary	05/15/2012	FY2014	05/15/2012	FY2014

\*Red highlighted measures are proposed for the FY 2014 APU.  
TBA= To Be Announced

## Current and Proposed Quality Measures for Reporting in 2011 through 2015

OUTPATIENT Current and Proposed		
Measures Collected and Submitted by Hospital		
MEASURE	HOQRP	
	Reporting effective date	Affects APU
<b>Cardiac Care (AMI and CP) Measures</b>		
OP-1 Median time to fibrinolysis	Ongoing	Ongoing
OP-2 Fibrinolytic therapy received within 30 minutes of ED arrival	Ongoing	Ongoing
OP-3 Median time to transfer to another facility for acute coronary intervention	Ongoing	Ongoing
OP-4 Aspirin at arrival	Ongoing	Ongoing
OP-5 Median time to ECG	Ongoing	Ongoing
<b>Surgery Measures</b>		
OP-6 Timing of antibiotic prophylaxis	Ongoing	Ongoing
OP-7 Prophylactic antibiotic selection for surgical patients	Ongoing	Ongoing
<b>Chart-Abstracted Process Measure</b>		
OP-16 Troponin results for ED AMI patients or CP patients (with probable cardiac CP) received within 60 minutes of arrival	Jan 2012	CY 2013
OP-18 Median time from ED arrival to ED departure for discharged patients	Jan 2012	CY 2013
OP-19 Transition record with specified elements received by discharged patients	Jan 2012	CY 2013
OP-20 Door to diagnostic evaluation by a qualified medical professional	Jan 2012	CY 2013
OP-21 ED – Median time to pain management for long bone fracture	Jan 2012	CY 2013
OP-22 ED – Patient left before being seen	Jan 2012	CY 2013
OP-23 ED – Head CT scan results for acute ischemic stroke or hemorrhagic stroke who received head CT scan interpretation within 45 minutes of arrival	Jan 2012	CY 2013
OP-25 Diabetes: Hemoglobin A1c Management	<sup>^</sup> Jan 2013	<sup>^</sup> CY 2014
OP-26 Diabetes Measure Pair: A) Lipid management: low density lipoprotein cholesterol (LDL-C)<130 B) Lipid management: LDL-C<100	<sup>^</sup> Jan 2013	<sup>^</sup> CY 2014
OP-27 Diabetes: Blood Pressure Management	<sup>^</sup> Jan 2013	<sup>^</sup> CY 2014
OP-28 Diabetes: Eye Exam	<sup>^</sup> Jan 2013	<sup>^</sup> CY 2014
OP-29 Diabetes: Urine Protein Screening	<sup>^</sup> Jan 2013	<sup>^</sup> CY 2014
OP-30 Cardiac rehabilitation Patient Referral From an Outpatient Setting	<sup>^</sup> Jan 2013	<sup>^</sup> CY 2014

<sup>^</sup>Purple highlighted measures are proposed for the CY 2014 APU.  
<sup>^^</sup>Orange highlighted measures are proposed for the CY 2015 APU.  
<sup>^^^</sup>Blue highlighted measures are proposed for the CY 2016 APU.  
 TBA= To Be Announced

## Current and Proposed Quality Measures for Reporting in 2011 through 2015

<b>Healthcare Associated Infections Reported to NHSN</b>		
OP-24 Surgical Site Infection	^Jan 2013	^CY 2014
Influenza Vaccination Coverage among Healthcare Personnel	^^Oct 2013	^^CY 2015
<b>Structural Measures</b>		
OP-12 The ability for providers with health information technology (HIT) to receive laboratory data electronically directly into their qualified/certified electronic health record (EHR) system as discrete searchable data	Jan- Jun 2011Data Reported Jul-Aug 2011	CY 2012
OP-17 Tracking clinical results between visits	Jan-Jun 2012 Data Reported Jul-Aug 2012	CY 2013
OP-31 Safe Surgery Checklist Use	^2012 Data Reported in 2013	^CY 2014
Op-32 Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	^2012 Data Reported in 2013	^CY 2014

^Purple highlighted measures are proposed for the CY 2014 APU.

^^Orange highlighted measures are proposed for the CY 2015 APU.

^^^Blue highlighted measures are proposed for the CY 2016 APU.

TBA= To Be Announced

## Current and Proposed Quality Measures for Reporting in 2011 through 2015

<b>Claims Based Measures Calculated by CMS (Outpatient)</b>		
	<b>HOQRP</b>	
<b>MEASURE</b>	<b>Reporting effective date</b>	<b>Affects APU</b>
<b><i>Imaging Efficiency Measures</i></b>		
OP-8 MRI lumbar spine for low back pain	Ongoing	Ongoing
OP-9 Mammography follow-up rates	Ongoing	Ongoing
OP-10 Abdomen computed tomography (CT) use of contrast material	Ongoing	Ongoing
OP-11 Thorax CT use of contrast material	Ongoing	Ongoing
OP-13 Cardiac imaging for preoperative risk assessment for non-cardiac low-risk surgery	TBA	CY 2012
OP-14 Simultaneous use of brain CT and sinus CT	TBA	CY 2012
OP-15 Use of brain CT in the ED for atraumatic headache	TBA	CY 2012

^Purple highlighted measures are proposed for the CY 2014 APU.

^^Orange highlighted measures are proposed for the CY 2015 APU.

^^^Blue highlighted measures are proposed for the CY 2016 APU.

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**Current and Proposed Quality Measures for Reporting in 2011 through 2015**

<b>AMBULATORY SURGERY CENTER Proposed</b>		
<b>Measures Collected and Submitted by Hospital</b>		
<b>ASC QRP</b>		
<b>MEASURE</b>	<b>Reporting effective date</b>	<b>Affects APU</b>
<b><i>Chart-Abstracted Measures Reported Through Quality Data Codes on Part B Claims</i></b>		
ASC-1 Patient Burn	^Jan 2012	^CY 2014
ASC-2 Patient Fall	^Jan 2012	^CY 2014
ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	^Jan 2012	^CY 2014
ASC-4 Hospital Transfer/Admission	^Jan 2012	^CY 2014
ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing	^Jan 2012	^CY 2014
ASC-6 Ambulatory Surgery Patients with Appropriate Method of Hair Removal	^Jan 2012	^CY 2014
ASC-7 Selection of Prophylactic Antibiotic First OR Second Generation Cephalosporin	^Jan 2012	^CY 2014
<b><i>Healthcare Associated Infections Reported to NHSN</i></b>		
ASC-8 Surgical Site Infection Rate	^Jan 2013	^CY 2014
ASC-11 Influenza Vaccination Coverage among Healthcare Personnel	^^^Oct 2013	^^^CY2016
<b><i>Structural Measures</i></b>		
ASC-9 Safe Surgery Checklist Use	^^ 2012 Data Reported in 2013	^^2015
ASC-10 ASC Facility Volume Data on Selected ASC Surgical Procedures	^^ 2012 Data Reported in 2013	^^2015

^Purple highlighted measures are proposed for the CY 2014 APU.  
 ^^Orange highlighted measures are proposed for the CY 2015 APU.  
 ^^Blue highlighted measures are proposed for the CY 2016 APU.  
 TBA= To Be Announced

Current and Proposed Quality Measures for Reporting in 2011 through 2015

LONG TERM CARE HOSPITAL		
Measures Collected and Submitted by Hospital		
LTCH QRP		
MEASURE	Reporting effective date	Affects APU
<b>Chart-Abstracted Measures Reported Through CARE Tool</b>		
Percent of Patients with New or Worsened Pressure Ulcers	Oct 2012	FY 2014
<b>Healthcare Associated Infections Reported to NHSN</b>		
Urinary Catheter-Associated Urinary Tract Infection (CAUTI)	Oct 2012	FY 2014
Central Line Catheter-Associated Bloodstream Infection (CLABSI)	Oct 2012	FY 2014

^Purple highlighted measures are proposed for the CY 2014 APU.  
 ^^Orange highlighted measures are proposed for the CY 2015 APU.  
 ^^Blue highlighted measures are proposed for the CY 2016 APU.  
 TBA= To Be Announced

## Current and Proposed Quality Measures for Reporting in 2011 through 2015

INPATIENT REHABILITATION FACILITY		
Measures Collected and Submitted by Hospital		
IRF QRP		
MEASURE	Reporting effective date	Affects APU
<b><i>Chart-Abstracted Measures Reported Through IRF-Patient Assessment Instrument (IRF-PAI)</i></b>		
Percent of Patients with New or Worsened Pressure Ulcers	Oct 2012	FY 2014
<b><i>Healthcare Associated Infections Reported to NHSN</i></b>		
Urinary Catheter-Associated Urinary Tract Infection (CAUTI)	Oct 2012	FY 2014

CY 2012 OPSS proposed rule was published July 18, 2011. Comments are due by August 30, 2011. The final rule is scheduled for Display November 2, 2011.

Prepared by the Indiana Hospital Association  
08/19/2011

^Purple highlighted measures are proposed for the CY 2014 APU.  
 ^^Orange highlighted measures are proposed for the CY 2015 APU.  
 ^^^Blue highlighted measures are proposed for the CY 2016 APU.  
 TBA= To Be Announced

**Sec. 4. "National Healthcare Safety Network" or "NHSN" means a secure, Internet-based system developed and managed by the CDC to collect, analyze, and report risk-adjusted healthcare associated infection data related to the incidence of healthcare associated infections and the process measures implemented to prevent these infections.. (Indiana State Department of Health; 410 IAC 15-4-4)**

**410 IAC 15-4-5 Hospital data collection of health care-associated infections**

**Authority: IC 16-21-1-7; IC 16-41-2-1**

**Affected: IC 16-21; IC 16-41-2**

**Sec. 5. Hospitals shall collect surveillance data on the healthcare associated infections and hospital locations listed in section 7 of this rule. (Indiana State Department of Health; 410 IAC 15-4-5)**

**410 IAC 15-4-6 National Healthcare Safety Network (NHSN) participation**

**Authority: IC 16-21-1-7; IC 16-41-2-1**

**Affected: IC 16-21; IC 16-41-2**

**Sec. 6. (a) Hospitals shall do all of the following:**

**(1) Enroll in the CDC's NHSN by January 31, 2012.**

**(2) Submit data through NHSN on the health care associated infections listed in section 7 of this rule.**

 **(3) Confer to the state department of health the NHSN access rights to their hospital specific healthcare associated infection data contained in the NHSN on the healthcare associated infections specified in section 7 of this rule.**

**(b) Hospitals who are expelled from the NHSN shall submit the same information through electronic means to the department at the sole cost of the hospital, if necessary. (Indiana State Department of Health; 410 IAC 15-4-6)**

**410 IAC 15-4-7 Reportable healthcare associated infections**

**Authority: IC 16-21-1-7; IC 16-41-2-1**

**Affected: IC 16-21; IC 16-41-2**

 **Sec. 7. Hospitals shall submit all NHSN-required data to the NHSN on the following healthcare associated infections effective January 1, 2012:**

**(1) Central line associated bloodstream infections in all intensive care units.**

**(2) Surgical site infections for abdominal hysterectomies and colorectal surgeries.**

**(3) Catheter associated urinary tract infections in adult and pediatric intensive care units.**

*(Indiana State Department of Health; 410 IAC 15-4-7)*

Issue: Should Indiana hospitals be mandated by the Indiana Legislature to vaccinate their employees?

IHA's Position: A mandate is not needed *at this time*. Hospitals, without a mandate, are already developing immunization programs. Furthermore, a mandate might not allow hospitals to develop vaccination programs that best fit their employees, patients and the community at large. A "one size fits all" approach would be counterproductive.

July 22, 2011

## **AHA Endorses Patient Safety Policies Requiring Influenza Vaccination of Health Care Workers**

### **BACKGROUND**

Influenza is a highly contagious disease that can be spread before symptoms appear and results in about 150,000 hospital admissions and 24,000 deaths annually. Hospitalized patients are particularly vulnerable to the dangers of influenza because their immune systems are often compromised by the illness that caused their admission or the treatments they are undergoing. Vaccination of health care workers (HCWs) has been shown to prevent illness and death in patients, and reduce influenza infections and absenteeism among HCWs. While the Centers for Disease Control and Prevention (CDC) has recommended annual vaccination of HCWs since 1981, only about half of HCWs in the United States are immunized annually.

In recent years, more and more hospitals and health care organizations are putting into place policies making seasonal influenza vaccinations mandatory for employees, affiliated medical staff, students, volunteers and contract workers as part of their commitment to patient safety. These policies often have resulted in vaccination rates above 90 percent.

Several key national professional organizations have endorsed mandatory policies for influenza vaccination as a condition of employment within health care facilities, including the Association of Professionals in Infection Control, American Academy of Pediatrics, Infectious Disease Society of America, National Patient Safety Foundation and Society for Healthcare Epidemiology of America. The American Medical Association supports “universal” influenza vaccination of HCWs, but leaves it to each facility to decide whether or not a mandate is needed to achieve 100 percent vaccination coverage.

While the resources needed to implement a mandatory policy are significant, especially in terms of financial and personnel resources, the benefits of protecting vulnerable patients and reducing employee illness and absenteeism far outweigh the costs. Further, employee resistance can be overcome through careful education and open communication between hospital leadership and staff, as well as policies that permit certain reasonable exclusions and allow employees who cannot receive influenza

vaccination to wear masks when they are in the presence of patients during the influenza season.

### **AT ISSUE**

AHA members and staff spent time earlier this year discussing these issues in the context of the spring round of AHA Regional Policy Board meetings and with AHA's Committee on Health Professions. In April, taking into consideration the findings of these discussions, the AHA's Board of Trustees approved the following new AHA policy:

America's hospitals are committed to protecting the health and well-being of patients and staff. Evidence has emerged over the past few years clearly indicating that health care workers can unintentionally expose patients to seasonal influenza if they (the workers) have not been vaccinated, and such exposure can be dangerous to vulnerable patients.

To protect the lives and welfare of patients and employees, AHA supports mandatory patient safety policies that require either influenza vaccination or wearing a mask in the presence of patients across health care settings during flu season. The aim is to achieve the highest possible level of protection.

### **NEXT STEPS**

The AHA will hold three conference calls featuring speakers from hospitals that have implemented mandatory vaccination policies, with a focus on best practices for putting such policies into practice.

If your hospital has not implemented such a patient safety policy regarding influenza vaccination of health care workers, or if you are in the midst of trying to develop or implement such a policy, we encourage you to participate in one of these calls to learn more about the strategies and best practices used by hospitals that have put mandatory worker seasonal influenza vaccination policies into place.

These calls will be held at the following dates and times:

- Friday, July 29 at 1:00 p.m. EDT
- Tuesday, August 23 at 1:00 p.m. EDT
- Thursday, September 8 at 1:00 p.m. EDT

For more information and to register to participate, visit <http://www.surveymonkey.com/s/HSDCC2K>.

# Influenza Vaccination for Staff and Licensed Independent Practitioners

## Hospital Accreditation Program

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### IC.02.04.01

1 The hospital offers vaccination against influenza to licensed independent practitioners and staff.

#### Elements of Performance for IC.02.04.01

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- 2 1. The hospital establishes an annual influenza vaccination program that is offered to licensed independent practitioners and staff.
- 3 2. The hospital educates licensed independent practitioners and staff about, at a minimum, the influenza vaccine; non-vaccine control and  
4 prevention measures; and the diagnosis, transmission, and impact of influenza. (See also HR.01.04.01, EP 4)
- 5 3. The hospital provides influenza vaccination at sites accessible to licensed independent practitioners and staff.
- 6 4. The hospital annually evaluates vaccination rates and the reasons given for declining the influenza vaccination.
- 7 4. **The hospital includes in its infection control plan the goal of improving influenza vaccination rates. (For more information, refer to**  
8 **Standard IC.01.04.01)**
- 9 5. The hospital takes steps to increase influenza vaccination rates.
- 10 5. **The hospital sets incremental influenza vaccination goals, consistent with achieving the 90% rate established in the national**  
11 **influenza initiatives for 2020.**  
12 **Note: The HHS Action Plan to Prevent Healthcare-Associated Infections is located at:**  
13 **[http://www.hhs.gov/ash/initiatives/hai/tier2\\_flu.html](http://www.hhs.gov/ash/initiatives/hai/tier2_flu.html).**
- 14 6. **The hospital develops a written description of the methodology used to determine influenza vaccination rates. All hospital staff and**  
15 **licensed independent practitioners are to be included in the methodology for determining the influenza vaccination rates. (See also**  
16 **IC.02.04.01, EP 1)**  
17 **Note 1: See the Glossary definition of staff to determine those who are to be included in the rate denominator. See the Glossary**  
18 **definition of licensed independent practitioner to determine those who are to be included in the rate denominator.**  
19 **Note 2: The Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization**  
20 **Practices (ACIP) provides recommendations for the target population or denominator for this rate. See:**  
21 **<http://www.guideline.gov/content.aspx?id=8697>**
- 22 7. **The hospital evaluates the reasons given by staff and licensed independent practitioners for declining the influenza vaccination at**  
23 **least annually.**
- 24 8. **The hospital improves its vaccination rates according to its established goals and at least annually. (For more information, refer to**  
25 **Standards PI.02.01.01 and PI.03.01.01)**

## Hospital Accreditation Program

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- 26  
27
- 9. The hospital provides influenza vaccination rate data to key stakeholders including leaders, licensed independent practitioners, nursing staff, and other staff at least annually.**



# **Maximizing Employment Opportunities for Individuals with Disabilities**

*Presentation to the Health Finance Commission*

Julia Cunningham Holloway, Director

Division of Disability & Rehabilitative Services

September 28, 2011

2

## Employment Initiatives

DDRS has committed to make employment of individuals with disabilities—developmental, intellectual, and all others—a priority throughout the next fiscal year

# Vocational Rehabilitation Services

3

- Total served per year = 35,000
- Total annual successful closures = 4200
- Average wages at closure = \$11.38/hour
- Average hours worked at closure = 28.7

# Employment Partnerships

4

- 57 employers are now business partners with our Corporate Development Unit, including Lowe's, Walgreen's, Dometic, Best Buy, Pitney Bowes, and Hyatt
- Walgreens-Indiana Statewide Consortium (WISC) is in place to locate and employ individuals with disabilities
- WISC serves as a primary resource for creation of natural supports, job aids, & reasonable accommodations
- WISC coordinates qualified candidates for stores when there are openings

# Employment Partnerships

5

- Corporate Development Placements
  - Average hourly wage for 40 hours worked from April 1-June 30, 2011 was \$9.36
  - 71 placements total from Jan.-August 2011
- Project SEARCH:

Total Number of Interns who Successfully Completed the Program	Total Number Hired	Average Starting Wage/Hour	Average Starting Hours Per Week
73	40 = 55%	\$8.37	28

# Blind Vending

6

- Facilities Served by Blind Vending include:
  - Camp Atterbury
  - Indiana Government Center Snack Shops
  - Highway Vending Areas
  - DOC Facilities
- There are 44 licensed Blind Vending Managers
  - 25 people are employed with other disabilities
- Vendor Net Profit = \$2,359,079
- Average Vendor Earnings = \$53,313

# Employment Data

7

- Sheltered Workshops:
  - Hourly wage = \$2.53
  - Hours worked/week = 24 hours
- Off-Site Group Placement
  - Hourly wage = \$4.99
  - Hours worked/week = 27 hours
- Individual Community Jobs
  - Hourly wage = \$7.87
  - Hours worked/week = 22 hours
- Self-Employed
  - Hourly wage = \$8.33
  - Hours worked/week = 36

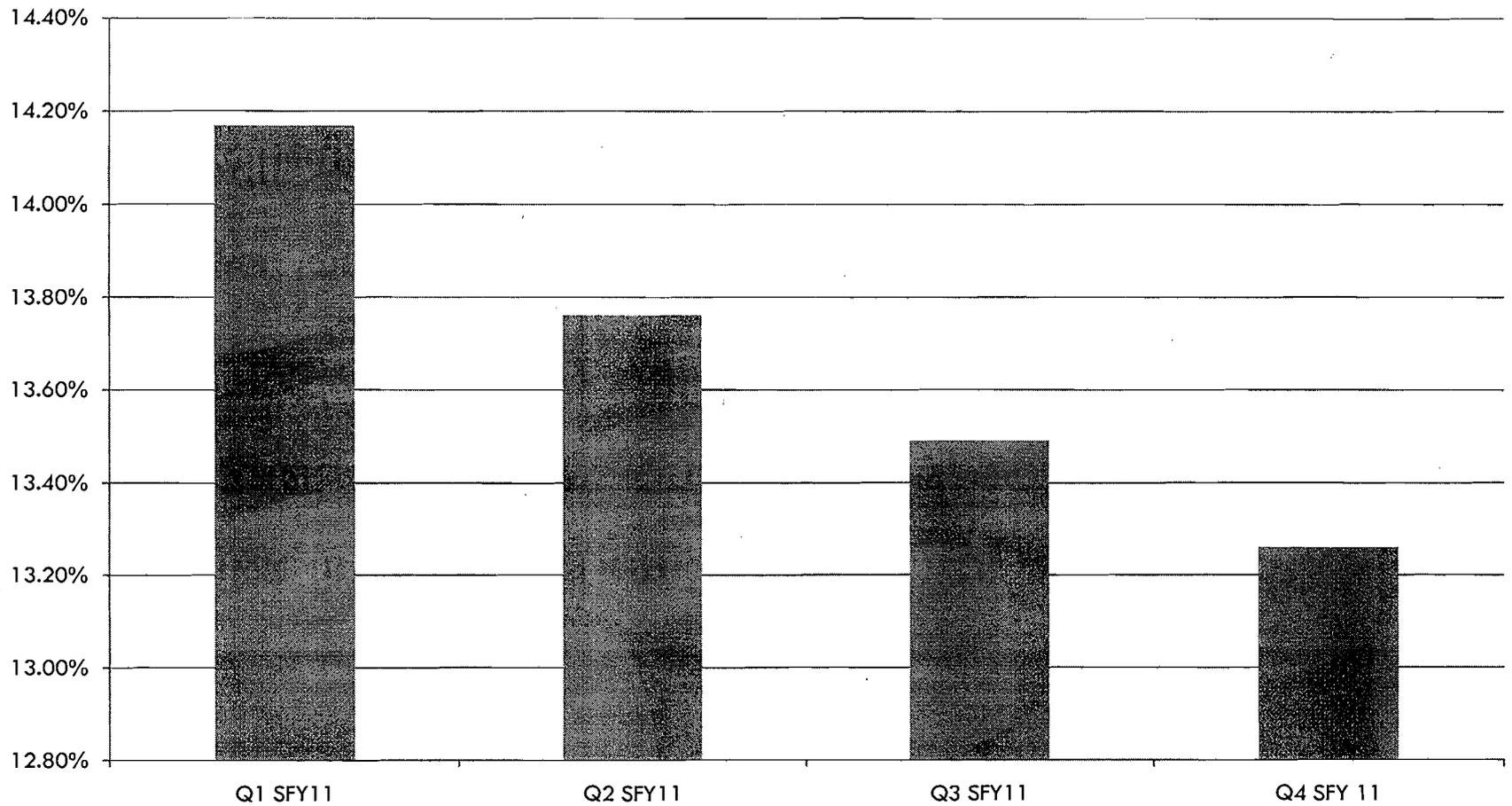
\*Indiana Day and Employment Services Outcomes System Report, Reporting Period: June 2011

# Waiting List and Employment

8

- 1,457 of 19,358 BDDS Wait List consumers have active VR cases (7.5%)
- 5,104 of 19,358 BDDS Wait List consumers have no active case, but did have a prior closed VR case(s) (26.4%)
- 12,821 of 19,358 BDDS Wait List clients have never worked with VR (66.2%)

# Employment Rate of Waiver Participants



# Demonstration Projects

10

- Maximize integrated employment for people with intellectual disabilities and autism spectrum
- New BDDS consumers will be referred to VR
- Employer outreach, training and communication plans
- Data collection and metrics to measure success
- Bloomington, South Bend, Marion, and Kokomo have developed written proposals and are working with DDRS on implementation and timelines.

# State Employment Leadership Network

- As part of Indiana's Employment 1<sup>st</sup> Initiative, DDRS became a member of the State Employment Leadership Network (SELN), which brings states together to improve employment outcomes for people with developmental disabilities.
- Upon joining SELN, Indiana has participated in a site visit and qualitative review. These activities focused on assessing Indiana's current employment practices and strategies, and will assist with development of employment work plan goals.
- The work plan will offer guidance and a working set of goals and finite activities that can serve as a blueprint for its efforts to improve the quality and accessibility of employment supports statewide.



# **Maximizing Employment Opportunities for Individuals with Disabilities**

*Presentation to the Health Finance Commission*

Julia Cunningham Holloway, Director

Division of Disability & Rehabilitative Services

September 28, 2011

## Indiana Department of Administration Procurement Division



### Employment and Training Opportunities for Individuals with Disabilities

## IDOA Strategy: State-Use Program

- Increase contract opportunities
  - Promote philosophy of understanding industry trends with State-Use work centers through competitiveness analysis.
- Increase employment opportunities
  - Encourage all Contractors to create opportunities and develop programs that emphasize employment of individuals with disabilities.



## Reduce Total Cost of Ownership

IDOA is working with State of Indiana contractors to extend the State's pricing for products and services to all State-Use work centers.

- Example: Reduce material costs
  - Fastenal Company (maintenance, repair and operations products)
  - Acorn Distributors (janitorial products)
- Example: Reduce transportation costs
  - FedEx (shipping)



## Utilize Directed Sourcing

Directed Sourcing language allows for State of Indiana contractors to add products and services exclusively from State-Use work centers directly into their catalogs.

- Example: Products for vending
  - IDOA will pilot Direct Sourcing with Fastenal Company (maintenance, repair and operations products) to add products to their vending machine solution. Possible products: Safety Vests, First Aid Kits and Work Gloves.



## Identify Future Opportunities

Align State-Use work centers with select State agencies to assess current needs, identify future needs and form partnerships to develop solutions.

- Example: Opportunity based on current needs
  - IDOA is coordinating exploratory meetings with various State agencies to discuss using Contact Center Solutions offered through Bosma Enterprises.
- Example: Future opportunities
  - State-Use work centers will participate at the IDOA Vendor Fair (October, 2011).



## Increase Employment Opportunities

Encourage all State of Indiana contractors to partner with State-Use work centers as well as develop programs that promote hiring of individuals with disabilities.

- Example: Sub-Contracting
  - Nishida Services (janitorial services) sub-contracts janitorial services to Noble Center.
- Example: Direct Employment
  - Pitney-Bowes (print / mail) - 10% of current workforce that supports the State's contract are individuals with disabilities.
  - Pitney-Bowes has committed to pilot a new national hiring program for individuals with disabilities with the State of Indiana.



# **GENERIC SUBSTITUTION OF SEIZURE MEDICATIONS**

Steven D. Maynard, MD  
United Associated Physicians Clinic,  
Terre Haute, IN  
Adjunct Professor Neurology,  
IU School of Medicine,  
Terre Haute, IN

# Generic Seizure Medications are not Equivalent

- ▣ Generic medications promoted due to lower cost
  - FDA requires generics to have 80% - 125% bioavailability
- ▣ Bioavailability does not equal bioequivalence
  - Seizure medications only effective under narrow therapeutic range (Meredith, Drug Safety, 1996)
  - “The principle that generic epilepsy drugs are interchangeable with brand-name epilepsy drugs is controversial.” (Epilepsy Health Center, 2004)
  - “Recent studies confirm that for people who experienced adverse reactions, the level of medication was dramatically different, even while on reputedly equivalent products.” (Health Care Reform, Epilepsy Foundation, 2009)

# Generic Seizure Medications are not Effective

- ▣ “More than two-thirds neurologists reported that their patients experienced breakthrough seizures after switching from a brand name epilepsy drug to a generic one.”
- ▣ “More than half also reported that their epilepsy patients experienced side effects attributable to the switch.” (Epilepsy Health Center, 2004)

# Generic Seizure Medications are not Effective

- ▣ A patient switched from brand name seizure drug to generic had an 81% greater risk of having an ambulance trip, ER visit, or hospitalization (Zachary, Epilepsia)
- ▣ “Two academic institutions have validated the results with almost identical results.” (Smith, Epilepsy Foundation)

# Generic Seizure Medications are not Effective

- ▣ March, 2009 – the Epilepsy Foundation surveyed over 1000 people with epilepsy: Seizures worsened for 59% of people who had switched from brand-name to generic anticonvulsant medications
- ▣ October 2009 – The Epilepsy Foundation obtains congressional request for the FDA to look into adverse events occurring as a result of generic substitution of seizure medications

# Generic Seizure Medications are not Effective

- ▣ Germany: Anticonvulsant medications not included in the final list of medications suitable for substitution
- ▣ Denmark: Certain anticonvulsant medications exempt from substitution due to bioequivalence problems
- ▣ Finland: All anticonvulsant medications are exempt from substitution

# **Brand-name Seizure Medications are Cost-effective**

- ▣ A patient switched from brand name seizure drug to generic had an 81% greater risk of having an ambulance trip, ER visit, or hospitalization (Zachary, Epilepsia)

# Brand-name Seizure Medications are Cost-effective

- ▣ “The potential saving to consumers and insurers from switching from branded to generic AEDs needs to be balanced against the possibility of serious consequences of breakthrough seizures, adverse events, and unpredictable effects on other medications.”  
(Schachter, Epilepsy Editorial Board, 2006)

# Brand-name Seizure Medications are Cost-effective

- ▣ “The bottom line – use of a generic AED was associated with a significant increase in healthcare costs, both for drugs and for total utilization. The incidence of injuries (e.g., fracture, head injury), both total and epilepsy-related, was higher during periods of generic use.” (Labiner, Neurology, 2010)

# Brand-name Seizure Medications are Cost-effective

- ▣ “Although drug costs are the rationale for drug substitutions, - - such switching may in fact increase costs. - -The costs of treating medical complication, including emergency room visits, doctors office visits, drug level monitoring, - - not to mention the potential for accidents, severe bodily harm, or even death can outweigh the intended savings from the mandatory substitution of products.”  
(Schachter, Epilepsy Editorial Board, 2009)

# Brand-name Seizure Medications are Cost-effective

- ▣ “savings made from generic prescribing of AEDs may be outweighed by the cost of adverse consequences”
- ▣ “potential medico-legal consequences if adverse consequences arise in a patient who did not give informed consent to switching of AED” Crawford, Seizure, 2005)

# Indiana Medicaid Problems

- ▣ 68 year old female on brand Keppra with total control of seizures
- ▣ Filled script early July, told Indiana Medicaid would no longer cover brand name.
- ▣ Pt. accepted generic without knowledge of her neurologist.
- ▣ Admitted to hospital on 7-23-09 for seizures
- ▣ Brand name Keppra not in stock
- ▣ Continued on generic Keppra in hospital

# Continued

- ▣ I wrote script for brand Keppra and sister took to pharmacy.
- ▣ Pharmacy refused to fill script because patient was Indiana Medicaid – stated PA needed which would take several days
- ▣ Patient continued to seize in hospital, transferred to ICU unconscious in status epilepticus
- ▣ Seizures eventually responded to IV meds
- ▣ Cost Indiana Medicaid \$44,361.25

# Indiana Medicaid Problems

- ▣ 19 year old male with seizures on Trileptal and Topamax
- ▣ Indiana Medicaid sent my nurse the wrong PA form to fill out to prevent generic substitution.
  - The forms take about 20 minutes to fill out
- ▣ Patient had multiple seizures as a result of the prolonged wait to get the proper medications.

# Indiana Medicaid Problems

- ▣ 36 year old male with seizures well controlled on brand-name Keppra
- ▣ Changed to generic without my knowledge
- ▣ Developed multiple seizures as a result, and had to be taken to hospital unconscious in an ambulance.
- ▣ Lives 60 miles from Terre Haute
- ▣ Ambulance ride alone cost Indiana Medicaid \$1,930 (Trans Care Ambulance)

# Indiana Medicaid Problems

- ▣ 59 year old female with total control of seizures on brand-name Keppra
  - As a result has no restrictions
- ▣ Switched to generic without my knowledge
- ▣ Had a seizure while driving and drove her car into a restaurant
  - No one injured (!)

## Summary:

- ▣ Generic seizure medications are not effective
- ▣ Brand-name seizure medications are cost-effective



## COVERAGE OF ANTICONVULSANT DRUGS FOR THE TREATMENT OF EPILEPSY

The American Academy of Neurology (AAN), representing over 20,000 neurologists and neuroscience professionals, has taken an active interest in the clinical, ethical, and policy considerations concerning the coverage of anticonvulsant drugs for people with epilepsy. The AAN has developed evidence-based guidelines which strongly support complete physician autonomy in determining the appropriate use of anticonvulsants for the patients with epilepsy. Based on this evidence, the AAN has adopted the following principles concerning coverage of anticonvulsants for adults and children with epilepsy.

**The AAN opposes generic substitution of anticonvulsant drugs for the treatment of epilepsy without the attending physician's approval.** The FDA has allowed for significant differences between name-brand and generic drugs. This variation can be highly problematic for patients with epilepsy. Even minor differences in the composition of generic and name-brand anticonvulsant drugs for the treatment of epilepsy can result in breakthrough seizures.

- Anticonvulsant drugs for the treatment of epilepsy differ from other classes of drugs in several ways that make generic substitution problematic.
- For anticonvulsant drugs, small variations in concentrations between name-brands and their generic equivalents can cause toxic effects and/or seizures when taken by patients with epilepsy.
- The AAN opposes all state and federal legislation that would impede the ability of physicians to determine which anticonvulsant drugs to prescribe for the treatment of patients with epilepsy.
- The AAN believes that formulary policies should recognize and should support complete physician autonomy in prescribing, and patients in accessing, the full range of anticonvulsants for epilepsy.
- The AAN opposes policies that would result in arbitrary switching among anticonvulsants. Therefore, the AAN opposes generic substitution of anticonvulsants for patients with epilepsy at the point of sale (e.g., in the pharmacy), without prior consent of the physician and the patient.
- The AAN supports legislation that would require informed consent of physicians and patients before generic substitutions of anticonvulsants are made at the point of sale.
- The AAN believes that the use of anticonvulsant drugs in the treatment of epilepsy should be distinguished from the use of anticonvulsant drugs in treating other disorders. The AAN recognizes that different strategies may be appropriate in using anticonvulsants for the treatment of conditions other than epilepsy.
- Unlike other diseases, a single breakthrough seizure due to change in delivered medication dose can have devastating consequences, including loss of driver's license, injury, and even death.

**The AAN supports the use of newer-generation anticonvulsant drugs in the treatment of epilepsy.** Newer-generation anticonvulsant drugs generally result in fewer and less severe side effects, although they may be more expensive to prescribe. For patients with epilepsy, the AAN does not believe that economic considerations alone should determine the prescribing pattern of physicians. The AAN believes that physicians should make every effort to identify when patients may be effectively treated with less expensive alternatives. However, the discretion for this decision should remain with the prescribing physician and should not be determined by coverage limitations.

- Physicians should have prescribing access to all anticonvulsants for the treatment of epilepsy, including newer-generation drugs.
- The AAN recognizes that, unlike in most other conditions, requiring the “fail first” approach (i.e., using trial and error in determining the best treatment option) will put patients with epilepsy at risk for breakthrough seizures, accidents, injury and loss of income.
- The AAN believes that preventing access to newer-generation anticonvulsants for the treatment of epilepsy is not cost effective in the long term. Newer drugs may have less tendency to produce some of the side effects associated with older medications, including osteoporosis, cognitive impairment, sedative impairment, and depression, all of which require costly medical interventions.
- The AAN opposes cost-based strategies such as high co-pays on newer-generation AEDs that effectively limit therapy options for lower-income patients.

**AAN opposes prior authorization requirements by public and private formularies.** Prior authorization (i.e., requiring a physician to seek approval to prescribe a drug before the drug may be dispensed) is one method formularies may utilize to limit access to anticonvulsant drugs for the treatment of epilepsy.

- The AAN opposes prior authorization for anticonvulsant drugs in the treatment of epilepsy.
- Prior authorization impedes patient access to quality care and places an unnecessary and costly administrative burden on physicians.
- Prior authorization may affect compliance among patients with epilepsy, creating additional barriers that discourage them from seeking appropriate medication that will prevent future seizures.

Ensuring appropriate coverage of anticonvulsant drugs for the treatment of epilepsy contributes to ethical, high-quality neurological care. The AAN is pleased to serve as a resource for health care professionals, policy makers, and the public on this important issue.

**Approved: AAN Board of Directors – November 2006 (Policy 2006-72)**

#### References

- American Medical Association. AMA Policy H-115.974 Prescription Labeling  
American Medical Association. AMA Policy H-125.984 Generic Drugs  
American Medical Association. AMA Policy H-125.993 Legislation Prohibiting Therapeutic Substitution  
French JA, Kanner AM, Bautista, J et al., “Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new onset epilepsy; Efficacy and tolerability of the new antiepileptic drugs II; Treatment of refractory epilepsy”; Reports of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society; Special Article; *Neurology* 2004;62:1252-1260.

# Certified Professional Midwives in the United States

- **North American Registry of Midwives  
NARM**
- **Midwifery Education Accreditation  
Council  
MEAC**
- **National Association of Certified  
Professional Midwives  
NACPM**
- **Midwives Alliance of North America  
MANA**

“Certified Professional Midwives  
Are trained and credentialed  
to offer expert care,  
education, counseling  
and support to women  
for pregnancy, birth  
and the postpartum period.”

“Certified Professional Midwives  
provide care that is prevention oriented  
with particular attention to education and support for the consumer.  
This process creates an essential health care partnership between the woman and her  
midwife resulting in exemplary outcomes.  
These qualities of care are among those most needed to address and solve the  
problems that exist in the health care system in the U.S. today.”

From Issue Brief—Certified Professional Midwives in the United States  
June 2008



# Indiana Midwives Association

The Indiana Midwives Association, IMA, is an organization dedicated to promoting high standards of midwifery and safe childbirth alternatives. Founded in 1981



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## IMA Functions

- Statewide annual conference
- Peer support
- Standards of practice
- Voluntary credentialing
- Educational guild meetings
- Quarterly Newsletter
- Consumer referrals
- Consumer support

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## International Definition of a Midwife

- A midwife is a person, who having been regularly admitted to a midwifery educational program, recognized in the country (state) in which it is located, has successfully completed the prescribed course of studies in midwifery and has acquired the requisite qualifications to be registered and/or licensed to practice midwifery.

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## Scope of Practice

A midwife:

- gives necessary guidance and care to women throughout the preconception period, pregnancy, labor and postpartum
- conducts deliveries on her own
- provides normal care for the newborn.
- provides safe and natural care for normal birth
- take preventive measures
- detects abnormal conditions of the mother and child,
- has the ability to access medical assistance when necessary

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## INDIANA MIDWIVES TASKFORCE

- Founded in 1993 by midwives and consumers to promote and support legal home birth options.
- Nearly 900 families a year in Indiana are having home births. Home births are legal in Indiana but consumers need qualified attendants. Without a licensure law, consumer choices and safety are limited.
- Home birth families come from all parts of the population and every economic group.

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Amish "bruddas" (brothers)- Born at home.

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## Certified Professional Midwives

- Certified Professional Midwives, CPMs, are qualified and well-trained home birth midwives. The CPM credential is nationally recognized and supported by the American Public Health Association and the National Commission on Certifying Agencies.
- The Certified Professional Midwife credential was developed in the late 1980's and was first issued in 1994 by the North American Registry of Midwives.
- The Certified Professional Midwife credential is accredited by the National Commission for Certifying Agencies.

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- Certified Professional Midwives are one of the fastest growing healthcare professions in the country with over 1700 certified.
- CPM midwifery care is safe. Medical research supports the safety of out of hospital birth as reported in the prestigious British Medical Journal in June of 2005. The CPM 2000 Study found that home birth is just as safe as hospital birth for low risk women but with much lower intervention rates.
- CPMs are currently licensed, certified, or registered to provide home birth services in 28 states. In 10 states, CPMs can provide services to Medicaid recipients.
- Only nine states prohibit this type of midwifery. Indiana is one

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## LICENSING TRENDS FOR CERTIFIED PROFESSIONAL MIDWIVES:

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In 1970 there were  
no laws licensing  
Direct Entry Midwives



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By 1980  
AZ, NM, SC, DE



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By 1990  
Add: WA, AR, LA



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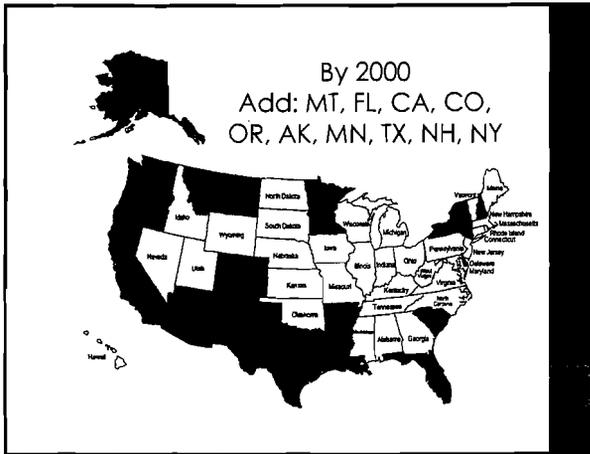
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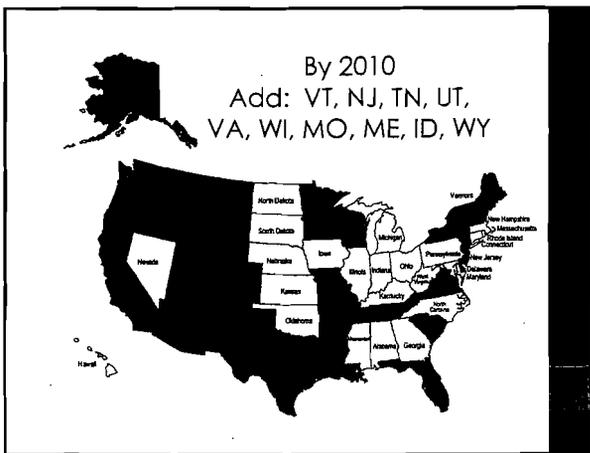
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No state that has licensed  
Certified Professional Midwives  
has ever rescinded its program.

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## Important Facts Addressing Concerns about Licensing Midwives

Information Provided by the North American Registry of Midwives

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## Safety:

Home birth is safe

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**CPM 2000 Study "Outcomes of planned home births with Certified Professional Midwives"** Kenneth C Johnson and Betty-Anne Daviss. *BMJ* 2005;330:1416 (18 June).

- The researchers used prospective data on more than 5400 planned home births in North America attended by Certified Professional Midwives during the year 2000.
- The largest study of home births attended by Certified Professional Midwives has found that home birth is safe for low risk women and involves far fewer interventions, such as cesarean sections and inductions, than similar births in hospitals. The results of this study attest to the safety of births attended by CPM and the significant cost savings of reduced intervention in birth.
- 99% of these births were attended by midwives who received the CPM credential through the NARM Portfolio Evaluation Process.

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**Netherlands Study: Perinatal mortality and morbidity in a nationwide cohort of 529 688 low-risk planned home and hospital births.** A de Jongea, BV van der Goesb, ACJ Ravellc, MP Amelink-Verburga,d, BW Molb, JG Nijhuis,e, J Bennelroek Gravenhorsta, SE Buitendijlca

- A nationwide cohort study
- Main outcome measures; Intrapartum death, intrapartum and neonatal death within 24 hours after birth, intrapartum and neonatal death within 7 days and neonatal admission to an intensive care unit.
- Results No significant differences were found between planned home and planned hospital birth
- Conclusions This study shows that planning a home birth does not increase the risks of perinatal mortality and severe perinatal morbidity among low-risk women, provided the maternity care system facilitates this choice through the availability of well trained midwives and through a good transportation and referral system.

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**Canadian Study: Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician,** Patricia A. Janssen, PhD, Lee Szarek, MA, Lesley A. Page, PhD, Michael C. Klein, MD, Robert M. Liston, MD and Shoo K. Lee, MBBS PhD

- **Methods:** We included all planned home births attended by registered midwives from Jan. 1, 2000, to Dec. 31, 2004, in British Columbia, Canada (n = 2889), and all planned hospital births meeting the eligibility requirements for home birth that were attended by the same cohort of midwives (n = 4752). We also included a matched sample of physician-attended planned hospital births (n = 5331). The primary outcome measure was perinatal mortality; secondary outcomes were obstetric interventions and adverse maternal and neonatal outcomes.
- **Interpretation:** Planned home birth attended by a registered midwife was associated with very low and comparable rates of perinatal death and reduced rates of obstetric interventions and other adverse perinatal outcomes compared with planned hospital birth attended by a midwife or physician.

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**Medications Increase Safety:**

- The medications allowed by proposed legislation provide a safety net for homebirth.
- Midwives administer these medications only in pre-determined situations, following the instructions set out in the rules.
- No pain medications are in the formulary. The medications are either routine (eye meds and vitamin K for the baby) or for limited emergency use, such as to prevent excessive bleeding in the mother. Oxygen is used in resuscitation. Local anesthetics would only be used for stitches that may be needed.
- Use of emergency medications is rare.

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# Support

CPMs are nationally recognized

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Support from the American Public Health Association

**"Recognizing the evidence that births to healthy mothers, who are not considered at medical risk after comprehensive screening by trained professionals, can occur safely in various settings, including out-of-hospital birth centers and homes. ...Therefore, APHA supports efforts to increase access to out-of-hospital maternity care services..."**

American Public Health Association, "Increasing Access to Out-of-Hospital Maternity Care Services through State-Regulated and Nationally-Certified Direct-Entry Midwives (Policy Statement)". *American Journal of Public Health*, Vol 92, No. 3, March 2002.

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Support from Childbirth Connections- the oldest independent analyzers of maternity care.

**The low CPM rates of intervention are benchmarks for what the majority of childbearing women and babies who are in good health might achieve.**

The Millbank Memorial Fund, a nonpartisan institute devoted to health policy analysis, issued a new report titled "Evidence-Based Maternity Care: What It Is and What It Can Achieve." October, 2008

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# Economic Benefits:

Midwife Care is cost effective

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Midwifery Licensure and Discipline Program in Washington State:  
Economic Costs and Benefits, (A report to the Washington Department of  
Health), Health Management Associates, October, 2007

## Conclusions

- The economic benefits of the midwifery program to the State of Washington far exceed the costs of operating the Program in estimating cost of deliveries, using the most conservative assumptions regarding C-section rates. These figures exclude prenatal care costs, newborn costs, and potential long term costs related to morbidity.
- The estimated cost savings for deliveries to Medicaid FFS in the most recent biennium is \$488,147; about 1.8 times the cost of operating the state program which is \$277,400.82.
- Cost savings to the health care system (Medicaid and private insurance) are much greater, about \$2.7 million and this savings is close to 10 times the cost of operating the state program.

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# Education

Important Facts about the  
Education of CPMs

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- The education of the CPM follows an extensive curriculum of over 750 topics.
- All educational routes to the CPM must follow the same curriculum, which may be verified through diplomas from accredited midwifery schools, licenses from states with equivalent requirements, or an extensive evaluation of alternative pathways through the Portfolio Evaluation Process (PEP).
- Students from all routes to certification must meet the same extensive educational goals, follow the same curriculum, and pass the same nationally standardized examinations.
- Instructors and preceptors are responsible for the education and supervision of student CPMs, which may occur in classroom, private, and clinical settings

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- Instructors must verify that the student has mastered all knowledge and skills and has demonstrated competency in the clinical setting before proceeding through the testing process.
- Students then must pass a hands-on skills assessment and an 8-hour written examination.
- The clinical training for CPM certification must cover a minimum of at least one year of supervised clinical work, which is equivalent to 1350 hours of supervision.
- The average length of clinical training is 3-5 years.
- All students must document this supervised clinical work, regardless of route of education.

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### Comparison of Midwives Credentialing Requirements

There are three types of credentialed midwives in the United States:

- Certified Professional Midwives (CPMs) who are credentialed by the North American Registry of Midwives, NARM.
- Certified Nurse-Midwives (CNMs) who are credentialed by the American College of Nurse-Midwives, ACNM.
- Certified Midwives (CMs) who are credentialed by the American College of Nurse-Midwives.

CMs and CPMs are direct-entry midwives, meaning that they have received education specific to midwifery without the pre-requisite of nursing.

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- Both the CPM & CNM credentials are accredited by the National Commission for Certifying Agencies (NCCA) which requires validated, psychometrically sound testing based on third party job analysis .
- CPMs follow the practice standards of the National Association of Certified Professional Midwives (NACPM) which includes the development of collaborative relationships with other healthcare practitioners who can provide care outside the scope of midwifery practice when necessary.
- The National Association of Certified Professional Midwives (NACPM) standards limit the CPM scope of practice to the primary maternity care of healthy women experiencing normal pregnancies.
- Certified Professional Midwives are the only birth attendants specifically trained in out of hospital birth.

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**Clinical Experience Requirements for Birth Attendants**

Category of Participation	Certified Professional Midwives <sup>1</sup>	Certified Nurse Midwives and CMs <sup>2</sup>	Family Practice Physicians <sup>3</sup>
Births as Assistant	20	Not specified	Not specified
Birth as Primary Attendant	20	20	40 (at least 30 vaginal)
Out-of-Hospital	10	none	none
Continuity of Care	3	Not specified	10
Prenatal Exams	75 (20 initial)	85 (15 initial)	-
Newborn Exams	20	20	-
Postpartum Exams	40	35	-

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**In Addition:**

Indiana would require a candidate to:

- Observe an additional twenty (20) births,
- assist with an additional (20) births,
- and act as primary attendant for an additional twenty (20) births.

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**Also:**

- The board shall set up formal education requirements in addition to those required in section 1.
- The requirements must include course material on:
  - (1) emergency life support procedures;
  - (2) identification of high risk births for mothers;
  - (3) identification of potential complications during labor; and
  - (4) other material the board specifies.

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**CPMs Are Legally Authorized to Provide Maternity Care in Over Half the States**

- Over 58% of the US population has legal access to CPMs.
- Indiana Families are still waiting.

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## CPM2000 Study Published!

June 26, 2005

### Landmark Study Shows Giving Birth at Home is Safe

"Outcomes of planned home births with certified professional midwives: large prospective study in North America." Kenneth C Johnson, senior epidemiologist, Betty-Anne Daviss, project manager. *BMJ* 2005;330:1416 (18 June). Published online at <http://bmj.bmjournals.com/cgi/content/full/330/7505/1416?ehom>.

The largest prospective study of planned home birth with a direct-entry midwife shows that homebirth is as safe as hospital birth for low risk women, yet carries a much lower rate of medical interventions, including Cesarean section.

This landmark study is reported in the *British Medical Journal*, June 2005. Planning a home birth attended by a Certified Professional Midwife (CPM) offers as safe an outcome for low-risk mothers and babies as does hospital birth. This study is the largest yet of its kind. The researchers used prospective data on more than 5400 planned home births in North America attended by Certified Professional Midwives during the year 2000.

Canadian researchers Kenneth Johnson and Betty-Anne Daviss studied over 5,400 low-risk pregnant women planning to birth at home in the United States and Canada in 2000. The researchers analyzed outcomes and medical interventions for planned home births, including transports to hospital care, and compared these results to the outcomes of 3,360,868 low risk hospital births. According to the *British Medical Journal* press release, they found:

- 88% of the women birthed at home, with 12% transferring to hospital.
- Planned home birth carried a rate of 1.7 infant deaths per 1,000 births, a rate "consistent with most North American studies of intended births out of hospital and low risk hospital births."
- There were no maternal deaths.
- Medical intervention rates of planned home births were dramatically lower than of planned hospital births, including: episiotomy rate of 2.1% (33.0% in hospital), cesarean section rate of 3.7% (19.0% in hospital), forceps rate of 1.0% (2.2% in hospital), induction rate of 9.6% (21% in hospital), and electronic fetal monitoring rate of 9.6% (84.3% in hospital).
- 97% of over 500 participants who were randomly contacted to validate birth outcomes reported that they were extremely or very satisfied with the care they received.

The Midwives Alliance of North America celebrates the publication of this groundbreaking study demonstrating the safety and satisfaction that are hallmarks of the care provided to North American women birthing at home with midwives. This study is a landmark in many ways, being by far the largest study of its kind to date; by eliminating confounding factors by distinguishing between planned and unplanned birthplace; and because of the study's prospective nature, which is able to assure accounting for all outcomes. The authors' finding that Certified Professional Midwives "achieve good outcomes among low risk women without routine use of expensive hospital interventions" challenges the unnecessary proliferation of many interventions performed routinely on women and babies in low-risk hospital births.

This study provides irrefutable evidence in support of the American Public Health Association's resolution (2001) to increase access to out-of-hospital births attended by direct-entry midwives. This study supports the World Health Organization's 1996 position: "Midwives are the most appropriate primary healthcare provider to be assigned to the care of normal birth (1996)." This study supports the Coalition for Improving Maternity Services (CIMS) 1996 statement: "Midwives attend the vast majority of births in those industrialized countries with the best perinatal outcomes." And finally, this study supports what midwives have always asserted: that planned home birth with a trained midwife is a safe, high-quality, satisfying, cost-effective choice for healthy women and their babies that results in superior outcomes. The Midwives Alliance of North America (MANA) recommends making midwifery care the gold standard in maternity care in North America.

# *Perinatal mortality and morbidity in a nationwide cohort of 529 688 low-risk planned home and hospital births.*

A de Jonge,<sup>a</sup> BY van der Goes,<sup>b</sup> ACJ Ravelli,<sup>c</sup> MP Amelink-Verburg,<sup>a,d</sup> BW Mol,<sup>b</sup> JG Nijhuis,<sup>e</sup> J Bennebroek Gravenhorst,<sup>a</sup> SE Buitendijk<sup>a</sup>

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**Objective** To compare perinatal mortality and severe perinatal morbidity between planned home and planned hospital births among low-risk women who started their labour in primary care.

**Design** A nationwide cohort study.

**Setting** The entire Netherlands.

**Population** A total of 529 688 low-risk women who were in primary midwife-led care at the onset of labour. Of these, 321 307 (60.7%) intended to give birth at home, 163 261 (30.8%) planned to give birth in hospital and for 45 120 (8.5%), the intended place of birth was unknown.

**Methods** Analysis of national perinatal and neonatal registration data, over a period of 7 years. Logistic regression analysis was used to control for differences in baseline characteristics.

**Main outcome measures** Intrapartum death, intrapartum and neonatal death within 24 hours after birth, intrapartum and neonatal death within 7 days and neonatal admission to an intensive care unit.

**Results** No significant differences were found between planned home and planned hospital birth (adjusted relative risks and 95% confidence intervals: intrapartum death 0.97 (0.69 to 1.37), intrapartum death and neonatal death during the first 24 hours 1.02 (0.77 to 1.36), intrapartum death and neonatal death up to 7 days 1.00 (0.78 to 1.27), admission to neonatal intensive care unit 1.00 (0.86 to 1.16).

**Conclusions** This study shows that planning a home birth does not increase the risks of perinatal mortality and severe perinatal morbidity among low-risk women, provided the maternity care system facilitates this choice through the availability of well trained midwives and through a good transportation and referral system.

# Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician

**Patricia A. Janssen, PhD, Lee Saxell, MA, Lesley A. Page, PhD, Michael C. Klein, MD, Robert M. Liston, MD and Shoo K. Lee, MBBS PhD**

From the School of Population and Public Health (Janssen), the Departments of Family Practice (Klein) and Obstetrics and Gynecology (Janssen, Liston) and the Division of Midwifery (Saxell), Faculty of Medicine, University of British Columbia, Vancouver, BC; the Child and Family Research Institute (Janssen, Klein, Liston), Vancouver, BC; the Nightingale School of Nursing and Midwifery (Page), King's College, London, UK; the Department of Pediatrics (Lee); and the Integrated Centre for Care Advancement Through Research (Lee), University of Alberta, Edmonton, Alta.

**Correspondence to:** Dr. Patricia A. Janssen, School of Population and Public Health, University of British Columbia, 5804 Fairview Cres., Vancouver BC V6T 1Z3; fax 604 806-8006; [pjanssen@interchange.ubc.ca](mailto:pjanssen@interchange.ubc.ca)

**Background:** Studies of planned home births attended by registered midwives have been limited by incomplete data, nonrepresentative sampling, inadequate statistical power and the inability to exclude unplanned home births. We compared the outcomes of planned home births attended by midwives with those of planned hospital births attended by midwives or physicians.

**Methods:** We included all planned home births attended by registered midwives from Jan. 1, 2000, to Dec. 31, 2004, in British Columbia, Canada ( $n = 2889$ ), and all planned hospital births meeting the eligibility requirements for home birth that were attended by the same cohort of midwives ( $n = 4752$ ). We also included a matched sample of physician-attended planned hospital births ( $n = 5331$ ). The primary outcome measure was perinatal mortality; secondary outcomes were obstetric interventions and adverse maternal and neonatal outcomes.

**Results:** The rate of perinatal death per 1000 births was 0.35 (95% confidence interval [CI] 0.00–1.03) in the group of planned home births; the rate in the group of planned hospital births was 0.57 (95% CI 0.00–1.43) among women attended by a midwife and 0.64 (95% CI 0.00–1.56) among those attended by a physician. Women in the planned home-birth group were significantly less likely than those who planned a midwife-attended hospital birth to have obstetric interventions (e.g., electronic fetal monitoring, relative risk [RR] 0.32, 95% CI 0.29–0.36; assisted vaginal delivery, RR 0.41, 95% CI 0.33–0.52) or adverse maternal outcomes (e.g., third- or fourth-degree perineal tear, RR 0.41, 95% CI 0.28–0.59; postpartum hemorrhage, RR 0.62, 95% CI 0.49–0.77). The findings were similar in the comparison with physician-assisted hospital births. Newborns in the home-birth group were less likely than those in the midwife-attended hospital-birth group to require resuscitation at birth (RR 0.23, 95% CI 0.14–0.37) or oxygen therapy beyond 24 hours (RR 0.37, 95% CI 0.24–0.59). The findings were similar in the comparison with newborns in the physician-assisted hospital births; in addition, newborns in the home-birth group were less likely to have meconium aspiration (RR 0.45, 95% CI 0.21–0.93) and more likely to be admitted to hospital or readmitted if born in hospital (RR 1.39, 95% CI 1.09–1.85).

**Interpretation:** Planned home birth attended by a registered midwife was associated with very low and comparable rates of perinatal death and reduced rates of obstetric interventions and other adverse perinatal outcomes compared with planned hospital birth attended by a midwife or physician.

## **Highlights from the October, 2007**

### **Washington Economic Costs and Benefits of the Licensed Midwife Program**

#### **Statement of Purpose and Summary of Findings**

On August 6, 2007, Health Management Associates (HMA) was contracted by the State of Washington Department of Health (DOH) to conduct a review of existing research literature related to the economic costs and benefits of the practice of licensed midwifery. The review was to form the basis of a report, required by the legislature, to present the economic benefits of midwifery out-of-hospital births to the health care system and the economic benefits to the consumers who elect to have out of-hospital births, including any reduced use of procedures that increase the costs of childbirth. The purpose of the report is to determine whether the economic benefits of the Midwifery Licensure and Discipline Program (subsequently referred to as "the Program") exceed the state expenditures to subsidize the cost of the Program.

We conducted a thorough review of the literature and identified credible and recent studies that provided sufficient evidence to enable us to draw the conclusion that planned out-of-hospital births attended by licensed professional midwives in the U.S., and in the State of Washington, had similar rates of intrapartum and neonatal mortality to those of low-risk hospital births, and that medical intervention rates for planned out-of-hospital births were lower than for planned low-risk hospital births. The studies cited did not and could not account for all morbidity experienced by mothers and/or newborns in populations of women cared for by licensed midwives and compare them with populations of women cared for by other health professionals. Any differences are unknown, and may involve potential long term costs unaccounted for in the projections. Medicaid claims data from the Washington Department of Social and Health Services First Steps Database were the basis of the economic analysis. Using conservative cost estimates, described in the report, we estimate the recoveries from Medicaid Fee for Service (FFS) alone to be more than \$473,000 which is about 1.8 times the cost of operating the Program. Cost savings to the health care system (public and private insurance) is estimated at \$2.7 million which is close to ten times the cost of the Program.

#### **Conclusions**

The economic benefits of the midwifery program to the State of Washington far exceed the costs of operating the Program in estimating cost of deliveries, using the most conservative assumptions regarding c-section rates. These figures exclude prenatal care costs, newborn costs, and potential long term costs related to morbidity. The estimated cost savings for deliveries to Medicaid FFS in the most recent biennium is \$488,147; about 1.8 times the cost of operating the state program which is \$277,400.82. Cost savings to the health care system (Medicaid and private insurance) are much greater, about \$2.7 million and this savings is close to 10 times the cost of operating the state program.

# AMERICAN LUNG ASSOCIATION®

IN INDIANA

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September 27, 2011

The Honorable Scott Reske  
Indiana House of Representatives  
Indianapolis, IN 46204

The American Lung Association in Indiana is writing to you today to express support for the proposal before the Health Finance Commission, that would require hospitals to report employee influenza vaccination rates.

Every year the American Lung Association helps countless people understand the importance of flu vaccination with programs like our *Faces of Influenza* campaign. We also educate the public about influenza treatment and prevention. The American Lung Association in Indiana strongly believes that all persons over 6 months of age, as recommended by the Centers for Disease Control and Prevention (CDC), should get a flu vaccination unless contraindicated, especially health care providers/workers.

According to CDC, health care providers/workers, including those who care for the most at-risk patients, fall far short of the level of influenza vaccination rates needed to best protect their patients. In 2008, roughly 48 percent of health care providers received a vaccination nationally; a number mirrored in previous years throughout the past decade and unacceptably low.

This low vaccination rate has serious public health consequences. Flu outbreaks in hospitals have been linked to higher mortality rates, thus putting both health care providers and the most vulnerable patients, including those with lung disease, at risk. Another consequence of low vaccination rates is staff shortages, which, according to CDC, usually affect hospitals during the "peak influenza season" when facilities are already struggling due to the increased number of flu patients. This demonstrates the urgent need for the Health Finance Commission to move ahead with this proposal.

Requiring hospitals to report on their employees' influenza vaccination rates will provide a clearer picture on the percentage of healthcare workers/providers getting vaccinated in Indiana, and, if low rates of vaccination are discovered, the American Lung Association in Indiana hopes that further action will be taken to encourage or require vaccination of healthcare workers/providers.

Although some have proposed waiting until the federal government requires the reporting of hospital employee vaccination rates, which would occur in 2015 if there are no delays, we feel that it is crucial for Indiana to move ahead on this issue now to truly understand the scope of the problem, and ultimately get more healthcare workers/providers and the patients they serve protected from influenza.

In conclusion, the American Lung Association in Indiana offers our support for the proposal before the Health Finance Commission to require reporting of influenza vaccination rates for hospital employees. Thank you for allowing us to comment and taking our views into consideration.

Sincerely,

Lindsay A. Grace  
Manager, Mission Services and Advocacy  
American Lung Association in Indiana

Casey Kline

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To: Lisa Hays  
Subject: RE: Dr. Ardeshtna's testimony re: 9/28 Health Finance Commission Mtg

To,

## HEALTH FINANCE COMMISSION

*Legislative Services Agency  
200 West Washington Street, Suite 301  
Indianapolis, Indiana 46204-2789  
Tel: (317) 233-0696 Fax: (317) 232-2554*

Sept. 26, 2011

*Re: issue of anti-epileptic drug substitution*

Background: I am currently a practicing neurologist with a sub-specialty in epilepsy (epileptologist) working with Indiana Neuroscience Associates and St. Vincent Health, in Indianapolis.

In addition, to the diagnosis and management of epilepsy (seizure patients) on an inpatient and outpatient basis, my other interests since residency have been advocating for the needs of epilepsy patients in the community and at national level of government.

One of the issues of ongoing concern for epilepsy patients has been the substitution of brand-name versus for generic anti-epileptic medication.

**The basics:** This concern applies to patients of all ages with epilepsy. Unlike other medications, anti-epileptic medications are "unique" with respect to these concerns. Undoubtedly, brand name medications are more expensive than generics, and this difference will exist forever; and understandably in this time of expenditure cutbacks, this difference becomes even more important.

**Central Issue:** The central issue is that of patient care, patient safety, and keeping the patient seizure and side-effect free. Remember: the goal for all epilepsy patients is seizure freedom (no seizures) and no side-effects. By ensuring that a patient is seizure and side effects free, a patient can maintain as normal life style as

possible and be a productive member of society (hold a job), which in turn is essential for an individual to support their family and the economy.

Though generic and brand name medications are considered equivalent by the FDA (it is really a range of equivalence), technically they are not equal.

I prefer all of my epilepsy/seizure patients to be on brand name medications, unless they cannot afford it. There have been well documented cases (anecdotes below) of patients that have been switched from a brand name to generic anti-epileptic medications and who have had break through seizures after having gone through a prolonged period seizure free. Also, other patients have had worsening or new onset side effects on the generic anti-epileptic medication compared to the brand medication. Examples of side effects include worsening fatigue, dizziness, or balance difficulties.

In fact, in the United States there have been cases of patients who had a break through seizure when a brand to generic switch was done, and this seizure in turn was fatal or caused significant injuries.

Examples:

Patient A: switched from brand to generic Keppra (leviteracetam), had three breakthrough seizures in one day, and spent one week in the hospital.

Patient B: switched from brand to generic Lamictal (lamotrigine) developed nausea and vomiting necessitating a visit to the local emergency room, than a follow up with her primary care doctor, and time off work.

The key here is that the consequences of a brand to generic switch can be large. Moreover, the cost of health care for the emergency room visit, in patient stay, and lost productivity in the economy after a breakthrough seizure greatly exceeds the cost saving when switching from a brand to generic medication.

In fact, many other states as well as countries are well ahead of us in addressing the issue of brand to generic substitution.

### **Suggestions and Recommendations:**

1. Patients be allowed to remain on brand name anti-epileptic medication if desired by the physicians. Insurance companies should not be allowed to the switch patient to a generic equivalent automatically for cost savings.
  - a) Please note: Even though as a physician I have written a prescription for a brand name anti-epileptic medication (dispense as written, brand medically necessary), the pharmacy is substituting it for the generic without informing the patient or physician. Dispense as Written should mean just that.
2. In the event of a substitution of the patient and the physician should be informed. The physician's office should be called the day the prescription is filled. Currently, our office is not informed (nor the patient). When the patient comes in for follow up in one to three months, or sometimes in one year, I discover that a switch has been made.
3. Similar to other countries, if a letter has been inserted into the patient's medical record that the patient requires brand name anti-epileptic medication per the physician. This request must be honored by the patient and the insurance company.
4. If a patient is on a generic anti-epileptic medication it should be noted, there are also differences between generic versions (similar consequences for switching from generic A to generic B as a brand to

generic switch). Hence there is also a convincing argument that these patients should remain on the same generic (for instance generic phenytoin, made by the same manufacturer). Consequently, if mandated by a physician the patient should remain/be able to obtain the generic anti-epileptic medication made by the same manufacturer (consistent supply).

In Summary: As a epileptologist who cares for seizure patients, I am requesting that brand to generic anti-epileptic drug substitution not be permitted for patient safety reasons as, there is a significant risk of breakthrough seizures and side effects. These can have a detrimental affect on the patient's health as well as increase health care costs.

Please do not hesitate to contact me if you have any further questions.

Thank you for the opportunity to allow me to submit the above testimony.

Sincerely,

Nikesh I. Ardeshta, MD, MS, HBSc

Epileptologist and Neurologist

Indiana Neuroscience Associates and St. Vincent Hospital

Indianapolis, Indiana

[niaregency@hotmail.com](mailto:niaregency@hotmail.com)

MEMORANDUM

To: Concerned Legislators

From: Diane Graves

Date: September 28, 2011

Re: Independent Access To Prescription Information

Though I am unable to attend the hearing today, I felt compelled to add my voice to the others advocating the availability of the Scrip-talk system to those who request it.

I am totally blind myself, and am currently on 5 regular prescription medications. A few of these medications are very similar in size and shape, and, if distracted or in a rush, could be easily confused. When calling for a refill on any of these medications, I am typically asked for an RX number, which I am unable to access independently. There is also no way to independently review dosage, instructions or possible side effects, without seeking sighted assistance.

All of this information is available to sighted patients, and we are simply asking for equal access. I urge you to consider this very important bill, mandating the availability of the Script-talk system to those who request it.

If further testimony or verification is needed I may be contacted at 317-416-8100 or via email at [Princess.di2007@gmail.com](mailto:Princess.di2007@gmail.com)