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Sen. Patricia Miller, Chairperson  
Sen. Ryan Mishler  
Sen. Vaneta Becker  
Sen. Rodric Bray  
Sen. Ed Charbonneau  
Sen. Ron Grooms  
Sen. Jean Leising  
Sen. Pete Miller  
Sen. Jean Breaux  
Sen. Frank Mrvan  
Sen. Mark Stoops  
Sen. Greg Taylor  
Rep. Ed Clere, Vice-Chairperson  
Rep. Steven Davisson  
Rep. Ronald Bacon  
Rep. Robert Behning  
Rep. Suzanne Crouch  
Rep. David Frizzell  
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Rep. Eric Turner  
Rep. Dennis Zent  
Rep. Charlie Brown  
Rep. B. Patrick Bauer  
Rep. Gregory Porter  
Rep. Robin Shackelford



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## HEALTH FINANCE COMMISSION

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Authority: IC 2-5-23

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

Meeting Date: October 22, 2013  
Meeting Time: 10:00 A.M.  
Meeting Place: State House, 200 W. Washington St., the Senate Chamber  
Meeting City: Indianapolis, Indiana  
Meeting Number: 5

**Members Present:** Sen. Patricia Miller, Chairperson; Sen. Ryan Mishler; Sen. Vaneta Becker; Sen. Rodric Bray; Sen. Ed Charbonneau; Sen. Ron Grooms; Sen. Jean Leising; Sen. Pete Miller; Sen. Jean Breaux; Sen. Frank Mrvan; Sen. Mark Stoops; Sen. Greg Taylor; Rep. Ed Clere, Vice-Chairperson; Rep. Steven Davisson; Rep. Robert Behning; Rep. Suzanne Crouch; Rep. David Frizzell; Rep. Dennis Zent; Rep. Charlie Brown; Rep. B. Patrick Bauer; Rep. Gregory Porter.

**Members Absent:** Rep. Ronald Bacon; Rep. Donald Lehe; Rep. Eric Turner; Rep. Robin Shackelford.

Chairperson Patricia Miller called the meeting to order at 10:07 a.m.

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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.



### **Health Insurance Exchange Update**

Mr. Logan Harrison, Indiana Department of Insurance, provided an update on the Affordable Care Act (ACA) and the federal Health Insurance Exchange Marketplace (Exchange). See Exhibit 1. Mr. Harrison discussed the waiver Indiana submitted (which was denied by the federal government) for an exemption from the requirements in the ACA concerning the medical loss ratio (the percent of premiums collected by an insurance company and spent on medical services) for small insurance carriers in an attempt to curb the withdrawal of insurance carriers. Mr. Harrison also discussed insurance rating restrictions, essential health benefits, guarantee availability, and guarantee renewability. See Exhibit 1. Mr. Harrison reviewed the actuarial values of insurance plans on the market and discussed the different levels of plan, from bronze (the cheapest plan) to platinum (most expensive and most extensive plan). Mr. Harrison stated that insurers are still allowed to increase premiums for individuals who use tobacco by as much as 1.5 times the regular rate and that individuals will not receive a subsidy to help pay for the increased premium portion of the cost of the policy. Mr. Harrison discussed Indiana's benchmark insurance policy used for the Exchange and the services covered. Mr. Harrison stated that the open enrollment period for the Exchange for 2014 is October 1, 2013 through March 31, 2014 unless the individual experienced a qualifying event. See Exhibit 1. Mr. Harrison explained that individuals seeking coverage on the Exchange are expected to pay between two percent and 9.5 percent of the individual's income towards health insurance premiums before the premium tax credits apply. Mr. Harrison discussed premium rates and eligibility for premium tax credits. Mr. Harrison stated that over 200 navigators have been certified in Indiana.

### **Food Handling Report Update**

Mr. Scott Zarazee, Indiana State Department of Health (Department), stated that the Department has met with and will continue to meet with interested stakeholders to address issues concerning food handling and will report back to the Indiana General Assembly next summer. Mr. Zarazee stated that the Department has developed an information packet to educate food handlers on safely handling food and available food certification programs.

### **Biosimilar Drugs**

Chairperson Miller stated that Angela Hoover, Walgreen Co., was unable to attend but had provided her testimony in writing. See Exhibit 2. Ms. Ambre Marr, AARP, stated that the average annual cost of a biosimilar drug is \$72,000. Ms. Marr expressed the concern that no biosimilar has been approved yet by the federal Food and Drug Administration (FDA) in the United States so that this discussion is premature. Ms. Marr also stated that biosimilars could be added to the existing generic drug statute instead of creating a new law with new requirements.

Ms. Brynna Clark, Generic Pharmaceutical Association, stated that biosimilar language has only passed in one state in its entirety and three states have passed the legislation with a sunset clause. Ms. Clark said that California's governor vetoed the bill. Ms. Clark stated that there is an absence of scientific need to require physician notification for substitution with a biosimilar product and that this requirement would lower use of the biosimilar drugs.

Mr. Jim McKay, Sandroz/Novartis, discussed the current market of biologicals, and the difference between biosimilars and interchangeable biosimilars. Mr. McKay stated that physician notification does not improve patient safety and that the current generic substitution law protects patients. Mr. McKay stated that 11 other states have rejected similar biosimilar language that was considered but failed in Indiana last session.



Mr. Robert Spolyar, CVS, stated that CVS opposes the biosimilar legislation because it is premature since the FDA has not yet approved a biosimilar drug. Mr. Spolyar discussed the expense of biosimilar drugs and stated that requiring physician notification implies that the interchangeable biosimilar drug is inferior.

Ms. Allyson Blandford, Express Scripts, testified that Express Scripts supports the use of generic medication and opposes the requirement of physician notification. Ms. Blandford stated that physician notification causes an additional step that undermines the efficacy of the biosimilar drug. Ms. Blandford discussed Tennessee's experience in requiring physician notification for substitutions, which caused an increase in the use of the brand name drug, resulting in Tennessee removing this requirement. Mr. John Cardwell, Indiana Health Care Task Force, discussed the potential cost to the consumer and requested that this legislation wait until the FDA completes its process in evaluating the biosimilar drugs.

Mr. Fritz Bitenbender, BIO, discussed five principles<sup>2</sup> that should be included in legislation concerning the substitution with interchangeable biosimilar drugs and stated that all the principles were included in the biosimilar substitution legislation considered in Indiana last session. Mr. Bitenbender stressed the importance of transparency for the patient, pharmacist, and physician and stated that notification to the physician concerning the substitution after dispensing is not an undue barrier and should not hamper marketplace development.

Mr. Mike Brady, Indiana State Medical Association, introduced Dr. Robert Flint and distributed written testimony from Dr. B. H. Barai and Dr. Michael Dugan. See Exhibit 3. Dr. Flint testified that it is important for a patient's physician to know what is happening with the patient in order to achieve successful treatment, so it is important for the physician to be notified if a biosimilar drug is substituted.

Mr. Andrew Spiegel, Global Colon Cancer Association, discussed colon cancer and stated that biologic medicines offer promise and enable cancer patients to live longer, healthier lives. Mr. Spiegel stated that since the introduction of biologic medicines, the average life expectancy of the metastatic colon cancer patient has almost tripled. See Exhibit 4. Mr. Spiegel recognized the inherent safety challenges associated with this class of drugs. Mr. Spiegel said that the Alliance for Safe Biologic Medicines (of which his Association is a member) conducted a survey of physicians and found that 86% of the 350 physicians who participated in the survey responded that the physician wanted to be notified before a patient is switched to a biologic other than the one prescribed. Mr. Spiegel testified that he supports the legislation considered last session because the language contained the five principles discussed earlier.

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<sup>2</sup> The five principles include:

- (1) the biosimilar product has been determined by the FDA to be interchangeable with the prescribed product for the indicated use;
- (2) the prescriber does not designate verbally or in writing on the prescription that substitution is prohibited;
- (3) The person presenting the prescription provides written consent for the substitution;
- (4) The pharmacist notifies the prescriber in writing and as soon as practicable but not later than 72 hours after dispensing; and
- (5) the pharmacy and the prescriber retain a written record of the biosimilar substitution for at least five years.



Ms. Jan Ferris, Lupus Foundation, discussed the cost of biological drugs and provided information concerning lupus. Ms. Ferris indicated that the patient-doctor relationship is important with lupus and requires constant monitoring of all of the medications that a person with lupus has to take. Ms. Ferris stated that physician notification is important. Ms. Connie Shella, lupus patient, explained that because of her multiple diseases, she takes 14 medications and has eight physicians. Ms. Shella stated that it is important to have her physicians know all the medications she is taking.

Ms. Kimberly Greco, AMGEN, discussed the sensitivity and complexity of biosimilar drugs and stated that manufacturers of biosimilar drugs wanted to be held accountable for the product and manufacturers rely on the adverse reporting by physicians. Mr. Joey Wohlhieter, Global Healthy Living Foundation, said that patients that his Foundation represents take biologic drugs. Mr. Wohlhieter stated that notification of both the patient and the provider should occur when substituting an interchangeable biosimilar and that a record of the substitution should be kept for five years. Representative Dennis Zent stated that as a health care provider, he would want to be informed of any substitution and that he does not feel that notification is onerous.

### **Dental Issues**

Mr. John Hammond, Ice Miller, discussed the role of a "dental support organization" or "dental services organization" (DSO). See Exhibit 5. Mr. Hammond stated that DSOs provide support services for dentists and have operated in Indiana for 20 years. Mr. Hammond said that a DSO cannot direct or control patient treatment. Dr. Neil Pinney, Professor at the Indiana School of Dentistry, stated that he uses a DSO so that he can continue to maintain his skills when practicing dentistry one day a week at the school clinic. Dr. Pinney said that using a DSO frees him from the administrative components of dental practice.

Dr. Kristen Stevens, dentist, stated that when she graduated from dental school, she was nervous about having to do the administrative part of the job, such as billing and insurance. Dr. Stevens said that using a DSO has given her flexibility for having time to spend with her family. Dr. Clark Downey, dentist, said that he wants to focus on dentistry, not the business portion of the practice and use of a DSO has allowed him to travel to perform dental outreach in other countries. Dr. Tom Frank, dentist, says that use of a DSO allows him to work on the weekends and that he sees many Medicaid patients.

Ms. Polly Boehnlein, Kool Smiles, informed the Commission that Kool Smiles is a Medicaid provider for many Indiana Medicaid recipients and owns the patients records. See Exhibit 6. Ms. Boehnlein stated that there is a need for transparency. Mr. Dave Kind, NCDR, LLS, stated that his company provides business services for dental practices and that there are many similar models for other health care providers. Mr. King stated that NCDR does not own the practice, records, or have any role in patient treatment. Mr. King said that he opposes the legislation from the last legislative session requiring a DSO to register because it does not provide patient protection or achieve any other purpose.

Mr. Ed Popcheff, Indiana Dental Association, testified that in the legislation considered last session, the Indiana State Board of Dentistry simply asked for DSOs to register with the state. Mr. Popcheff provided written testimony from Dr. Don Helfert. See Exhibit 7. Dr. Leila Aiter, dentist, testified concerning her experience working with a DSO. Dr. Aiter testified that the entity signed the dentists up for any insurance plan then withdrew the dentist from the plan to try to renegotiate higher reimbursement rates. Dr. Aiter stated that the entity did not have an infectious disease policy or training, did not have working smoke detectors, did not repair or provide maintenance to dental equipment, and used her provider identification



information even after she stopped working there. Dr. Steve Towns, dentist and instructor at the Indiana School of dentistry, stated that he has seen patients asking for a second opinion after receiving excessive treatment plans from DSOs and that there is no accountability. Dr. Brent Swinney, dentist, stated that he has seen patients seeking a second opinion after receiving inflated dental treatment plans from DSOs. Dr. Matthew Pate, pediatric dentist, said that he has seen patients who formerly went to DSOs where work was performed or suggested that was not necessary.

Mr. David Miller, Office of the Attorney General, provided information concerning regulatory and other legal actions that have been taken or are being taken by his office against DSOs. See Exhibit 8. Mr. Miller stated that there is ambiguity in the law that should be addressed, either by statute or by giving the state dental board the authority to regulate DSOs.

### **Commission Action**

The Commission considered its Final Report, affirmed that today's testimony and action should be inserted into the Report, and approved the Final Report 18-0. See Exhibit 9.

#### Preliminary Draft (PD) 3352

PD 3352 requires the Commission for Higher Education of the state of Indiana to study and make recommendations concerning the issue of the high cost of dental education. The Commission approved PD 3352 18-0. See Exhibit 10.

#### PD 3296

PD 3296 requires, before September 1, 2014, the State Department of Health to: (1) adopt rules concerning the regulation of facilities for treatment of traumatic brain injuries; and (2) make recommendations to the Legislative Council and Health Finance Commission concerning food handling law changes. The Commission approved PD 3296 18-0. See Exhibit 11.

#### PD 3364

PD 3364 prohibits a person less than 16 years of age from using a tanning device in a tanning facility and repeals a provision requiring a person less than 16 years of age to be accompanied by a parent or guardian when using a tanning device in a tanning facility. PD 3364 requires the State Department of Health to adopt standards concerning the safe use of tanning devices by individuals. The Commission approved PD 3364 17-2. See Exhibit 12.

#### PD 3341

PD 3341 allows a pharmacist to substitute an interchangeable biosimilar product for a prescribed biological product if certain conditions are met. This PD requires the Board of Pharmacy to maintain an Internet web site that lists the biosimilar biological products that are determined to be interchangeable and allows the Board of Pharmacy to adopt rules. This PD provides that a written or electronic prescription for a biological product must comply with the existing prescription form requirements. The Commission considered two amendments to this PD which failed. The Commission approved PD 3341 without amendments 14-5. See Exhibit 13.

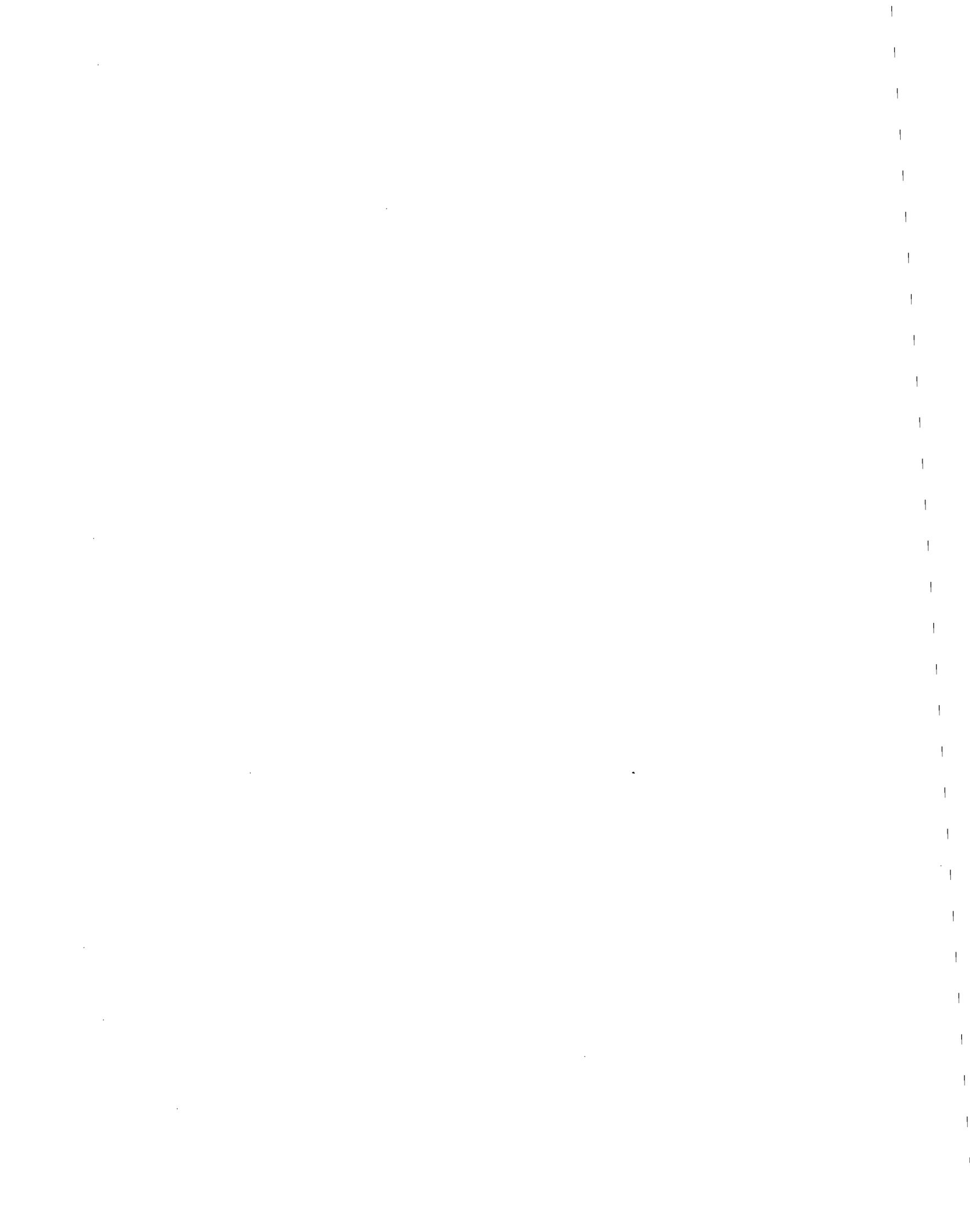
#### PD 3361

PD 3361 requires the State Department of Health and the Office of the Secretary of Family and Social Services to establish a work group to study uniform access to electronic health data by health providers. The Commission approved PD 3361 19-0. See Exhibit 14.

Additional documents were distributed to Commission members in response to questions



raised at previous Commission meetings. See Exhibit 15. The meeting was adjourned at approximately 4:15 p.m.



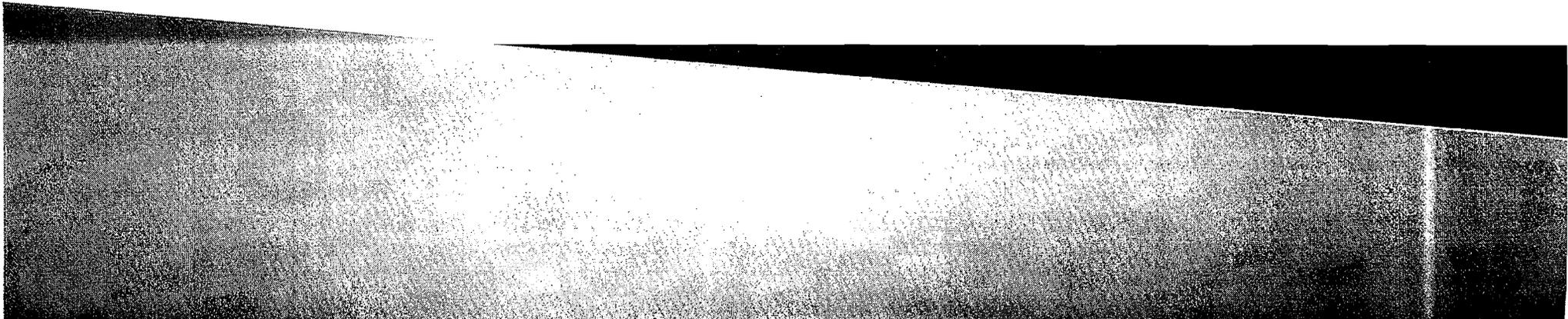
**Indiana Department of  
Insurance  
Health Finance Commission  
ACA Update**

**October 22, 2013**

**Logan P. Harrison  
Chief Deputy Commissioner of Insurance  
lharrison@idoi.IN.gov**

# Indiana Actions to Prepare for the Affordable Care Act (ACA)

2010–Current



# Indiana Actions to Prepare for the Affordable Care Act (ACA)

## ACA Rules, Regulations, and Guidance:

- › Developed a cost analysis of the impact of the ACA on the state of Indiana. Cost analysis can be found at: [http://www.in.gov/aca/files/ACA\\_Fiscal\\_Impact\\_Update\\_10-20-11.pdf](http://www.in.gov/aca/files/ACA_Fiscal_Impact_Update_10-20-11.pdf)
- › Undertook a large research effort toward exploring an Indiana based Exchange, including:
  - Developing an Exchange operational plan, defining IT system needs, exploring Exchange policy options and developing a budget
  - Completed a study on promoting health care quality through an Indiana Exchange. Report can be found at: [http://www.in.gov/aca/files/HIC\\_IX\\_Package\\_Final\\_Draft\\_04-23-12.pdf](http://www.in.gov/aca/files/HIC_IX_Package_Final_Draft_04-23-12.pdf)
  - Documented Exchange research and progress for the federal government. Progress reports can be found at <http://www.in.gov/aca/2221.htm> under Exchange Planning Grant and Level 1 Exchange Grant
- › Developed an analysis of the impact of the ACA on the Indiana insurance marketplace. Analysis can be found at: [http://www.in.gov/aca/files/Indiana\\_memo\\_and\\_table\\_final\\_3-28-2011.pdf](http://www.in.gov/aca/files/Indiana_memo_and_table_final_3-28-2011.pdf)
- › Participated in hundreds of calls hosted by the federal Department of Health and Human Services
- › Reviewed all federal guidance and submitted comments:
  - Example letters to Centers for Medicare and Medicaid Services (CMS) can be found at [http://www.in.gov/aca/files/Final\\_Regulation\\_Comment\\_Oct\\_11.pdf](http://www.in.gov/aca/files/Final_Regulation_Comment_Oct_11.pdf) and [http://www.in.gov/aca/files/Risk\\_Adjustment\\_10-11-11.pdf](http://www.in.gov/aca/files/Risk_Adjustment_10-11-11.pdf)
- › Developed and delivered training to state employees on the ACA

# Indiana Actions to Prepare for the Affordable Care Act (ACA)

## Implement Mandatory Medicaid Changes including:

- ▶ Primary Care Physician Rate Increase  
Information for physicians to receive higher payment rates can be found online at [http://www.in.gov/health/indianamedicaid/2010/01/01/aca\\_provider\\_qualifiers\\_for\\_primary\\_care\\_physicians.html](http://www.in.gov/health/indianamedicaid/2010/01/01/aca_provider_qualifiers_for_primary_care_physicians.html)
- ▶ Developed new application to meet federal requirements (federal approval in process)
- ▶ Analyzed and implemented the new Modified Adjusted Gross Income (MAGI) methodology for determining Medicaid eligibility  
Modified Adjusted Gross Income flow charts can be found at [http://www.in.gov/health/indianamedicaid/2010/01/01/aca\\_provider\\_qualifiers\\_for\\_primary\\_care\\_physicians.html](http://www.in.gov/health/indianamedicaid/2010/01/01/aca_provider_qualifiers_for_primary_care_physicians.html)
- ▶ Upgraded IT system to interact with federal HUB to verify eligibility components (income, citizenship, etc.)
- ▶ Changed eligibility notices as directed by CMS
- ▶ Completed all federal planning, testing, and security requirements for online applications, program eligibility checks and sharing information
- ▶ Updated eligibility rules and State law to comply with ACA  
Updates to key Family and Social Services Administration (FSSA) program eligibility requirements can be found at [http://www.in.gov/health/indianamedicaid/2010/01/01/aca\\_provider\\_qualifiers\\_for\\_primary\\_care\\_physicians.html](http://www.in.gov/health/indianamedicaid/2010/01/01/aca_provider_qualifiers_for_primary_care_physicians.html)
- ▶ Implemented new State legislation designed to satisfy ACA requirements. Legislation can be found at: [http://www.in.gov/legislative/2010/01/01/aca\\_provider\\_qualifiers\\_for\\_primary\\_care\\_physicians.html](http://www.in.gov/legislative/2010/01/01/aca_provider_qualifiers_for_primary_care_physicians.html)

# Indiana Actions to Prepare for the Affordable Care Act (ACA)

## Protecting consumers and educating consumer outreach workers:

- ▶ Implemented state law to reduce fraud and abuse and to protect Hoosiers that apply for health coverage programs. State law created to certify individuals helping Hoosiers apply for health coverage can be found at <http://www.in.gov/legislative/ic/code/title27/ar19>
- The new Indiana Navigator certification program that requires individuals that are assisting individuals with applying for programs have been certified by the State. Certification requirements include criminal background check, and required training and testing.
- Requirements can be found at <http://www.in.gov/idoi/2823.htm>
- ▶ Developed comprehensive training manual and training slides for use by organizations or individuals seeking certification. Materials provide training on ACA and applying for programs and can be used by the general public. <http://www.in.gov/idoi/2826.htm>

# Indiana Actions to Prepare for the Affordable Care Act (ACA)

## Communicating with Stakeholders:

- ▶ Conducted a survey on stakeholder perspectives on the ACA.
  - Reports can be found at:
    - [http://www.in.gov/aca/files/Affordable\\_Care\\_Act\\_Questionnaire\\_Report.pdf](http://www.in.gov/aca/files/Affordable_Care_Act_Questionnaire_Report.pdf)
    - [http://www.in.gov/aca/files/Executive\\_Summary\\_ACA\\_Questionnaire.pdf](http://www.in.gov/aca/files/Executive_Summary_ACA_Questionnaire.pdf)
- ▶ Conducted a survey on stakeholder perspectives on an Exchange in Indiana
  - Reports can be found at:
    - <http://www.in.gov/aca/files/DraftExchangeQuestionnaire.pdf>
    - <http://www.in.gov/aca/files/DraftExchangeQuestionnaireExecutiveSummary.pdf>
- ▶ State staff made numerous presentations to stakeholder groups and to the General Assembly to provide education on the ACA and updates on state activity related to the ACA
- ▶ Presentations for legislators and stakeholder groups can be found under “Related Documents” and “Stakeholder meetings” at <http://www.in.gov/aca/2330.htm>

# Indiana Actions to Prepare for the Affordable Care Act (ACA)

## Insurance Regulation:

- ▶ Developed an analysis of insurance market ACA requirements and options
- ▶ Implemented State legislative changes to comply with the ACA. Legislative changes can be found at:  
<http://www.in.gov/legislative/bills/2011/SE/SE0461.html> and  
<http://www.in.gov/legislative/bills/2011/SE/SE0461.html>
- ▶ Surveyed Indiana health insurers to gain perspective on key policy issues
- ▶ Completed comprehensive analysis of Indiana's essential health benefit options
- ▶ Issued bulletins on regulatory changes including geographic rating areas, medical loss ratio, dependent age 26 among other ACA provisions. Bulletins can be found at: <http://www.in.gov/health/2391.html>

# Indiana Actions to Prepare for the Affordable Care Act (ACA)

## Insurance Regulation (cont'd):

- ▶ Completed federal requirements to document external review and rate review authority and state process
  - ▶ Made improvements to the rate review process to assure Indiana retained authority over the Indiana insurance marketplace.
  - ▶ Documentation of correspondence with the federal government on external review and rate review requirements can be found at <http://www.in.gov/aca/3530.htm> under Federal Correspondence.
- ▶ Applied for federal recognition of our rate and form filing to preserve state-based health insurance regulation. The federal government granted this to Indiana in July 2011: [http://www.in.gov/aca/files/4492\\_001.pdf](http://www.in.gov/aca/files/4492_001.pdf)
- ▶ Created new processes to review plans seeking approval for rate review as a Qualified Health Plan for the Exchanges
- ▶ Applied for a waiver and/or phase-in of the medical loss ratio to curb the numerous individuals insurance carriers that were withdrawing from our market: [http://www.in.gov/aca/files/May\\_13\\_2011\\_MLR\\_Letter.pdf](http://www.in.gov/aca/files/May_13_2011_MLR_Letter.pdf)

# Insurance Market Changes Overview



# Insurance Market Changes Overview

## ▶ Medical Loss Ratio (MLR)

- Ensure Premiums Pay Healthcare Costs (80/20 Rule)
- Insurers with low Medical Loss Ratio (MLR) will be required to issue refunds to enrollees

## ▶ Unreasonable Rate Review

- State review of all premium rate increases

Federal Marketplace will look at any premium rate increase over 10% and make recommendation to the state

## ▶ Rating Restrictions

- Premiums based on age, location, and smoking status
- No rating based on health history or health status

## ▶ Guaranteed Availability and Guaranteed Renewability

- Health insurance companies required to issue and renew policies
- Cannot be denied for pre-existing conditions

# Insurance Market Changes Overview (cont.)

## ▶ **Age 26**

- Since 2010, insurers required to offer the option for members to include adult dependents up to age 26 on their health coverage plan

## ▶ **Preventive services expanded**

- Many preventive services required to be covered without cost sharing

## ▶ **Essential Health Benefits (EHB)**

- List of benefits that insurers in the individual and small group market are required to cover

## ▶ **Elimination of lifetime and annual maximum coverage limits**

- Insurers may no longer put dollar limits on coverage that are part of the essential health benefits

# Insurance Market Changes Overview (cont.)

## Actuarial Value (AV)

- AV is a number that indicates the average percent of plan costs the insurer expects to pay for *all* enrollees in that plan
  - Individual and Small Group Plans must have a standard AV that is displayed to the consumer
  - Plans with higher AV will have higher premiums and lower cost-sharing

## Minimum Value (MV)

- Employer-sponsored insurance must offer minimum value, or a plan that has an AV of at least 60%
  - Employees may be eligible for insurance affordability programs and the employer may be subject to a fine if employer-sponsored insurance does not offer minimum value

# Medical Loss Ratio (MLR)

- ▶ Definition of MLR:
  - Percent of premiums collected by an insurance company and spent on medical services
- ▶ New requirement of the Affordable Care Act (ACA):
  - Health insurance companies must maintain a certain MLR
  - MLR requirements vary by market segment:

	Large Group	Small Group	Individual
MLR Requirement	85%	80%	80%

- ▶ Insurance company does not meet MLR requirement:
  - Individuals and small businesses will receive a refund
- ▶ IN applied for MLR waiver to help our small carriers
  - ▶ This request was denied by the federal government

# New Rating Restrictions for Non-Grandfathered\* Health Insurance Plans

## To determine health insurance premiums:

- ▶ Health insurance plans may **only use three factors**:
  - Age – limited to 3 to 1 ratio
  - Tobacco use – limited to 1.5 to 1 ratio
  - Geographic area
- ▶ Health insurance plan premiums **CANNOT** rate based on:
  - Gender
  - Health status
    - \* Insurers may not exclude individuals or health conditions from their health coverage based on pre-existing conditions

\*Plans developed after the passage of the Affordable Care Act in 2010

# Tobacco Use

- ▶ Insurers are still allowed to increase premiums for individuals that use tobacco by as much as 1.5 times
  - ACA definition: use of any tobacco product on average four or more times per week over the past six months
  
- ▶ Individuals that are subject to an increased premium due to tobacco use will not receive a subsidy to help them pay for the increased premium
  
- ▶ Individuals that use tobacco but do not make this clear on their application cannot be terminated from their plan for this omission
  - Can be required to pay back premiums
  - Can be terminated if they do not pay
  
- ▶ Employer plans are required to have an option for individuals to enroll in a tobacco cessation program and receive a waiver of the premium increase
  - Not required for individual market plans

# Actuarial Value (AV)

- ▶ **Actuarial Value (AV) is:**
  - The average percentage of medical cost expected to be paid by the health plan over *all* covered enrollees
- ▶ **AV applies to health plans that are:**
  - Non-grandfathered
  - Individual & small group markets
  - On and off the federal Marketplace
  - Required to offer Essential Health Benefits (EHB)

Plan Level	Estimated/target total costs covered by health plan*	Estimated/target total costs covered by enrollees
Bronze	60%	40%
Silver	70%	30%
Gold	80%	20%
Platinum	90%	10%

**Premium Tax Credit based on the cost of the 2<sup>nd</sup> lowest cost Silver Plan**

\*At each plan level, the actual total costs covered by the health plan must be within two percentage points of the following estimates/targets (i.e. for Bronze plan, health plan costs must be 58–62% of total costs)

# Cost-Sharing Structure

- ▶ All health plans are required to offer plans in bronze, silver, gold, or platinum metal tiers
  - These tiers represent the cost of care that will be covered by the individual compared to the cost covered by the insurer
- ▶ To ensure alignment with the Actuarial Value tier requirements, health plans used an actuarial value calculator
  - The calculator could not take all benefit designs and did not include all offered benefits
- ▶ To get to the required actuarial values copayments and coinsurance structures were substantially modified
  - Some plans have large copayments for x-rays and prescription drugs

# Essential Health Benefits (EHBs)

## ▶ Starting in 2014:

- The Affordable Care Act requires health plans to cover certain benefits
- Must offer benefits in each of the following 10 Essential Health Benefits categories:

1. Ambulatory patient services
2. Emergency services
3. Hospitalization
4. Maternity and newborn care
5. Mental health and substance abuse disorder services, including behavioral health treatment
6. Prescription drugs
7. Rehabilitative and habilitative services and devices
8. Laboratory services
9. Preventive and wellness services and chronic disease management
10. Pediatric services, with oral and dental

# Essential Health Benefits (EHB) (cont.)

- The exact benefits and services covered by EHB vary by state and are based on a benchmark plan
  - In Indiana the benchmark plan is the Anthem PPO plan
  - All plans in the individual and small group market are required to cover at a minimum the benefits covered in this plan
- EHB benefits are set for 2014 and 2015
  - Can change in 2016

There were seven options for the EHB benchmark in Indiana. The Anthem PPO plan was the default option. Cost and benefits in this plan were the median of costs and benefits in all options.

Indiana EHB Benchmark Options Analysis: Benefit Variations Among Plans								
Plan	Federal GEHA	Federal BCBS	State Employee Plan	Lumeno's HSA	Anthem PPO	United Health 19L POS	Advantage HMO	Estimated Benefit PMPM Cost
Estimated Monthly Cost	\$398.61	\$398.38	\$397.67	\$395.12	\$394.75	\$392.31	\$392.24	
Chiropractic	+	+	+	+	+	+	-	\$1.72
Acupuncture	+	+	-	-	-	-	-	\$1.25
Morbid Obesity (MO) Surgery	+	+	+	-	-	-	-	\$2.25
MO non-surgical treatment	+	+	+	-	-	-	+	N/A
TMJ	+	+	+	+	+	-	-	\$0.68
Hearing Aids	+	+	-	-	-	+	-	\$0.20
Artificial organ transplants	+	-	-	-	-	-	+	N/A
Smoking Cessation	+	+	*	+	-	-	+	\$0.37
Infertility Diagnoses	+	+	-	-	-	+	+	N/A
Infertility Treatment	+	+	-	-	-	+	-	\$0.10
Breast Feeding Education	+	+	+	+	+	-	+	\$0.10

# Indiana's Benchmark- Anthem PPO

- Largest plan by enrollment in Indiana's Small Group Market in March 2012
- Offers Comprehensive coverage including:
  - Inpatient, Outpatient, Mental Health and Substance Abuse
  - Physical, Speech and Occupational Therapy (20 visits each)
  - Maternity & Newborn
  - Preventive
  - Access to specialist treatments and therapies
    - TMJ
    - Transplants
    - Chemotherapy
- Covers all Indiana Mandates
- Does not cover: hearing aids, infertility diagnoses and treatment, morbid obesity surgery, or smoking cessation
  - These benefits are not considered EHB in Indiana for 2014 & 2015, though health insurers may offer them above EHB

# Changes to Covered benefits

- ▶ Due to the EHB requirements all plans in the individual market will now be required to offer:
  - Maternity & Newborn Care
  - Mental Health & Substance Abuse
  - Prescription Drugs
  - Pediatric dental & vision
  - Applied Behavioral Therapy for Autism
    - Not subject to rehabilitative service limits
  
- ▶ Pre-2014 most individual market plans did not include these services
  - Some services could be purchased in addition to the policy, but were cost-prohibitive
  
- ▶ Plans in the small group market are also required to offer these services beginning in 2014
  - Many small group plans already offered some or all of these services but there may have been a waiting period before a benefit kicked in
    - For example 1 year waiting period before eligible for maternity benefits
  - Benefits must now be offered without waiting periods applied to any benefit that is EHB

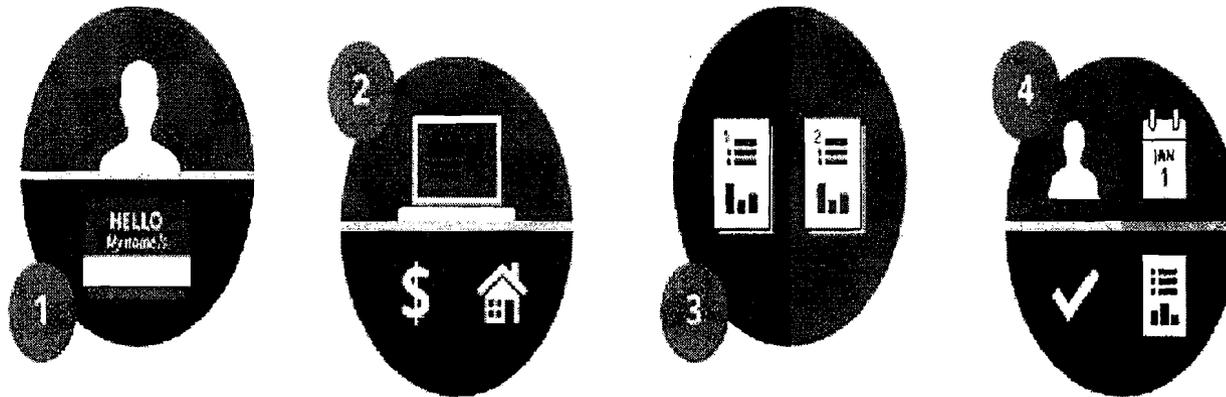
# How does the market change by 2019?

Source of Health Insurance	2010 Estimate	2019 Projection
Uninsured	875,000	425,000 - 675,000
Public Programs	950,000	1,200,000 - 1,300,000
Individual Insurance	200,000	575,000 - 1,050,000
Employer-Sponsored Insurance		
Insured Small Group (2-50 employees)	300,000	225,000 - 300,000
Insured Large Group (51+ employees)	475,000	350,000 - 475,000
Self-Funded (All employer sizes)	2,825,000	2,850,000 - 3,125,000
<b><i>Total Indiana Residents Ages 0 to 64</i></b>	<b>5,625,000</b>	<b>6,200,000 - 6,500,000</b>

Source: Herbold, Jill S. and Paul R. Houchens. Milliman, Inc. "2019 Health Insurance Enrollment Projections for Indiana." May 2011.

Assumes that Indiana does not offer a federal basic health program.

# How the Marketplace works



## Create an account

First you'll provide some basic information. [Sign up for Marketplace](#) emails now and we'll let you know as soon as you can create an account.

## Apply

Starting October 1, 2013 you'll enter information about you and your family, including your income, household size, and more.

[Use this checklist](#) now to help you gather the information you'll need.

## Pick a plan

Next you'll see all the plans and programs you're eligible for and compare them side-by-side.

You'll also find out if you can get [lower costs](#) on monthly premiums and out-of-pocket costs.

## Enroll

Choose a plan that meets your needs and enroll!

Coverage starts as soon as January 1, 2014.

## Learn more about the Marketplace

# Individuals and the Marketplace

- ▶ Individuals will have to use the Marketplace application to:
  - Apply for coverage
    - Applications can be completed online, over the phone, by mail and in person
  - Receive federal subsidies
    - Individuals that apply for tax subsidies will be asked to verify their income
  - Compare and purchase plans
    - All Marketplace plans will be required to offer a standard short plan summary
  
- ▶ Summary will explain:
  - Covered benefits
  - Cost sharing
  - Provide illustrations of how coverage would work for common medical events
    - such as having a baby

# Overview of changes for buying insurance

- ▶ Plans will still be available outside of the marketplace
  - Can be purchased directly from the health insurer or through an agent or broker
- ▶ All plans offered will be required to cover the same benefits, including those that may be excluded or limited today
  - (e.g., maternity care, mental health, and prescription drugs)
- ▶ Individual market coverage will be standardized into tiers (from bronze to platinum)
  - Deductibles and copays will typically vary from plan to plan, but all plans in a given tier will provide the same overall level of protection to consumers.
- ▶ Issuers can no longer rate on health status, and the health status questionnaire will no longer be part of the application on or off the marketplace
  - Once enrolled issuers may ask health information for care management purposes
  - They may not charge sick individuals more than healthy individuals
- ▶ Without a qualifying event, coverage will only be available in the open enrollment periods

# Enrollment Periods

- ▶ Consumers seeking coverage in the individual market will be required to purchase coverage during an enrollment period
  - The open enrollment period applies to the Exchange, however, insurers selling individual plans on the outside market can limit sales to the Exchange period
  - Individuals that do not purchase coverage for 2014 between October 1 and March 31 will be locked out of coverage unless they experience a qualifying event
- ▶ Individuals can get special enrollment periods if they experience a qualifying event including:
  - Loss of other minimum essential coverage, gaining or losing a dependent, a permanent move, etc.

# Changes to Networks

- ▶ Federal government was responsible for determining network adequacy of Qualified Health Plans (QHPs) in the Federal Marketplace
- ▶ To offer competitive plans on the Marketplace health carriers have much *narrower* networks
  - This reduces individual choice of providers
- ▶ Individuals may find that their will only be one plan that their particular doctor or hospital system is associated with
  - May increase travel times for individuals seeking care
  - May increase wait times for specialist providers
- ▶ Health insurers can stop selling plans that reach network capacity

# How has the market changed since 2010?

2010 Market	2010 Covered Lives	Carriers > 100 Lives	Market Share Largest Carrier	Market Share Top 5 Carriers
Individual	200,000	30	59.6%	85%
Insured Small Group (2-50 employees)	300,000	30	50.5%	79%
Insured Large Group (51+ employees)	475,000	25	62%	88%
2012 Market	2012 Covered Lives	Carriers > 100 Lives	Market Share Largest Carrier	Market Share Top 5 Carriers
Individual	174,788	21	61.3%	87.6%
Insured Small Group (2-50 employees)	341,691	28	56.2%	86.2%
Insured Large Group (51+ employees)	656,068	28	70%	92.5%
Difference 2010 & 2012 Market	2012 Covered Lives	Carriers > 100 Lives	Market Share Largest Carrier	Market Share Top 5 Carriers
Individual	-25,212	-9	+1.7%	+2.6%
Insured Small Group (2-50 employees)	+41,691	-2	+5.7%	+7.2%
Insured Large Group (51+ employees)	+181,068	+3	+8.0%	+4.5%

# Vision and Dental Coverage

- ▶ With the ACA requirements more individuals will have coverage for vision and dental services
- ▶ Health plans are required to cover vision and dental services for individuals under 18
  - Some plans extend this coverage to adults
- ▶ Adult dental and vision benefits will be available on plans in the Marketplace
  - These benefits are not considered Essential Health Benefits
    - Tax subsidies may not be applied to benefits not considered essential health benefits, individuals will have to pay for the full cost of the benefits
  - Individuals may also purchase stand alone adult vision or dental services
    - Stand alone vision coverage will not be available on the Marketplace

# Pediatric Dental

- ▶ Individuals purchasing on the Marketplace
  - Can purchase a plan that does not include pediatric dental
  - Are *not* required to purchase a stand alone dental plan
  
- ▶ Individuals purchasing plans off the Marketplace
  - Will be required to purchase a plan that includes pediatric dental coverage *or*;
  - Certify that they have purchased an Exchange certified pediatric dental policy
  
- This is true even when there are no individuals under 18 covered on the policy

# Child only coverage

- ▶ Since 2010, all child only plans in Indiana have withdrawn from the market
  - This was due to the prohibition on excluding preexisting conditions for children that was put into place by the ACA
- ▶ Beginning in 2014, all QHPs on the Marketplace will be required to offer child only plans at the silver and gold levels
  - Children that are not eligible for coverage on their parents or guardians policies will be able to receive coverage through Marketplace child only plans

# Additional Coverage

- ▶ Coverage for benefits beyond the Essential Health Benefits (EHB) can be offered
  - Benefits beyond the EHB are not eligible for federal subsidies
    - Including more generous service limits
  - Benefits beyond the EHB must be paid for in full by the enrollee
    - Also applies to Non-EHB benefits

# High Risk Pool Dissolution

- ▶ Effective January 1, 2014, insurance companies **cannot refuse** to sell coverage or renew policies because of an individual's pre-existing conditions
  - Plans cannot impose annual or lifetime dollar limits on the amount of coverage an individual may receive.
- ▶ Based on these provisions, coverage by the Indiana Comprehensive Health Insurance Plan (ICHIA) will no longer be needed in Indiana
  - The Federally Facilitated Marketplace will be a way for all individuals to purchase health insurance

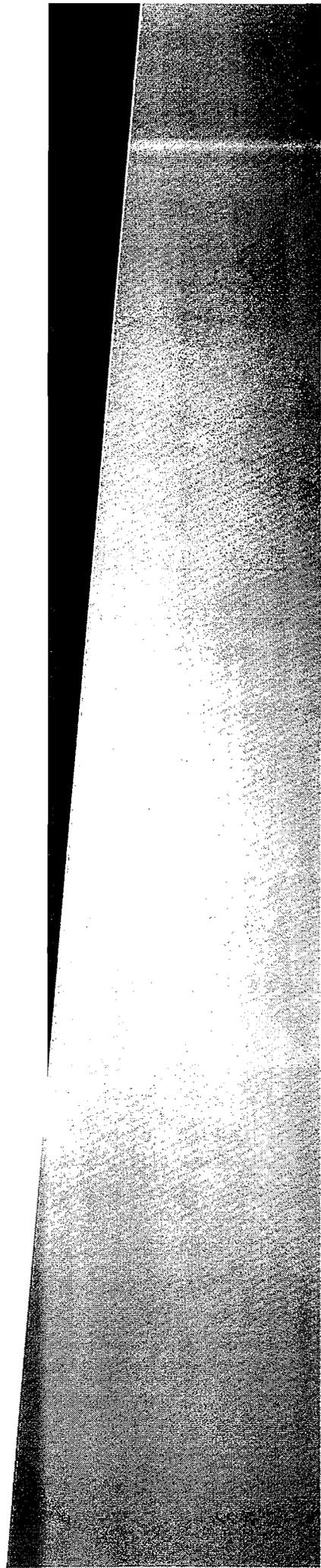
# Outside Market Overview

- ▶ Health insurers will continue to offer coverage on the outside market
- ▶ Not all health insurers on the outside market offer in the Exchange
- ▶ A wider variety of plans may be available off of the Marketplace
- ▶ Outside market offers coverage comparable to the Exchange
  - For individuals that are not subsidy eligible
  - For businesses

# Risk Programs

- ▶ Issuers will have to provide data to the federal government so that the Risk Adjustment, Reinsurance, and Risk Corridor Programs can be completed
- ▶ Data will include health status of individuals and total claims cost

# Affordability of ACA Coverage



# Is ACA coverage affordable?

- ▶ Will uninsured individuals be able to afford ACA coverage?
  - Individuals seeking coverage on the Marketplace are expected to pay between 2% and 9.5% of their income towards health insurance premiums before insurance subsidies kick in
  - This income contribution requirement doesn't count cost-sharing costs if individuals have to visit the doctor
    - Enrollees that select plans with less expensive premiums will have greater cost-sharing responsibilities when they need care

# Determine Affordable Coverage

## To Receive an Exemption

To receive an exemption from the requirement to have health insurance coverage because your coverage is unaffordable the premium must cost more than **8% of income**.

## To Receive a Tax Credit

To receive eligibility for a premium tax credit because your other coverage options are unaffordable the premium must cost more than **9.5% of income** for employee only coverage

- If dependent coverage is available the cost of this coverage is not considered when determining if dependents are eligible for PTC.

Individuals may be eligible for an exemption due to having unaffordable coverage that costs more than 8% of income but less than 9.5% of income but **NOT** eligible for a tax credit based on having affordable coverage

- Neither definition of affordable coverage includes any cost sharing requirements individuals may have
- Definitions of affordable coverage for the purposes of eligibility for tax credits or exemptions do not vary based on income

# Subsidized Coverage in the Marketplace— Second Lowest Cost Silver Plan

FPL	Percentage of Income Contribution towards Premiums	Estimated Annual Income* (Individual)	Estimated Monthly Income* (Individual)	Estimated Monthly Contribution (Individual)	Estimated % of Total Cost of Coverage % enrollee pays	Estimated Annual Out-of-Pocket Expenses (Individual)
100-133%	2%	\$11,490 - \$15,282	\$957- \$1,273	\$19-\$26	6%	\$2,250
133-150%	3% to 4%	\$15,282 - \$17,235	\$1,273 - \$1,436	\$26-\$58	6%	\$2,250
150-200%	4% to 6.3%	\$17,235 - \$22,980	\$1,436- \$1,915	\$58-\$121	13%	\$5,200
200-250%	6.3% to 8.05%	\$22,980 - \$28,725	\$1,915- \$2,393	\$121-\$193	27%	\$6,350
250-300%	8.05% to 9.5%	\$28,725 - \$34,470	\$2,393- \$2,872	\$193-\$273	30%	\$6,350
300-400%	9.5%	\$34,470- \$45,460	\$2,872- \$3,788	\$273-\$363	30%	\$6,350

\*Estimated income is pretax modified adjusted gross income

# Pay the Penalty?

- ▶ Will uninsured individuals be able to afford ACA coverage or will they choose to pay the individual mandate penalty?

	Subject to the maximum, penalty is the greater of:		Maximum Penalty
	Dollar Penalty**	Percent Penalty	
<b>2014</b>	Adult: \$95 Under 18: \$48 Maximum: \$285	1% of annual household income	National average premium for a Qualified Health Plan (QHP) Bronze Plan that would cover the applicable individual(s)
<b>2015</b>	Adult: \$325 Under 18: \$163 Maximum: \$975	2% of annual household income	
<b>2016</b>	Adult: \$695 Under 18: \$348 Maximum: \$2,085	3% of annual household income	

# ACA Coverage Costs and the Individual mandate Penalty

FPL	Annual Income* (Individual)	Premiums + Cost-sharing limit**	Individual Mandate Penalty 2014*	Individual Mandate Penalty 2015*	Individual Mandate Penalty 2016*
100-133%	\$11,490 - \$15,282	\$2,538-\$2,562	\$115-\$153	\$325	\$695
133-150%	\$15,282 - \$17,235	\$2,562-\$2,946	\$153-\$172	\$325-\$345	\$695
150-200%	\$17,235 - \$22,980	\$2,946- \$6,652	\$173-\$230	\$345-\$469	\$695
200-250%	\$22,980 - \$28,725	\$6,652- \$8,666	\$230-\$288	\$460-\$575	\$695 - \$862
250-300%	\$28,725 - \$34,470	\$8,666-\$9,626	\$288-\$345	\$575-\$689	\$862-\$1,035
300-400%	\$34,470- \$45,460	\$9,626- \$10,706	\$345-\$455	\$689-\$909	\$1,035-\$1,364

\*Penalty for single adult, penalties for a family will vary. Penalties estimates based on 2013 FPL, will change based on FPL in year assessed. \*\*Enrollees that select plans with less expensive premiums will have greater cost-sharing responsibilities when they need care

# Decline in the Uninsured

- ▶ Rate of individuals uninsured will decline
  - Implementation of subsidized Marketplace coverage
  - Requirement that individuals maintain insurance
- ▶ Uncertain by how much
- ▶ Newly insured will seek care

# Indiana Insurance Market 2010

Market	2010 Covered Lives <sup>1</sup>	Carriers >100 Lives <sup>1</sup>	Market Share Largest Carrier <sup>2</sup>	Market Share Top 5 Carriers <sup>1</sup>
Individual	200,000	30	59.6%	85%
Insured Small Group (2-50 employees)	300,000	30	50.5%	79%
Insured Large Group (51+ employees)	475,000	25	62%	88%

<sup>1</sup>Source: Milliman. Indiana Supplemental Health Exhibits, December 31, 2010 Annual Statement data submitted by Indiana insurance carriers. Collected using Insurance Analyst Pro®, Highline Data LLC. July 26, 2011.

<sup>2</sup>Source: Noble. Indiana Supplemental Health Exhibits, December Annual Statement data submitted by Indiana insurance carriers. August 4, 2011.

Note: Values are based upon the most recent information obtained from carriers as they work to make the Supplemental Health Care Exhibits more accurate. The fluctuation (as compared to July 15, 2011 presentation to Health Finance), results from: specific information regarding what needed to be filed and how it is calculated not being divulged until very shortly before deadline, lack of training from the federal government regarding the new forms, and a new requirement imposed upon carriers for 2011 reporting. The IDOI continues to reach out to carriers to encourage complete and accurate filing. This information is only reflective of the market on 12/31/2010.

# Indiana Insurance Market Post ACA Implementation

## ▶ Marketplace

- 4 insurance carriers in the individual Marketplace offering 241 different plans
  - Plans can close to new applicants when they meet their network capacity
  - Available plans vary by location, only carrier offers plans statewide

## ▶ Outside Market

- Some carriers have withdrawn from Indiana market citing ACA implementation
  - More difficult for small carriers to comply with new requirements

MARKET	NUMBER OF CARRIERS THAT HAVE WITHDRAWN
INDIVIDUAL	19
GROUP	10

# Multi-state plans

- ▶ The ACA requires the federal Office of Personnel Management to contract with a plan(s) to be offered in multiple Exchanges
  
- ▶ In 2014 the multi-state plan is Anthem Blue Cross Blue Shield
  - This plan is offered in the Exchange/Marketplace in 30 states (including Indiana) and D.C.
  
- ▶ OPM has authority to negotiate rates with the multi-state plan(s)
  - OPM has separate process for multi-state plans than the standard QHP and off-exchange processes
    - Handling of consumer complaints
    - External review
  
  - States still waiting on Memorandum of Understanding with OPM on multi-state plans

# Premiums under the ACA



# Premium Rates

- ▶ Provisions of the ACA impact premium rates
  - Guarantee Issue
  - Limit on rating factors
  - Required benefits
- ▶ The impact on any particular individual or family depends on current and eligibility for federal subsidies
- ▶ Not accounting for the application of federal subsidies, in general:

## 2014 Premiums Will Cost More

For:

- Individuals in good health
- Healthy young adults in general, with the greatest increase for young men

## 2014 Premiums will Cost Less

For:

- Individuals in poor health

# Indiana Premium Rate Changes

Age/Gender/Family	Health Status	Monthly Premium Bronze Plan Comparison			Monthly Premium Silver Plan Comparison		
		Current Lumenos HSA Plus \$5,500	2014 Lowest Cost Bronze	Rate Change	Current Lumenos HSA Plus \$5,500	2014 Lowest Cost Silver	Rate Change
25 Year Old Single Male	Excellent	\$82	\$212	+158%	\$108	\$266	+146%
25 Year Old Single Female	Excellent	\$118	\$212	+79%	\$154	\$266	+72%
25 Year Old Single Male	Poor	\$288	\$212	-26%	\$304	\$266	-12.5%
25 Year Old Single Female	Poor	\$551	\$212	-62%	\$582	\$266	-54.3%

Age/Gender/Family	Health Status	Monthly Premium Bronze Plan Comparison			Monthly Premium Silver Plan Comparison		
		Current Lumenos HSA Plus \$5,500	2014 Lowest Cost Bronze	Rate Change	Current Lumenos HSA Plus \$5,500	2014 Lowest Cost Silver	Rate Change
55 Year Old Single Male	Excellent	\$253	\$471	87%	\$108	\$591	+78%
55 Year Old Single Female	Excellent	\$262	\$471	80%	\$154	\$591	+72%
55 Year Old Single Male	Poor	\$840	\$471	-44%	\$304	\$591	-33%
55 Year Old Single Female	Poor	\$833	\$471	-44%	\$582	\$591	-33%

# Insurance Affordability Programs



# Premium Tax Credit (PTC) Subsidies

- ▶ Premium rate changes do not account for the premium tax credit subsidies
- ▶ Subsidies reduce the amount individuals will pay for their health insurance
  - Can be paid directly to insurance company to reduce premiums, OR
  - Consumers can claim the credit later when taxes are filed
- ▶ Value of the premium subsidy is highest for households with income near the poverty line and is reduced as household income increases
  - 100%–400% FPL
- ▶ Amount of PTC depends on:
  - Cost of the Marketplace's second lowest-cost Silver plan

# Who is Eligible for Premium Tax Credits (PTCs)?



Citizen, National or legal resident of the U.S. , Indiana resident, and non-incarcerated,

AND



Household income between 100% and 400% of the Federal Poverty Level (FPL)

AND



No other Minimum Essential Coverage (MEC) (including Medicaid and ESI) is available

OR

**Available MEC:**

- With individual premium more than 9.5% of household income
- OR
- Does not provide minimum value (at least 60% actuarial value)

\*Individuals must file taxes to be eligible for insurance affordability programs in coming years

# Premium Tax Credit (PTC) Required Premium Contribution

Income Level	2015 Estimated Annual Income (Individual)	Required % of Income Contribution	2015 Estimated Annual Contribution (Individual)
100-133%	\$11,490 - \$15,282	2%	\$230 - \$306
133-150%	\$15,282 - \$17,235	3% to 4%	\$458 - \$690
150-200%	\$17,235 - \$22,980	4% to 6.3%	\$690 - \$1,448
200-250%	\$22,980 - \$28,725	6.3% to 8.05%	\$1,448 - \$2,313
250-300%	\$28,725 - \$34,470	8.05% to 9.5	\$2,313 - \$3,275
300-400%	\$34,470 - \$45,460	9.5 %	\$3,275 - \$4,367

**\*NOTE:** This estimated contribution is for the second lowest-cost Silver plan available on the federal Marketplace; estimated annual contribution could change based on plan metal tier selected

# Example:

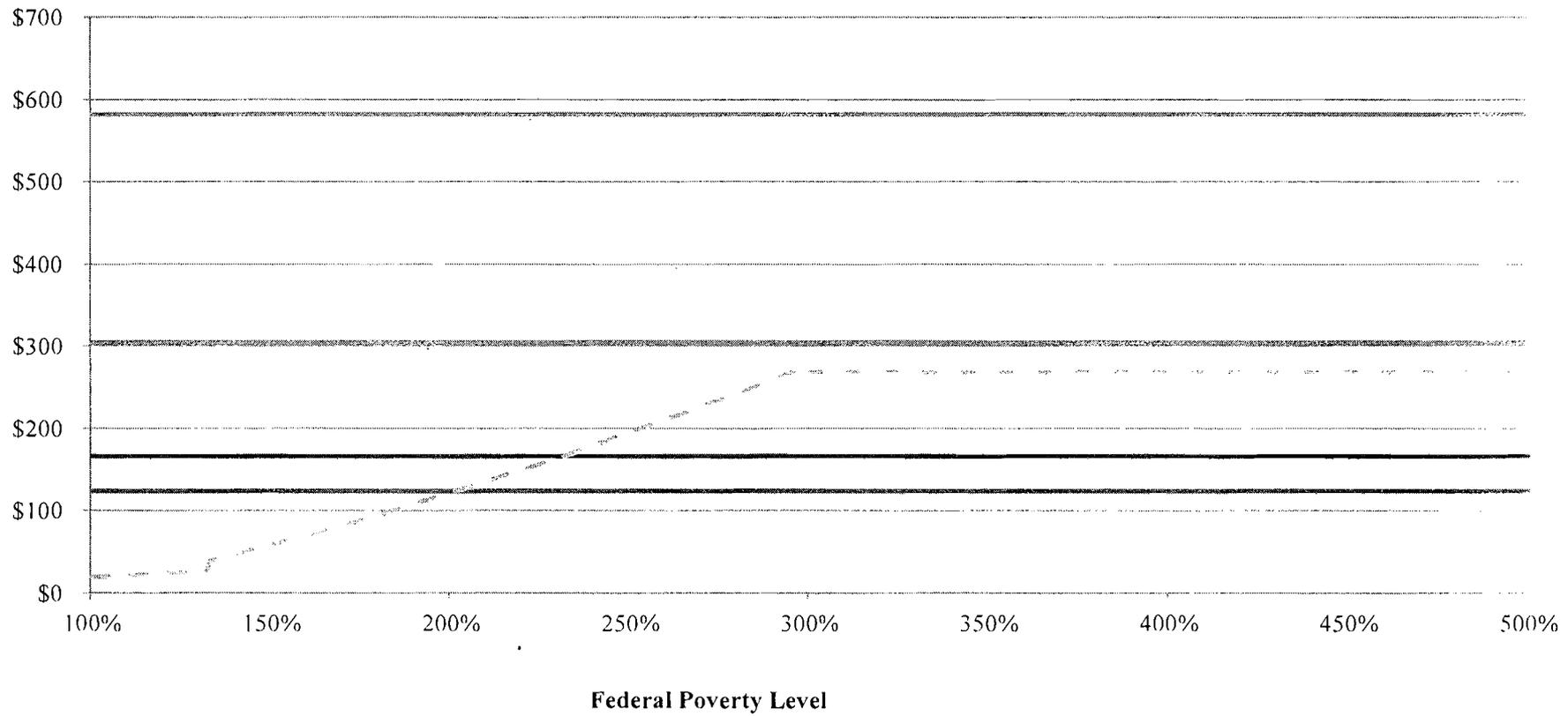
## Premium Tax Credit Calculation

- ▶ In Marion County, IN, the estimated annual premium for a 35-year old non-smoker's second-lowest Silver plan is **\$3,912 annually\* for 2014**. The PTC amount is calculated by taking this total premium cost and subtracting the required contribution.

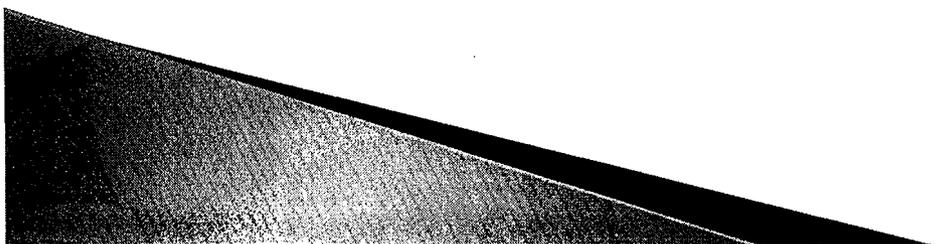
% FPL	2014 Estimated Second-Lowest Silver Plan Premium	Required Contribution**	PTC Amount
100%	\$3,912	\$230	\$3,682
150%	\$3,912	\$690	\$3,222
200%	\$3,912	\$1,448	\$2,464
250%	\$3,912	\$2,313	\$1,599
300%	\$3,912	\$3,275	\$637
400%	\$3,912	\$3,912	\$0

# Individual Marketplace Premiums

## Current Market \$2,500 Deductible Plan vs. 2nd Lowest Cost Silver Plan After Premium Tax Credit Subsidy

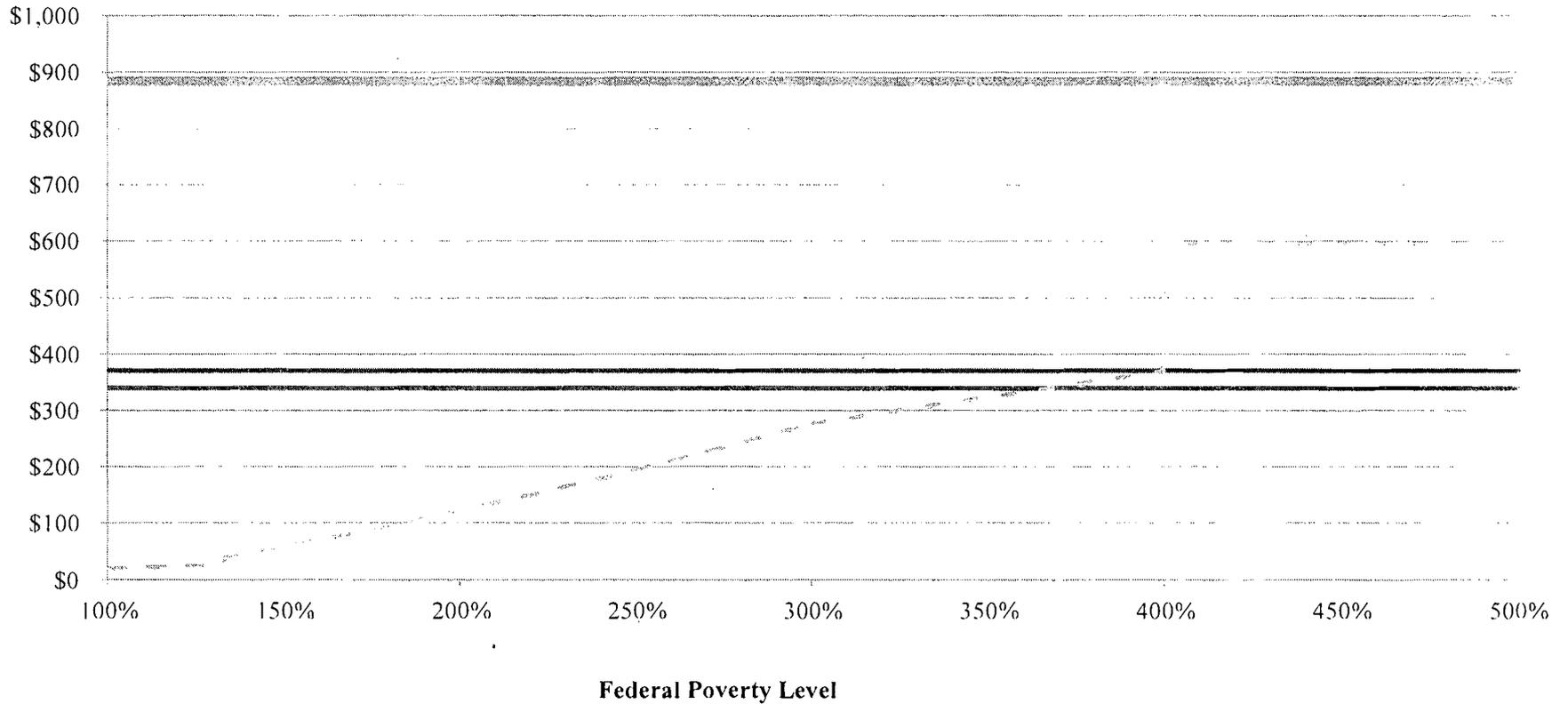


Male 25 - Excellent     
  Male 25 - Poor     
  Female 25 - Excellent     
  Female 25 - Poor     
  25 - Silver



# Individual Marketplace Premiums

## Current Market \$2,500 Deductible Plan vs. 2nd Lowest Cost Silver Plan After Premium Tax Credit Subsidy



Male 55 - Excellent
  Male 55 - Poor
  Female 55 - Excellent
  Female 55 - Poor
  55 - Silver

# Premium Tax Credit (PTC) Application to Premium Costs

- ▶ Can be used to purchase *any* plan on the federal Marketplace
  - Choosing a bronze plan:
    - Apply Silver plan level of PTC to a cheaper premium
    - *Lowers* consumer's premium contribution
  - Choosing a gold plan:
    - Apply Silver plan level of PTC to a more expensive premium
    - Consumer has to make up the cost difference
    - *Increases* consumer's premium contribution

# Example: Premium Tax Credit (PTC) Application to Premium Costs

- ▶ For 2014, in Marion County, IN, the estimated premium costs for a 35-year old non-smoker are:
  - Second-lowest cost **Silver plan: \$3,912\* annually,**
  - Lowest cost **Bronze plan: \$3,120\* annually,** and
  - Lowest cost **Gold plan: \$4,872\* annually.**
- ▶ Note how the PTC amount stays the same, based on the second-lowest cost Silver Plan, and how this impacts the amount someone would pay for his/her premiums, based on the selected plan.

**Plan cost - PTC amount = Individual Contribution**

% FPL	2014 Estimated PTC Amount	2014 Estimated Individual Contribution: Bronze Plan**	2014 Estimated Individual Contribution: Silver Plan**	2014 Estimated Individual Contribution: Gold Plan**
100%	\$3,682	\$0	\$230	\$1,190
150%	\$3,222	\$0	\$690	\$1,650
200%	\$2,464	\$656	\$1,448	\$2,408
250%	\$1,599	\$1,521	\$2,313	\$3,273
300%	\$637	\$2,483	\$3,275	\$4,235
400%	\$0	\$3,120	\$3,912	\$4,872

# Cost-Sharing Reductions (CSR)

## ▶ Purpose:

- Increase the Actuarial Value (AV) of health coverage plans for low-income consumers
- Reduce out-of-pocket costs for consumers

## ▶ Receiving CSR:

- CSR are offered **in addition** to Premium Tax Credits (PTC)
- Qualifying individuals do **NOT** have to apply for CSR separately

# Who is Eligible for Cost-Sharing Reductions?\*

- Meet all requirements for Premium Tax Credits (PTC) and;
- Household income between 100% and 250% of the Federal Poverty Level (FPL) and;
- Enroll in a Silver plan (70% Actuarial Value) on the federal Marketplace

2013 FPL	Estimated Annual Income (Individual)	AV of Silver plan after CSR (Originally 70%)	Individual Annual Out-of-Pocket Maximum (2014)*
100-133%	\$11,490 - \$15,282	94%	\$2,250
133-150%	\$15,282 - \$17,235	94%	\$2,250
150-200%	\$17,235 - \$22,980	87%	\$5,200
200-250%	\$22,980 - \$28,725	73%	\$6,350

\*Individuals must file taxes to be eligible for insurance affordability programs in coming years

\*Insurance companies do not have to charge less than the listed out-of-pocket maximum for their plans, but they cannot charge more than these amounts

# Requirements for Subsidized Individuals



# Premium Tax Credit and Non-payment of premiums

- ▶ 90 day grace period to pay premiums during the year
- ▶ First 30 days of unpaid premiums all health care services the individual receives will be covered as if the individual paid their premium
- ▶ For days 31 to 90 the health care services sought by the individual will not be covered by their insurance if they do not pay their premiums
  - Insurers are required to inform providers that individuals in this non-payment period may not have services covered
  - Individual will be liable for the cost of services received in this period and providers will be required to seek payment from the individual
- ▶ Individuals must pay all unpaid premiums by the close of the 90 day period
  - The individual will be disenrolled from coverage at the close of 90 days of non-payment

# Premium tax credit reconciliation

- ▶ Individuals that receive advanced payments of the premium tax credits will be required to reconcile the premium tax credit when they file their taxes
- ▶ The advanced payment granted is based on projected household income for 2014
  - Individual may owe money to the IRS if an individual received more tax credit than they were eligible
    - Determined when taxes are filed

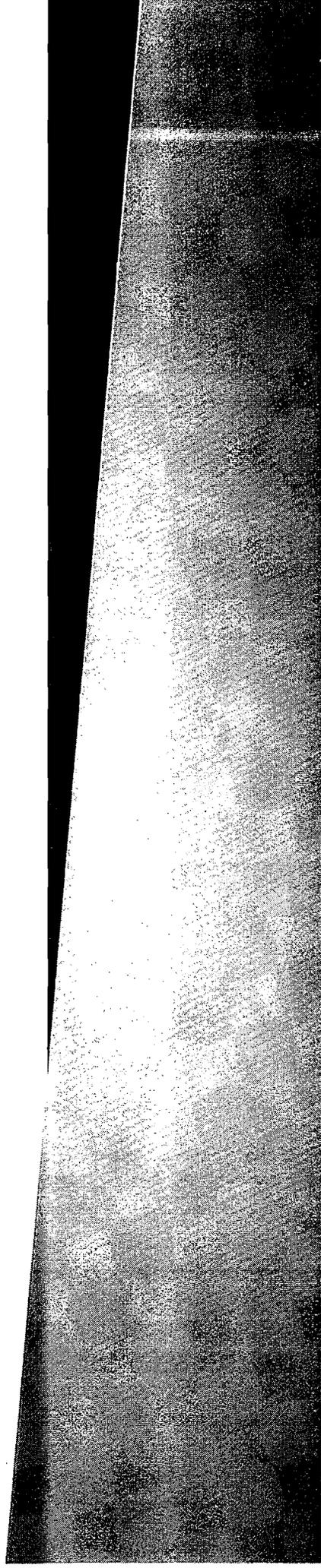
Individual eligible to receive a credit or refund if an individual received less tax credit than they are eligible

- Determined when taxes are filed

Amounts of premium tax credit that have to be repaid are limited by FPL:

Household income	PTC repayment limit: Single Individual	PTC repayment limit: Family
< 200% FPL	\$300	\$600
200% to 300% FPL	\$750	\$1,500
300% to 400% FPL	\$1,250	\$2,500
< 400% FPL	Full repayment required	Full repayment required

# Requirements for Individuals and Businesses



# The Individual Mandate and Minimum Essential Coverage

- ▶ Individual Mandate
  - Affordable Care Act (ACA) requirement
  - All individuals must maintain health coverage for themselves and their dependents
    - Minimum Essential Coverage (MEC)
- ▶ Understanding MEC
  - List of coverage types determined by the federal government
  - Coverage types may change
    - Some coverage types only classified as MEC in 2014
  - Types of coverage not currently considered MEC may apply for recognition as MEC
- ▶ Exemptions from MEC
  - Individuals may receive an exemption from the requirement to maintain MEC

# Individual Mandate

- Also known as the Shared Responsibility requirement
- Options
  - Maintain Minimum Essential Coverage (MEC) or;
  - Obtain an exemption or;
  - Pay a tax penalty for themselves and all uncovered dependents
- Tax penalty varies, as shown in the table below:

	Subject to the maximum, penalty is the greater of:		Maximum Penalty
	Dollar Penalty**	Percent Penalty	
<b>2014</b>	Adult: \$95 Under 18: \$48 Maximum: \$285	1% of annual household income	National average premium for a Qualified Health Plan (QHP) Bronze Plan that would cover the applicable individual(s)
<b>2015</b>	Adult: \$325 Under 18: \$163 Maximum: \$975	2% of annual household income	
<b>2016</b>	Adult: \$695 Under 18: \$348 Maximum: \$2,085	3% of annual household income	

# What is considered Minimum Essential Coverage (MEC)?

In order to meet Individual Mandate requirements, all Americans must have at least one of the following:

- ❑ Government sponsored health coverage Medicare Program
  - ❑ Most Medicaid Programs
  - ❑ Children's Health Insurance Program
  - ❑ Veterans Administration programs: including Tri Care and CHAMP VA
  - ❑ Coverage for Peace Corps Volunteers
- ❑ Employer-sponsored health coverage
- ❑ Individual market health coverage
- ❑ Grandfathered health plan
- ❑ Self-funded student health coverage - Limited to 2014
- ❑ Refugee medical assistance
- ❑ Medicare advantage plans
- ❑ State high risk pool coverage - Limited to 2014
- ❑ Additional Coverage as specified
  - ❑ Any health coverage not recognized may apply to be minimum essential coverage. The federal government will maintain a list of recognized types of minimum essential coverage.

# NOT Minimum Essential Coverage (MEC)

- Limited-scope coverage, or offered on a separate policy from primary health coverage
  - Examples:

Accidental death and dismemberment coverage	Benefits provided under certain health flexible spending arrangements	Coverage for employer-provided on-site medical clinics
Automobile liability insurance	Workers' compensation	Long-term care benefits
Disability insurance	Credit-only insurance	Vision benefits
General liability insurance	Fixed indemnity insurance	Medicare supplemental policies
TRICARE supplemental policies	Similar supplemental coverage for a group health plan	Separate policies for coverage of only a specified disease (example: cancer only policies)

They will need to either:  Obtain coverage that IS MEC

Obtain an exemption

Pay the tax penalty

# Student Health Insurance

- ▶ Student health plans will not count as Minimum Essential Coverage for the purposes of the Individual Mandate
  - For 2014 there is an exception for self-funded student health plans, however, most student health are not self-funded
- ▶ Options:
  - Stay on their parents plans as dependents or;
  - Obtain individual or employer sponsored insurance to meet the mandate requirements

# Exemptions for Unaffordable Coverage

- ▶ An individual may have Minimum Essential Coverage (MEC), but he or she may still qualify for:
  - Affordability Exemption
    - IF Unaffordable Coverage: Cost of coverage is more than 8% of household income
  - Premium Tax Credit (PTC)\*
    - IF Cost of coverage is more than 9.5% of household income
- ▶ Eligibility for the Affordability Exemption & PTC varies for those with access to employer-sponsored insurance (ESI)

	Employee Only	Employee & Dependents
Affordability Exemption	If contribution for ESI is more than 8% of income	If contribution for ESI for employee & dependents is greater than 8% of income, <b><u>dependents</u></b> may receive exemption (but not employee)
Premium Tax Credit	If contribution for ESI is more than 9.5% of income	If contribution for ESI that covers only the <i>employee</i> is greater than 9.5% of income

\*Typically someone that already has MEC cannot get a PTC

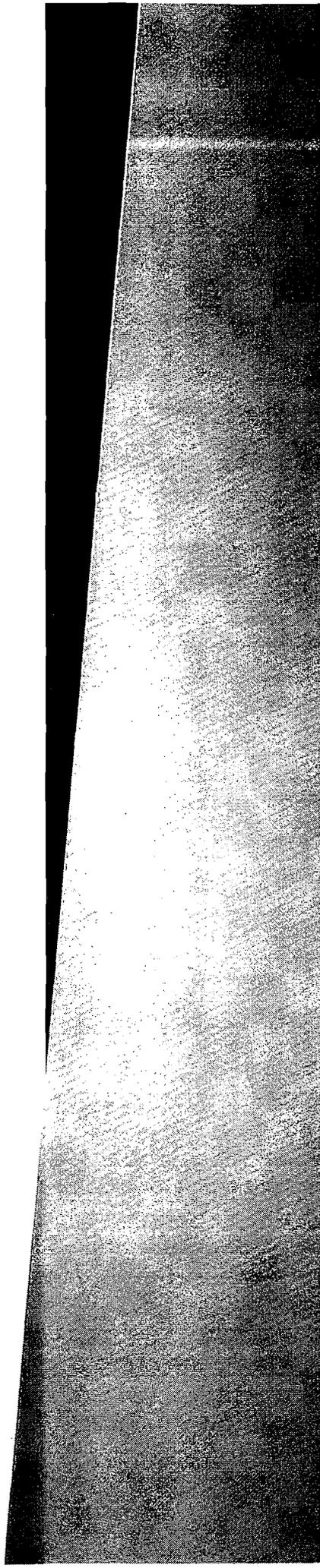
# Other Possible Exemptions

- ▶ Individuals may send an exemption application to:
  - The federal Marketplace OR
  - The Internal Revenue Service (IRS)
- ▶ In addition to Unaffordable Coverage, exemptions may be allowed for:

Religious Conscientious	Hardship
Household income below filing limit	Healthcare Sharing Ministry
Indian Tribe	Incarceration
Not lawfully present	Short coverage gaps

To see if they are eligible for an exemption, consumers should call the federal Marketplace call center at: 1-800-318-2596

# Employer Impacts



# Employer Mandate Delayed Until 2015

- Employer fines are triggered if one employee, who qualifies for a federal advanced premium tax credit or a cost-sharing subsidy, seeks insurance through the exchange
  - In that instance, a fine will be levied against the employer

Employers offering coverage to at least 95% of full-time employees

Employers not offering coverage to at least 95% of full-time employees

- Pay a penalty of the lesser of:
  - \$3,000 per employee receiving a PTC, OR
  - The penalty for employers not offering coverage
- Pay \$2,000 for every employee full time and full time equivalent employee, excluding the first 30 employees

\*Provision delayed by the federal government and will now begin in 2015. Employers with over 50 FTEs that have employees receive PTC in 2015 will owe a penalty payment.

# Small Employers

- ▶ Coverage on the SHOP Exchange
  - Available to employers with 2 to 50 employees
    - Small employers may use agent or broker or enroll in SHOP directly
    - Small employer tax credits for offering coverage only available through SHOP beginning in 2014
    - SHOP will not collect premiums from employers until 2015
      - Employer will pay carrier directly
- ▶ Employee selection among SHOP products delayed until 2015
- ▶ Small employers may also purchase coverage on the outside market as they do today
  - Different plan options on the outside market, potentially more plans available

# Large Employers

- ▶ Large employer mandate delayed until 2015
- ▶ Not eligible for SHOP enrollment in 2014 & 2015
  - Those with up to 100 employees will be eligible for SHOP in 2016

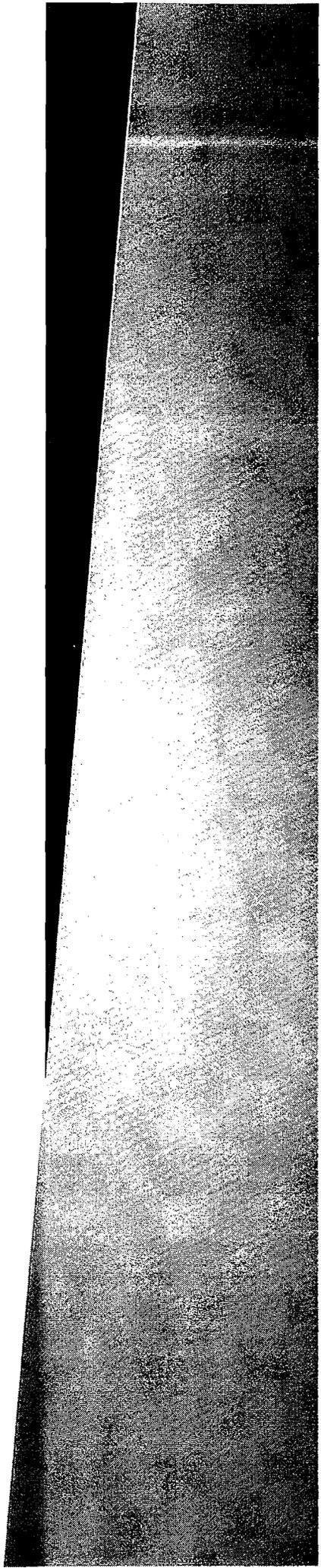
# Employer Actions

- ▶ Dropping coverage for spouses and dependents
- ▶ Other employer actions include:
  - Raising deductibles
  - Making HSAs look more like 401(k)s with matching contributions
  - Having employer options promote shopping for best prices
  - Reducing work weeks to under 30 hours
    - Educational institutions limit Adjunct hours
    - Restaurants limiting worker
  - No more health coverage for part-time employees
    - Transition part time employees to Exchange coverage
- ▶ Some COBRA eligible employees may transition to the Marketplace
  - Employers are required to inform employees of Marketplace options
  - COBRA only limits enrollee eligibility for subsidy if enrolled

# Employer Overview

- ▶ Some businesses may be considered large businesses by Indiana but eligible for small group coverage on the federal SHOP exchange
- ▶ Some businesses may be considered small businesses by Indiana but subject to the large employer mandate penalties by the federal government
- ▶ For purposes of SHOP coverage, small business tax credits, and determining employer mandate penalties beginning in 2015, the federal government will use a measure to count employees called 'full-time equivalent employees'
  - ▶ Indiana still use the full-time employee count
- ▶ Small Businesses that purchase coverage in the SHOP may be eligible for a tax credit towards the cost of coverage if they have fewer than 25 employees and an average wage of less than \$50,000
- ▶ Employers are required to notify employees of Exchange options
  - ▶ Employers will also be asked by employees applying for Exchange coverage to complete a form that provides information including the employee id number and details of any health insurance options offered
  - ▶ Employers will receive a notice from the Marketplace whenever one of their employees receives marketplace coverage with a premium tax credit
    - Employers can appeal an employees PTC eligibility

# Consumer Assistance



# Indiana Navigators

- ▶ Indiana initiated a training and certification requirement for individuals that assist consumers with eligibility and enrollment in Exchanges and Medicaid
  - Promotes consumer protection
  
- ▶ Indiana Navigators must be:
  - Trained by a certified training provider
  - Pass a certification exam
  - Adhere to privacy and security agreements
  - Disclose conflicts of interest
  - Annually renew their certification
  - Participate in continuing education
  - Pass a background check

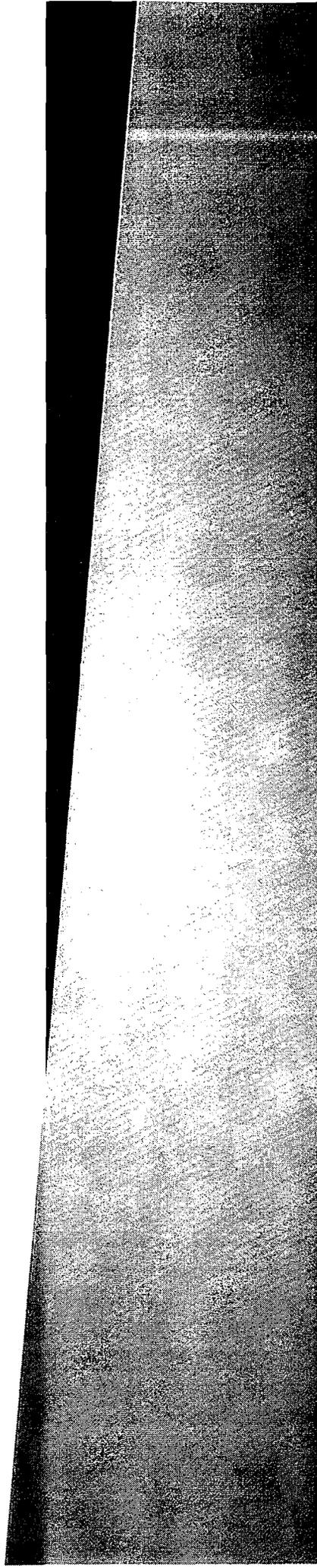
# Federal Navigators

- ▶ The ACA requires that each Marketplace have designated Navigators
  
- ▶ 4 Indiana organizations to serve as designated federal Navigators in the federal Marketplace in Indiana
  - Affiliated Service Providers of Indiana, INC
  - Plus One Enterprise
  - Health and Hospital Corporation of Marion County
  - United Way Worldwide
  
- ▶ These organizations also have to meet the requirements for Indiana Navigators

# Agents and Brokers

- ▶ Health insurance agents/brokers/producers are impacted by the ACA
- ▶ Greatest impact in individual market
  - Current role maintained in group markets
  - Some SHOP employers may not use a broker
- ▶ Requirement to register with federal Marketplace to sell QHPs
- ▶ Navigators and other consumer assistors fill part of the broker role
  - Cannot advise on health plan selection

# Exchanges and Marketplaces



# State Exchange Decisions



\*Utah & Mississippi will operate a state-base SHOP Exchange but individual Exchange will be federal

# State Responsibility In Federal Exchange

- ▶ Indiana Department of Insurance (IDOI) maintains jurisdiction for all IN plans
  - Licensure
  - Rate review
  - Financial solvency
  - Coordination with Federal Marketplace
- ▶ IDOI is responsible for assuring that all QHPs meet state requirements
  - QHPs apply first with IDOI
  - IDOI must complete review in alignment with federal timelines
  - IDOI sends recommendations on QHP certification to the federal government
- ▶ IDOI will receive complaints logged against QHPs from federal Marketplace

# State Responsibilities (cont.)

- IDOI sends recommendation on QHP certification to the federal government
  - FFM is responsible for certifying all offered QHPs

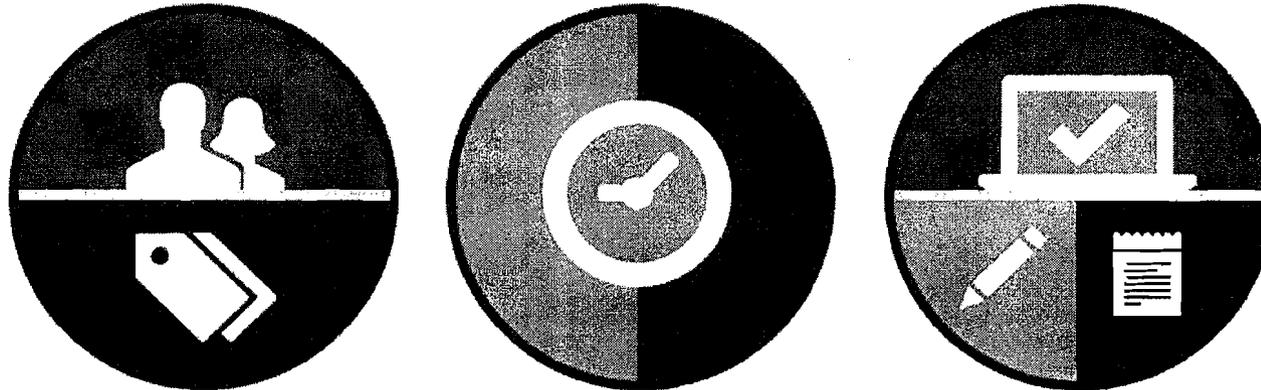
## FFE Responsibilities

- Reviews DOI certification recommendations
- Verifies QHP network adequacy
- Certifies qualified health plans
- Makes certified qualified health plans available to individuals on the federal Exchange

## IDOI Responsibilities

- Maintains current responsibilities for all plans in Indiana including QHPs:
  - Licensing
  - Rate review
  - Financial solvency
  - Communication with health plans
- Implements and enforces new ACA market rules
  - EHB
  - Rating requirements including geographic areas
  - Non-discrimination

# Federal Exchange Roll-out



We have a lot of visitors on the site right now.

Please stay on this page.

We're working to make the experience better, and we don't want you to lose your place in line. We'll send you to the login page as soon as we can. Thanks for your patience!

In a hurry? You might be able to apply faster at our Marketplace call center. Call 1-800-318-2596 to talk with one of our trained representatives about applying over the phone.

# Federal Exchange Progress

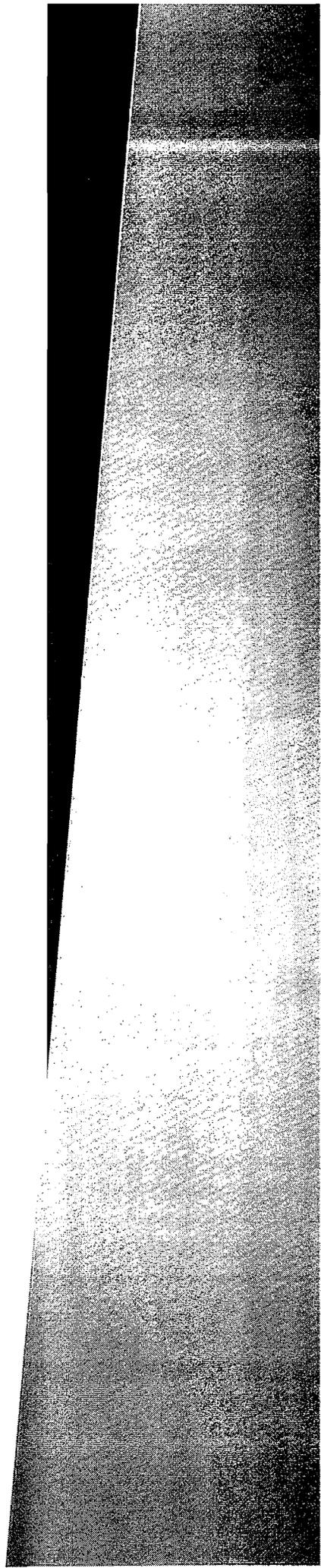
- ▶ Consumers facing issues:
  - Over capacity
  - Security questions blank
  
- ▶ Small employers
  - Can set up account but will have to fill out application by paper if they want to enroll in next month
  
- ▶ Spanish language delay
  - Spanish language enrollments delayed until October 21<sup>st</sup>
  
- ▶ Some did manage to enroll in first week
  
- ▶ No current official estimates of how many enrolled or how many have created an account

# Potential Users of an Indiana Exchange

	Without ACA – 2017 Projection	Estimated Exchange Enrollees 2017
<b>Current Source of Coverage</b>	<b>Individuals</b>	<b>Exchange Enrollees</b>
Employer Coverage 139% FPL to 400% FPL	1,699,914	101,816
Individual Coverage 139% to 399% FPL	130,734	119,444
Individual Coverage above 400% FPL	100,980	10,098
Currently Uninsured 139–399% FPL	396,856	354,311
Currently Uninsured, above 400% FPL	53,496	8,024
Other coverage 139%+	221,129	44,226
<b>Total – Individual Exchange</b>	<b>2,603,109</b>	<b>637,919</b>
<b>SHOP Exchange</b>	<b>Employees and Dependents</b>	<b>SHOP Exchange Enrollees</b>
Employers with less than 50 Employees	904,441	42,286
Employees with 50 to 99 Employees	202,359	5,603
<b>Total – SHOP Exchange</b>	<b>1,106,800</b>	<b>47,889</b>
<b>Total – Indiana Exchange 2017</b>	<b>3,709,909</b>	<b>685,810</b>

Source: SHADAC w/ projected estimated population growth to 2017.  
Nationalhealthcare.in.gov

# ACA Next Steps



# Delayed Provisions Review

Delayed to 2015:

- ▶ Employer Mandate
- ▶ SHOP premium aggregation
- ▶ SHOP reference plan selection
- ▶ Combined notices for Medicaid & Marketplace eligibility

# ACA provisions in later years

- ▶ 2017 State Innovation waivers
  - Allow states to receive Medicaid and PTC funding to implement state specific health coverage programs
- ▶ 2018 High cost plan tax
  - ‘Cadillac’ Health Plans, those plans that cost more than \$10,200 for an individual or \$27,500 for a family will be subject to a tax
  - For every dollar spent on health plans beyond these amounts a 40% tax will be implemented

# ACA Funding

- ▶ The most recent Congressional Budget Office estimates indicate that the ACA will cost \$1,375 billion between from 2014 to 2023
  
- ▶ The ACA includes several revenue raising mechanisms:
  - Additional Medicare payroll taxes
  
  - Tax on indoor tanning services
  
  - Tax on medical device manufactures
  
  - Annual fee on health insurers
  
  - Annual fee on prescription drug manufacturers
  
  - Increased tax on HSA disbursements not used for Medical purposes
  
  - Changes to HSAs and FSAs to eliminate before tax expenditures on over the counter drugs
  
  - Tax on high cost 'Cadillac' health insurance plans
  
  - Funding form individual mandate and employer mandate payments
    - Delay of the employer mandate to 2015 is estimated at \$12 billion over 10 years\*

# The Future

- ▶ With the implementation of the ACA individuals will have more opportunities to get health insurance
- ▶ Rate of uninsured individuals will decline
- ▶ Unclear of what the impact on the cost of health care will be
  - Health care spending expected to grow at 6.2% per year for the next decade
  - Currently 17.9% of GDP goes towards health spending
  - By 2022 this is expected to increase to 19.9% of GDP
- ▶ Health spending will continue to outpace economic growth

# Contact

Logan P. Harrison

Chief Deputy Commissioner

Indiana Department of Insurance

[Lharrison@idoi.in.gov](mailto:Lharrison@idoi.in.gov)



HFC Oct. 22, 2013 Exhibit 2

**Written Testimony on Interchangeable Biosimilars**

To:  
Indiana Health Finance Commission  
October 22, 2013

Respectfully submitted by:

Angela Hoover  
Regional Director, State Government Relations  
Walgreen Co.





October 22, 2013

Re: Interchangeable Biosimilars

**Dear Members of the Health Finance Commission:**

Chairperson Senator Miller, Vice-Chairperson Representative Clere, and honorable members of the Committee:

On behalf of Walgreen Co. (Walgreens), I thank you for the opportunity to submit written testimony to the Commission as it examines the issue of biosimilar substitution. The language contained in House Bill 1315 during the 2013 legislative session, placed unnecessary impediments on the subsequent substitution of interchangeable biosimilars and favored brand drug usage. We would respectfully ask that you oppose any language, or recommendation, that places unnecessary burdens on the substitution of biosimilars that the U.S. Food and Drug Administration (FDA) has deemed interchangeable.

Walgreens, the nation's largest drugstore chain, operates over 8,000 drugstores in 50 states, the District of Columbia and Puerto Rico. In the state of Indiana, Walgreens operates 204 locations.

Walgreens is opposed to legislative or regulatory efforts that would place unnecessary burdens on the substitution of biosimilars determined to be interchangeable by the FDA with reference biologic products. Legislation in Indiana would be premature, as the FDA has not yet finalized their guidelines for approving biosimilars and determining their interchangeability. Until the FDA completes its arduous process, there is no way to know if any additional steps are warranted prior to substitution of an interchangeable product. It is important to note that there are no biosimilars in the U.S. marketplace currently, nor are there any applications for approval of any biosimilar pending with the FDA.

Biologic products are already playing an important role in today's health care system, both in terms of scientific advancements in the treatment of disease and in skyrocketing medication costs. Biologic products are currently being used to treat medical conditions such as: Rheumatoid Arthritis, Psoriasis, Crohn's Disease, Asthma, Diabetes, and Multiple Sclerosis. The high costs of many of these products to treat these conditions threaten patient access to important therapies and place a significant burden on all payers trying to manage prescription drug spending.

Legislation like House Bill 1315 from last session placed an undue administrative burden on physicians and pharmacists. The legislation would have differed from the current generic substitution law and required a pharmacist, who substitutes an interchangeable biosimilar product, to notify the prescriber of the substitution. This notification is not currently required for the generic substitution of more traditional small-molecule drugs. Walgreens believes that additional requirements will discourage substitution, increase costs to patients and payers, and threaten patient access to more affordable treatments.

The FDA process to determine biosimilarity and interchangeability will be stringent. As such, states can take comfort that biosimilars deemed interchangeable by the FDA can be substituted without the need for additional prescriber intervention, which is consistent with the intent of federal law. The same law that regulates substitution of small molecule drugs (i.e. generics) should also apply to the substitution of interchangeable biosimilars. Walgreens recommends that Indiana amend its laws and align their regulations –without limitations-- to specifically permit substitution of interchangeable biosimilars for their reference biological products.

It is also important to note that under current law, a prescriber can mark a prescription "dispense as written". If there are any concerns regarding the therapeutic equivalence of a biosimilar product, the prescriber may prohibit substitution. In fact, by choosing to not mark a prescription "dispense as written", a prescriber is





already giving their implicit permission to substitute a drug product that has been determined interchangeable by the FDA.

Special notification and consent requirements for the substitution of interchangeable biosimilars would be redundant, unnecessary and serve no purpose other than to reaffirm decisions made by prescribers when prescriptions are first issued – at which point prescribers have ultimate authority. In addition, further requirements specific to written record retention would increase the administrative burden unnecessarily for physicians and pharmacies, while offering no patient benefits.

At Walgreens, we believe in providing the best care to our patients and improving overall public health. We again urge this Commission to recommend that Indiana amend its laws at the appropriate time (when the FDA completes its process), and align the regulations –without limitations-- to specifically permit substitution of interchangeable biosimilars for their reference biological products.

Again, thank you for the opportunity to submit this testimony. Should you have any questions or require additional information, please do hesitate to contact me.

Respectfully submitted,

Angela Hoover  
Regional Director  
State Government Relations  
[angela.hoover@walgreens.com](mailto:angela.hoover@walgreens.com)  
847-315-2457





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October 22, 2013

Health Finance Commission  
200 West Washington Street, Suite 301  
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James McIntire

Dear Health Finance Commission Member,

My name is Michael Dugan, M.D. and I am contacting you to address the issue of biological biosimilar products that will be discussed in the next Health Finance Commission meeting.

Through my capacities as a practicing Oncologist, the Co-Director of the Stem Cell Program at the Indianapolis-based Indiana Blood and Marrow Transplant (IBMT), and a member of the Indiana State Medical Association (ISMA), I urge you to support provisions that would reinforce timely communication between a pharmacist and a physician once a biologic medication is substituted for a biosimilar product.

Due to the complex nature of the manufacturing process for the biotech medicines, where the smallest of variations may create vastly different clinical outcomes, it is imperative for there to be a strong channel of communication between the prescribing physician and the pharmacist when considering a biosimilar substitution.

I believe that the legislation being considered takes a positive step forward toward covering biologic and biosimilar products in a way that protects patients.

Thank you for your time and attention to this very important patient care issue.

Regards,

PP   
Michael Dugan, M.D.

---

***The largest physician organization in Indiana,  
advocating for the well-being of doctors and their patients.***





## PREMIER ONCOLOGY HEMATOLOGY ASSOCIATES

Practice Limited to Oncology and Hematology

Page 2

B. H. BARAI, M.D.  
BOARD CERTIFIED  
• MEDICAL ONCOLOGY  
• HEMATOLOGY  
• INTERNAL MEDICINE

NISHEETH GUPTA, M.D.  
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• INTERNAL MEDICINE

MARION TRYBULA, M.D.  
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SHARON WHITE  
BILLING MANAGER

JULIE PRIEBOY, R.N., MS, CNS, AOCNS

Because of these concerns about possible side effects, allergic reactions, or the possibility of anaphylactic reaction, it will be prudent for the prescribing physician to be aware that his/her patient is receiving a biosimilar compound.

As an Oncologist/Hematologist, I would certainly insist that my patients receive a biosimilar compound for the first time in my office or in the hospital setting to be prepared to address any serious allergic or anaphylactic reactions.

We are just entering the infancy era of "biosimilar" products. It is possible that after experience with several "biosimilar" compounds and additional data, which may be available in the next few years, we should reexamine this issue.

If you have any further questions or need clarification, please feel free to contact me at my office (219.736.6676); on my mobile phone (219.614.7810); or email [bhbarai@yahoo.com](mailto:bhbarai@yahoo.com).

Sincerely,

B.H. Barai, M.D.  
BHB/pmb

Medical Director, Oncology Institute, Methodist Hospitals, Gary and Merrillville, IN  
Clinical Assistant Professor of Medicine, Indiana University Medical School  
Member and Former President, Medical Licensing Board, State of Indiana



# PREMIER ONCOLOGY HEMATOLOGY ASSOCIATES

Practice Limited to Oncology and Hematology

October 22, 2013

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JULIE PRIEBOY, R.N., MS, CNS, AOCNS

Michael Rinebold  
Director of Government Relations  
Indiana State Medical Association  
Indianapolis, IN 46202

Dear Michael,

In the interest of patient safety and to prevent serious allergic or anaphylactic reaction, I strongly support the concept of pharmacy notifying the prescribing physician before dispensing a "biosimilar" product. Here are my comments:

1. "Biosimilar" products are not generic medications. The generic medications in use today are chemical compounds, which are identical to the original compound that was patented by the pharmaceutical company. Since the compounds are identical and produced by synthetic chemical process, the therapeutic benefits and potential adverse effects should be identical to the original patented chemical compound/pharmaceutical product.
2. Unlike small molecular drugs, biologics generally exhibit high molecular complexity and may be sensitive to changes in manufacturing process. The biosimilar manufacturers do not have access to the original molecular clone and original cell bank.
3. These biosimilar products may be produced by a fermentation and purification process using different chemicals and biological compounds, which may cause different allergic or possible anaphylactic reaction to these chemical compounds or impurities or their breakdown products, used in the manufacturing process.



Andrew R. Spiegel, Esquire  
Executive Director  
Global Colon Cancer Association  
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Office: 610-668-8600  
[andrew.spiegel@globalcca.org](mailto:andrew.spiegel@globalcca.org)  
[www.globalcca.org](http://www.globalcca.org)

October 22, 2013

Re: Support of SB 272-Biosimilars

Indiana Health Finance Commission:

Thank you for providing this opportunity to speak about this important issue.

My name is Andrew Spiegel. I am the Executive Director of the Global Colon Cancer Association (GCCA). The GCCA is a community of colon cancer patient advocacy groups worldwide and is the international voice for the millions of colon cancer patients worldwide. Before running the GCCA, I was CEO and a founding member of the U.S. based Colon Cancer Alliance, the oldest and largest national colorectal cancer patient advocacy organization. The GCCA's mission is to effectively address issues and provide information surrounding colorectal cancer to clinicians, patients and caregivers across the globe. The Global Colon Cancer Alliance is uniting people from all corners of the world in the fight against colon cancer and is effectively increasing awareness, earlier diagnosis and access to treatment of a disease that kills more than 600,000 people worldwide annually.

I personally know the impact of cancer. In 1999 I lost my mother to colon cancer two days after losing my father to pancreatic cancer. I was only 35 years old. At the time, there were very few treatments for these cancers, and today, these diseases remain among the top killers of Americans from Cancer. In fact, many do not realize that Colon Cancer is the second leading cause of cancer death in the U.S. with 1.2 million Americans living with the disease and 1 out of 20 getting it in their lifetime. Pancreatic cancer is one of the fastest growing, and most deadly cancers in the U.S. Cancer is an epidemic in this country affecting 1 out of every 2 men and 1 out of every 3 women. These two diseases alone account for more than 20 billion dollars in treatment costs annually in the US.



While we wish that preventative methods alone were sufficient to defeat colon cancer, this is currently not the case. Biologic medicines offer such promise and enable patients to live longer, healthier lives. Since the introduction of biologic medicines, the average life expectancy of the metastatic colon cancer patient has almost tripled. Because these medicines have been shown to significantly improve the survivorship rates, the Global Colon Cancer Association has a vested interest in seeing biosimilar medicines introduced to the U.S. market. Lower cost medications means more access and more lives saved.

Yet we recognize the inherent safety challenges associated with this class of medicines and therefore, the issue of substitution has been a new challenge for policy-makers, such as you.

As you know, biologics are highly complex, advanced prescription medicines. Unlike drugs derived from chemicals, biologics are manufactured using a unique process with living cells and for this reason no two biologics made from different cell lines are ever identical. When attempting to replicate biologics, their “copies,” known as biosimilars, are similar to, but not exact versions of the biologic they aim to replicate and are often mistakenly referred to as “generics.” Even the smallest difference in the structure of a biologic medicine and its attempted copy can have a significant impact on a patient.

That is why the Global Colon Cancer Association appreciates the opportunity to contribute a patient-centered viewpoint to the discussion regarding the biosimilar regulatory pathway. Through the Alliance for Safe Biologic Medicines, of which GCCA is a founding member, we have been working with physicians and pharmacists for over a year to determine the best solutions on biosimilar interchangeability. In May 2012, we convened a working group of our Advisory Board members to discuss the elements of a physician notification policy for interchangeable biosimilars that prioritizes patient safety and protects the relationship between physicians and their patients but also respects the sovereignty of pharmacists as healthcare providers. Last September, ASBM conducted a physician survey at the FDA/DIA Biosimilars Conference that found that 86% of the more than 350 physicians who participated, responded they want to be notified BEFORE a patient is switched to a biologic other than the one prescribed.

In October of 2012, the Alliance for Safe Biologic Medicines (ASBM) released key principles that should be included in any formal policy recommendation. As an active Steering Committee member, we support these principles and believe that building policy around these common sense recommendations will help ensure patient safety without delaying the introduction of biosimilars. We support the measures in SB 272 because they track the ASBM principles by endorsing substitution of biosimilars as long as:



(1) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed product for the indicated use.

(2) The prescriber does not designate verbally or in writing on the prescription that substitution is prohibited.

(3) The person presenting the prescription provides written consent for such substitution.

(4) The pharmacist notifies the prescriber in writing and as soon as practicable but no later than 72 hours after dispensing.

(5) The pharmacy and the prescriber retain a written record of the biosimilar substitution for a period of no less than five years

This legislation enhances the communication between pharmacists and physicians ensuring that doctors and pharmacists share an awareness for the exact medicine being taken, a practice that is especially important when it involves biologics. This is a best practice and not much different than the process pharmacist practice today to ensure that patients are receiving the medicines that will serve them most effectively when they fill their prescriptions. We've come a long way in providing access to lifesaving drugs to colon cancer patients. We want to ensure that these efforts continue as biosimilars are introduced and above all else, we must ensure that patient safety and welfare is the priority. The last thing a cancer patient should have to worry about is the quality and safety of drugs prescribed by their physician. It is the patient's right to know, and the physician's duty to know when a biosimilar has been substituted for a prescribed biologic.

Thank you for taking the necessary steps to make patient safety a priority in Indiana. We have supported the FDA in its mission to safely bring biosimilars to the U.S. and we support your efforts with SB 272.



## THE DSO MODEL: FICTION vs. FACTS

### Fiction

The DSO model constitutes the "corporate practice of dentistry".

### Fact

- Only a professional corporation ("P.C.") that is 100% owned by licensed dentists can practice dentistry in Indiana.
- A dental practice owned by a non-dentist constitutes the unlicensed practice of dentistry and is a Class D felony under Indiana law.
- The attorney general, prosecuting attorney, the state board of dentistry or any citizen of any county can bring a lawsuit to stop someone from the unlicensed practice of dentistry.

### Fiction

"Corporate dental groups" employ the dentists who work in their clinics.

### Fact

Only a dental professional corporation may provide dental services or employ a dentist to provide dental services in a DSO-supported clinic.

### Fiction

DSOs require dentists to meet certain production goals and tell them what treatments to perform.

### Fact

Indiana law prohibits a DSO from interfering with a dentist's clinical judgment or directing/controlling:

- The treatment of patients inside a dental office.
- The use of dental equipment or materials being used to provide dental services.
- A patient's course of treatment.
- The referral of patients.
- The clinical content of advertising.
- Final decisions relating to the employment of dental office clinical personnel.

### Fiction

DSOs should be required to register with the dental board so it can know who to hold accountable if another Allcare-type situation occurs in Indiana.

### Fact

The dental board already has the authority to require every dentist in Indiana to list the name and address of all non-dentists in their practice, as well as describe the capacity in which any such person is

assisting in the practice (e.g. scheduling appointments, billing and insurance, owning stock etc.) IC 25-14-1-17

The dental board could, under its existing authority, require every dentist affiliated with a DSO to disclose the name of the DSO and any other relevant information at the time the dentist renews his or her license.

### Fiction

The DSO model is new and there isn't anything similar operating in Indiana.

### **Fact**

DSOs have been operating in Indiana for almost 20 years.

The DSO model is practically identical to the Physician Practice Management ("PPM") model in which the PPM runs the day-to-day operations of the practice and physicians are solely responsible for the clinical aspects.

Blue and Company offers a PPM product to physicians in Indiana that includes, according to its web site, the following services:

- New practice startup
- Practice management
- Vendor negotiations
- Billing and collection services
- Annual reviews
- Human resource management

### Fiction

The ownership structure of DSOs is deceptive because it hides from state authorities the fact that all rights of ownership actually flow to the DSO through the management services contract. Therefore, the dentists are owners of the practice in name only.

### **Fact**

- The stock of the dental professional corporation is 100% owned by dentists, not the DSO.
- Like a home loan or car lease, the dental professional corporation retains full control of the dental assets so long as it meets its payment obligations.
- These business arrangements are commonplace (e.g. PPM) and restricting how licensed professionals choose to organize their business practices is unnecessary to protect consumers.
- According to the Federal Trade Commission, "Consumers benefit when health professionals can organize their practices in the way they find most efficient."

The DSO with which I have contracted for administrative support services enables me to provide better care by:

- Handling all non-clinical needs of my practice, including scheduling, billing and collections, payroll processing, supply procurement, marketing plans and IT support.
- Providing access to the capital funds necessary for me to offer a state-of-the-art facility with the latest technology.
- Providing group purchasing power that helps me lower patient costs.
- Providing continuing education and training for me and my staff that allows us to stay abreast of new protocols, equipment, training and techniques.
- Allowing me the scheduling flexibility to better manage my professional and personal life.

The DSO with which I have contracted for non-clinical administrative support services does not:

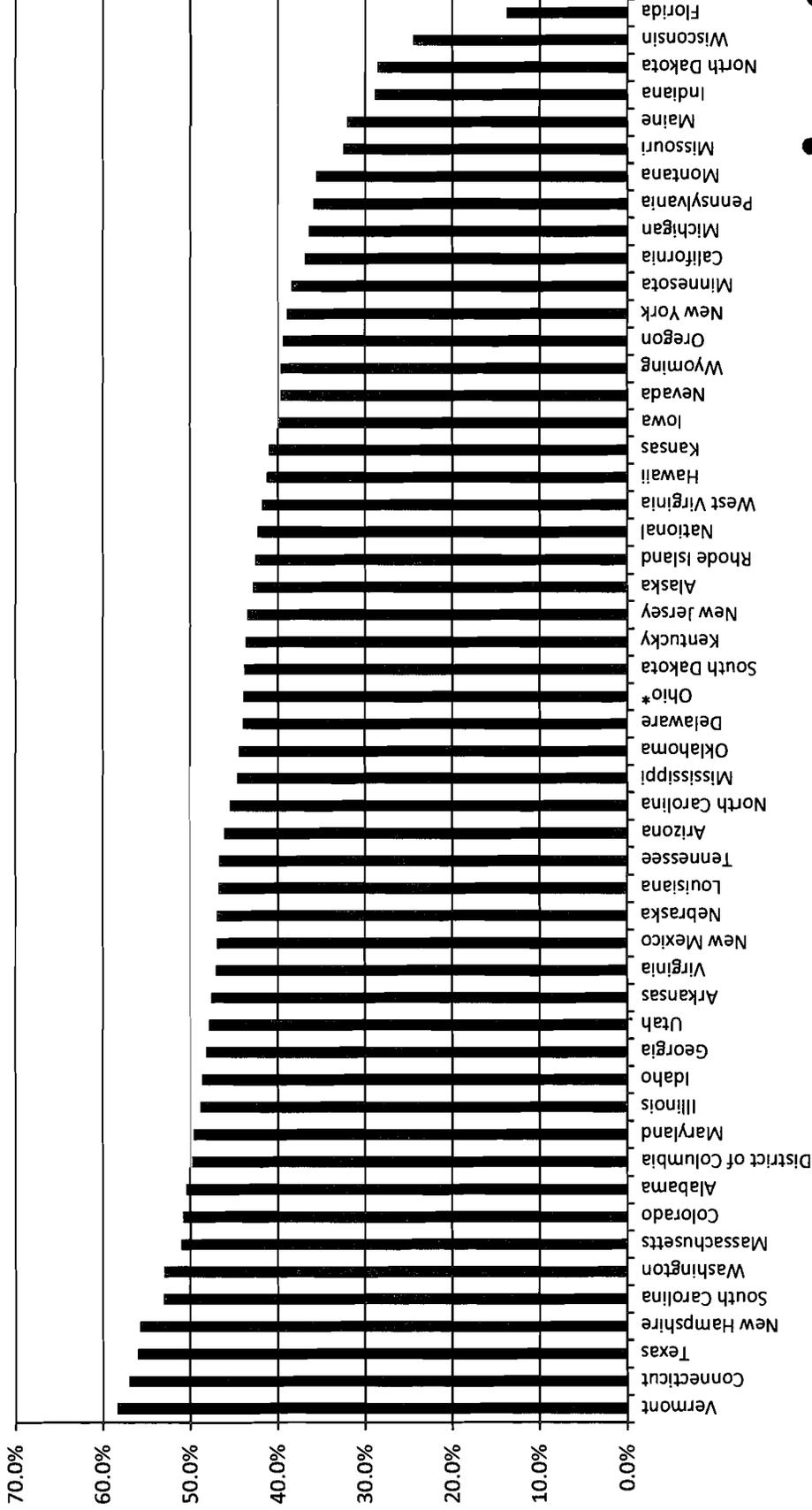
- Employ me to provide dental services.
- Interfere with my clinical judgment.
- Tell me when or how to use dental equipment or materials.
- Tell me what supplies to order.
- Direct or control my patients' course of treatment, referrals to other providers or the content of their records.
- Direct or control the clinical content of my advertising or final decisions related to the employment of non-administrative dental personnel.

Why the DSO model is good for Indiana patients and local communities

- DSOs help dentists expand access to dental care.
  - Most DSO supported dental offices treat a significant number of Medicaid patients, which is a patient population many dentists choose not to treat at all.
  - In 2012, DSOs in Indiana treated over 750,000 patients. More than 150,000 of those patients received Medicaid assistance.
  - According to the US Health Resources and Services Administration (HRSA), Indiana has 23 counties that qualify as Dental Health Professional Shortage Areas. There are DSO-affiliated practices in 15 of those counties and one within 40 miles of the other 8 counties.
  - Many dental practices supported by DSOs pass along their efficiencies in the form of lower patient fees, which increases access to care for all Indiana patients, not just those receiving Medicaid assistance.
- DSOs support the local economy.
  - There are 92 DSO-supported dental offices in Indiana that employ 930 dental care professionals, including 137 affiliated dentists.
- DSO-supported dental practices regularly give back to Indiana communities through charity care programs and free care days.



# Percentage of children, age 1-20, enrolled in Medicaid for at least 90 days who received any preventive dental service, FY2011 (12b)



Source: FY 2011 CMS-416 reports, Line 1b, 12b

Note: \*FY 2011 data for Ohio are not yet available so FY 2010 data was substituted. Estimates for OH are included in the National figure for FY 2011.



InsureKidsNow.gov



I am Dr. Don Helfert <sup>a</sup> ~~and I am~~ dentist in Avon, Indiana. I work in a single dentist practice and I serve the populations of Marion and Hendricks counties. I am a former adjunct professor of dentistry with the Oral Health Research Institute at the Indiana University School of Dentistry. I am also a veteran of the United States Army.

I want to thank you Senator Miller and the members of the committee for the opportunity to speak about the delivery of dental care in large corporate settings in Indiana.

In dental school we were taught ethical standards to use when making decisions about the treatment of our patients, and in the conduct of our own lives. Veracity – always tell the truth. Non-maleficence <sup>Reserve</sup> – first do no harm. Informed consent – ensure our patients know what we plan to do for them and get their consent before doing it. Beneficence – do good - and Justice. When we became dentists, we took an oath that centered around “...first, do no harm.”

With that in mind, I have been asked by the Indiana Dental Association to speak with you about my time



spent working with Heartland Dental. Specifically I have been asked to tell you if anyone at Heartland Dental ever unduly attempted to influence my practice of dentistry. The answer is yes, they did.

Second, I have been asked to answer the question ,‘who is in charge’ at Heartland Dental. I hope to do that before we finish.

On my first day at Heartland I was examining a patient. I saw a dark spot on her tooth which might have been a cavity. As dentists we don’t call a dark spot on a tooth a cavity unless it is also soft, and this spot was not. So I asked the assistant to record in the computer that there was a dark spot on the tooth and to ‘watch’ it. The assistant said, “Doctor, don’t you think we should put a filling in that tooth and make it white like the rest of the tooth?”

I was a little surprised, and I looked at her and said, “No.” and proceeded with my exam. The next tooth was much the same, so I asked the lady if she drank a lot of dark beverages like coffee, tea, or soft drinks, to which she replied, “Yes, lots”.



I asked the assistant to record the stain again, and the assistant said, “Doctor, don’t you think we should put fillings in those dark spots? They could be cavities.” The patient looked at the assistant, and then she looked at me. She appeared to be calculating in her mind which of us was correct.

I said to the assistant, “Go ahead and record what I tell you, and we will discuss it afterwards.” I then explained to the patient the reasons why I thought these marks were stains and not cavities, and explained we would watch them for changes.

I met with the assistant afterward and asked her what she had been doing. I told her that her words had a ‘canned’, formal feel, as if she had been coached to speak to me in a certain way. She apologized and said she had been instructed in her training at Heartland to encourage dentists to place fillings in all spots that were dark.

In another instance, I finished treating a child and took them to the front of the office to their father. The father said ‘hey doc, should I have all of my metal fillings removed and replaced with white fillings.’ My response



was that, since I had never examined him, I didn't know, but that I would be happy to take a look and see if his fillings were still good.

A person visiting from the corporate office said, "Doctor, isn't it true that there are always cracks in teeth under old metal fillings and that they should be replaced?" To this I replied that in dentistry there is no 'always', and each case is different.

The man then opened his mouth for me to look inside and what I saw were beautifully crafted metal fillings that turned out to be about a year old. They looked perfect. The man had no pain or other symptoms. I told him that without taking x-rays and examining him to be sure I still couldn't know, but that they looked nice and I suspected they would be ok.

The corporate person then said we should replace old metal fillings with new white tooth colored fillings because of the dangers of mercury.



I encouraged the man to make an appointment to let us take a look, excused myself and asked the corporate person to come to my office.

I printed for her a peer-reviewed research paper that showed metal fillings last on average 14 years, and white resin fillings last on average 7 years, and I told her that I think it is bad practice to remove good fillings unless there is a good reason. I also explained the FDA has determined that mercury in metal fillings cause no harm.

I asked her if she had any documentation to support the statements she had made to the patient, and she assured me the corporate office had told her this information, and that they had it on file there, and that when she got back to Illinois she would send me a copy. It has been over 2 years and I still haven't heard from her.

Every morning at Heartland dental there is a Morning Huddle. This is a meeting where they discuss each patient due that day, their treatment planned, and ANY REMAINING INSURANCE DOLLARS in their dental



insurance, with suggestions for treatment to ensure those dollars are used.

**I don't think its good for patients** to base our treatment choices on production amounts and remaining insurance. It's not good patient care.

Daily production statistics and amounts are shared with all offices. Not the number of teeth saved, not number of children who are no longer in pain – but dollars of production. There is a website where employees can go and talk about office successes so everyone can read. Most of the stories there were about meeting or exceeding financial production goals.

It was important for each office to meet their financial goals, and it was important not to be in the lowest 50% of producing offices in the region. If an office was in the bottom 50% of producers in the region, the staff had to drive to the corporate office in Illinois on Saturday mornings for meetings. I was told by people who had been that you were, quote, unquote, 'yelled at'.



To the second question, who is in charge at Heartland Dental?

This is a Reuters news article from November 5<sup>th</sup>, 2012 and it reads:

## Ontario Teachers (Pension Plan) acquires control of Heartland Dental

November 5<sup>th</sup>, 2012 - Reuters

Ontario Teachers' Pension Plan said on Monday it has agreed to take control of Heartland Dental Care Inc in a deal that values the U.S. dental practice management firm at about \$1.3 billion, according to a person familiar with the matter...

**To answer your question –**

**the Ontario Teachers' Pension Plan controls Heartland Dental.**

HOW DOES THIS IMPACT the CITIZENS<sup>of</sup> Indiana? HOW DOES IT IMPACT YOU and your children?



Ask yourself this question: Who do you want making dental treatment decisions for the children of Indiana?

Do you want it to be the dentists who live in and work in our communities? Who give to local charities and support their communities, and buy whatever the band kid in front of them is selling that day - because that's right thing to you do?

Or do you want it to be the pension fund manager of the Ontario Teachers' Pension Plan in Canada?

Thank you for your time.

Donald R. Helfert, DDS

[lalterdds@gmail.com](mailto:lalterdds@gmail.com)

317-446-7408

Ontario Teachers acquires control of Heartland Dental

November 5<sup>th</sup>, 2012 - Reuters

<http://www.reuters.com/article/2012/11/05/us-heartland-ontario-idUSBRE8A40SB20121105>



State/federal actions against dental service organizations/management companies:

*Aspen<sup>i</sup>:*

Aspen Dental Management, Inc. (ADMI) has 376 dental clinics located in 25 states. ADMI represents itself as a dental service corporation providing business support services to dental practices. It is wholly owned by ADMI Corp., who in turn is wholly owned by ADMI Holdings, L.P. The majority holders of ADMI Holdings, L.P. are the private equity firms Green Equity Investors V, L.P., Green Equity Investors Side V, L.P. and LGP Smile Coinvest LLC.

In January 2013, a class action suit was filed in United States District Court, Northern District of New York, against ADMI and its owners. One of the class plaintiffs is a resident of Indiana. The suit alleges that Aspen Dental clinics are "nominally 'owned' by sham-owner dentists" and that in fact ADMI maintains control over the dental clinics, including the delivery of patient care.

According to the suit, ADMI has complete control and responsibility for all accounting, finance, billing, collections, scheduling, advertising, marketing, technology support, customer service calls, denture production, payroll, equipment procurement, human resources, and hiring services for its local dental offices. All revenues and profits are channeled to ADMI.

ADMI reviews each local office's performance and sets performance metrics. ADMI trains all employees and stresses the importance of meeting production goals and revenue goals. Office managers are responsible for meeting these goals and are not required to have any background in dentistry. ADMI controls the hygiene treatment program, even adding treatments onto treatment plans automatically. ADMI requires that dentists follow the treatment plan, even if they did not do the initial exam. Bonuses are awarded for meeting production goals.

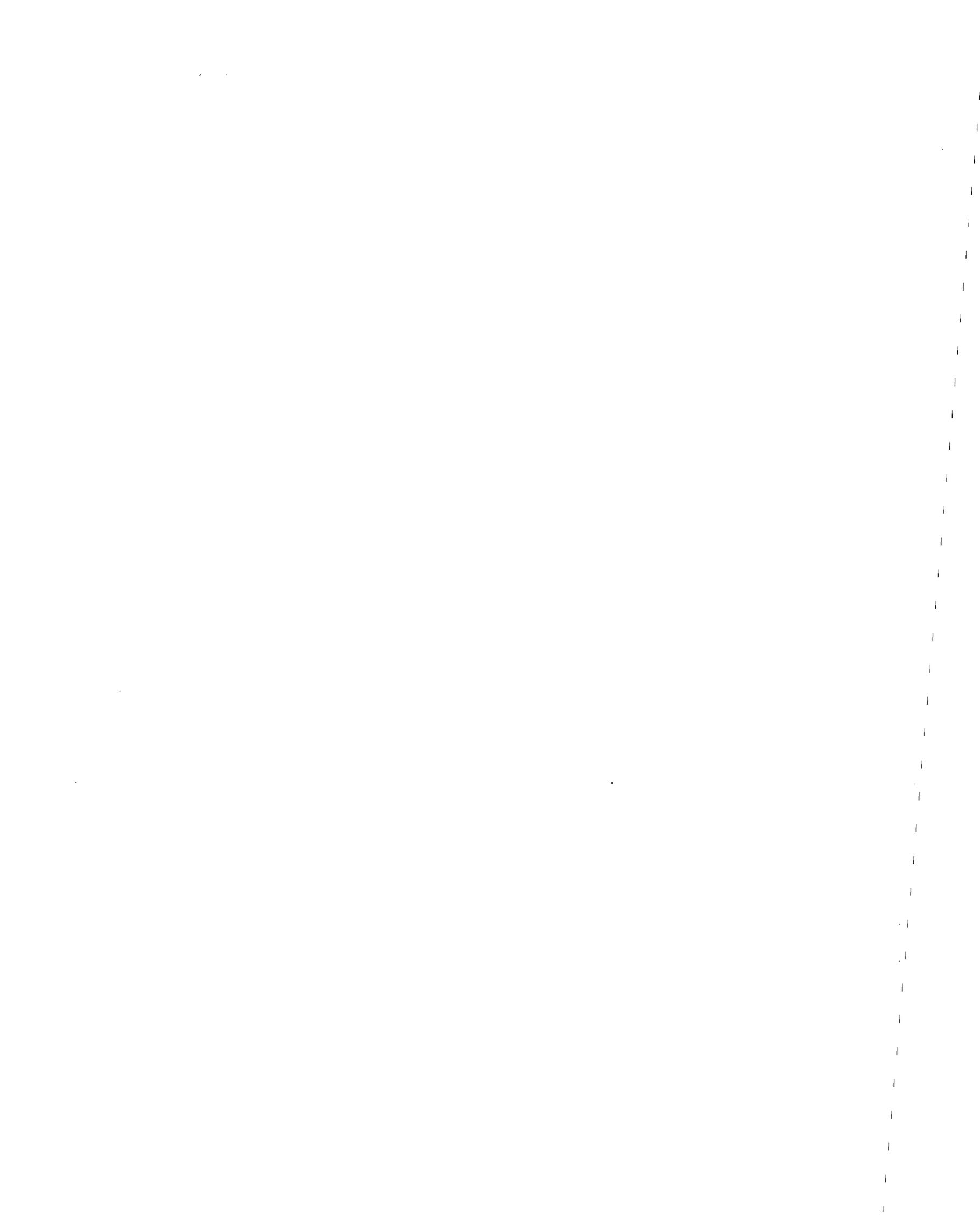
This suit is still pending.

In 2010, Aspen settled with the Pennsylvania Attorney General for \$175,000, after Aspen was accused of engaging in deceptive sales practices.<sup>ii</sup>

*Small Smiles:*

Small Smiles was purchased in 2006 by private equity investors, including the Carlyle Group, Arcapita Corporate Investments, and American Capital for \$470 million. Small Smiles is operated by Church Street Health Management, which filed for bankruptcy in 2012. In 2012, Small Smiles operated in 22 states and Washington, D.C.<sup>iii</sup>

In January 2010, 22 states joined Maryland's Attorney General and the federal government to settle allegations against FORBA Holdings, LLC, a dental management company that provided management services to Small Smiles. Three whistleblower lawsuits were filed in Maryland, Virginia and South Carolina. FORBA agreed to pay \$24 million, plus interest, in the settlement. Small Smiles was accused of submitting fraudulent claims to state Medicaid programs for providing unnecessary dental services to children. These services included performing pulpotomies (baby root canals), extractions, placing crowns, administering anesthesia, providing fillings/sealants, and using inappropriate methods to restrain child patients. FORBA also agreed to enter into a five-year "corporate integrity agreement" with



the Office of Inspector General of the Department of Health and Human Services, including review by external monitors.<sup>iv</sup>

Small Smiles is currently defending a suit in New York from three minor patients who allege that Small Smiles used inappropriate restraints and performed unnecessary root canals, crowns, and other treatments in order to increase profits. The suit alleges that FORBA exercised control over the clinical decision making in Small Smiles facilities, and created policies which put patients at risk.<sup>v</sup>

#### *All Smiles Dental Center:*

All Smiles is a chain of 51 dental clinics in Texas. All Smiles was purchased in 2009 by the private equity firm Valor Equity Partners. In 2010, an auditor for the Texas Office of Inspector General filed a complaint with the Texas State Board of Dental Examiners alleging that All Smiles was facilitating the unlicensed practice of dentistry and engaged in Medicaid fraud. The Board dismissed the complaint citing a lack of jurisdiction over management companies. All Smiles filed for bankruptcy in May 2012.<sup>vi</sup>

In March 2012, All Smiles settled allegations with the federal government and the Texas Attorney General. All Smiles was alleged to have submitted claims to Medicaid for orthodontic services that were not provided, improperly billed, or not properly documented. All Smiles agreed to pay \$1.2 million to the United States and Texas. All Smiles was also required to enter into a "corporate integrity agreement" with the Office of the Inspector General of the Department of Health and Human Services.<sup>vii</sup>

#### *DentalWorks:*

DentalWorks, the trade name for DentalOne Partners, Inc., is a dental company operating in 14 states. MSD Capital, L.P. owns a controlling interest. In February 2013, the North Carolina State Board of Dental Examiners filed a suit against DentalWorks alleging that it improperly influenced clinical policies and pressured dentists to make inappropriate diagnoses in order to bill for unnecessary treatment. DentalWorks is also accused of keeping two sets of records, one which it showed to the Board, claiming that it only provided management services, and the other, which shows that DentalWorks owns and operates the clinics, including interference with clinical decision making. North Carolina prohibits corporations from owning dental practices.<sup>viii</sup>

North Carolina requires that management arrangements, which include services to assist in development, promotion, delivery, financing, support or administration of the dentist or dentist's practice, be reviewed by the North Carolina State Board of Dental Examiners to ensure that the management company is not effectively controlling or operating the dental practice.<sup>x</sup>

Additionally, 14 dentists filed suit against DentalWorks claiming that the company exercised "excessive control over the practices' finances . . . and interfered with decisions regarding patient care." The lawsuit states that in 2003, DentalWorks started allowing dentists to buy into limited liability corporations which managed dental practices. The suit alleges these companies were just a shell, whose purpose was to pass funds through to DentalWorks and shield DentalWorks from liability. Furthermore, the suit alleged that dental hygienists received financial incentives based on how often they recommended Arestin, a drug product used to treat gum disease. Incentives were also provided for the placement of veneers and ceramic crowns.<sup>xix</sup>



*Kool Smiles<sup>xiii</sup>:*

Kool Smiles is an Atlanta based dental chain, and the largest Medicaid dental provider with 129 offices in 15 states and Washington, D.C., including Indiana. Kool Smiles is owned by the private equity firm Friedman Fleischer & Lowe. Kool Smiles also has NCDR LLC which hires dentists, opens locations, owns the offices and equipment, and manages employees.

Connecticut's Medicaid dental director noted that there was a spike in children receiving stainless-steel crowns to treat cavities, instead of fillings, after Kool Smiles opened offices in Connecticut. Stainless-steel crowns received twice the reimbursement than fillings. The use of these crowns is controversial in the treatment of small cavities. Connecticut started requiring pre-approval for their placement and noted that these crowns were being recommended without a justifiable need.

According to at least one source, Kool Smiles sets production goals for its dentists, and provides bonuses to those who exceed them, and terminates the employment of those who do not. NCDR LLC distributes "office scorecards" daily showing revenue and monthly/daily rankings.

As of June 2012, Kool Smiles was also under investigation for performing unnecessary procedures in Massachusetts, Georgia and Texas.

In Georgia, two Medicaid networks excluded Kool Smiles after an audit found that Kool Smiles patients were three times more likely to be physically restrained and five times more likely to get stainless steel crowns. A 2007 audit by the Georgia Department of Community Health found that 427 children, out of 6,600, received either unnecessary treatment or substandard care. A 2009 audit resulted in Kool Smiles repaying Georgia \$40,000 for unnecessary treatments.

A 2009 audit by the Massachusetts state auditor found that three Kool Smiles offices overbilled Medicaid by \$1.2 million.

*Heartland<sup>xiv</sup>:*

Heartland Dental Care, Inc. is a Delaware corporation headquartered in Effingham, Illinois. In September 2011, the North Carolina State Board of Dental Examiners filed a Complaint for Permanent Injunction seeking to enjoin Heartland from engaging in the unlicensed practice of dentistry.

Under North Carolina law, proposed management agreements must be submitted to the Board for review and approval. The Board found that the proposed management agreement Heartland submitted constituted the unlawful transfer of "ownership, management, supervision, conduct, and control of a dental practice" to an unlicensed entity.

The proposed management agreement included:

1. A "Letter of Intent to Acquire Certain Assets" whereby Heartland agreed to purchase the dentist's practice.
2. A "Management Agreement" between Heartland and the PC, which was specifically formed for the purpose of this transaction.
3. An "Irrevocable Power of Attorney" in which the PC assigned powers to Heartland as attorney-in-fact.
4. An "Employee Lease" between Heartland and the PC.



5. Employment agreements between the dentist and Heartland, and the dentist and the PC, both of which had a non-compete provision.
6. Transfer of "dental rights" to the PC and Heartland.
7. A requirement that the PC pledge its assets to secure debts Heartland owed to lenders.
8. Salaries were paid by both Heartland and the PC to the dentist.
9. The PC was required to lease employees from Heartland; give Heartland control or authority to approve the terms of the relationship between the PC and the dentist and employees; give Heartland the right to collect account receivables for dental services; and, surrender all equipment and realty to Heartland upon termination of the management agreement.

Subsequently, Heartland entered into an agreed order with the North Carolina Board. Heartland agreed to rescind its agreements with the dentist and the PC, and to not enter into any management agreements with North Carolina dentists for five years.

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<sup>i</sup> Carol Treiber, et al v. ADMI, et al. United States District Court, Northern District of New York

<sup>ii</sup> "Patients, Pressure and Profits at Aspen Dental," by David Heath and Jill Rosenbaum for Frontline and the Center for Public Integrity, June 26, 2012

<sup>iii</sup> "Private Equity Firms Eye Big Profits in Dentistry," by Donna Domino, May 30, 2012 for *Dr.Bicuspid.com*.

<sup>iv</sup> "Dental Management Company Pays \$24 Million to Resolve Fraud Allegations," Maryland Attorney General, January 21, 2010.

<sup>v</sup> In re Small Smiles Litigation, State of New York

<sup>vi</sup> "Private Equity Firms Eye Big Profits in Dentistry," by Donna Domino, May 30, 2012 for *Dr.Bicuspid.com*.

<sup>vii</sup> "Settlement Agreement" executed by the United States, Texas Attorney General, and All Smiles.

<sup>viii</sup> "DentalWorks Chain Misdiagnosed for Money, Dentists Say," by Sarah Childress, for *Frontline*, PBS, March 13, 2013.

<sup>ix</sup> North Carolina State Board of Dental Examiners v. DentalCare Partners, Inc. et al

<sup>x</sup> N.C. Gen. Stat. § 90-29(b)(11) and 21 NCAC 16X.0101.

<sup>xi</sup> "DentalWorks Chain Misdiagnosed for Money, Dentists Say," by Sarah Childress, for *Frontline*, PBS, March 13, 2013.

<sup>xii</sup> Dr. Hughes Aguero & Associates, et al v. DentalCare Partners, Inc. et al

<sup>xiii</sup> "Complaints about Kids Care Follow Kool Smiles," by David Heath and Jill Rosenbaum for Frontline and the Center for Public Integrity, June 26, 2012

<sup>xiv</sup> North Carolina State Board of Dental Examiners v. Heartland Dental Care, Inc. et al



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1st Session }

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**JOINT STAFF REPORT ON  
THE CORPORATE PRACTICE OF DENTISTRY  
IN THE MEDICAID PROGRAM**

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PREPARED BY THE STAFF OF THE

COMMITTEE ON FINANCE  
UNITED STATES SENATE

MAX BAUCUS, *Chairman*

AND

COMMITTEE ON THE JUDICIARY  
UNITED STATES SENATE

CHUCK GRASSLEY, *Ranking Member*



JUNE 2013

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## I. Preface

The United States Senate Committee on Finance has jurisdiction over the Medicare and Medicaid programs. As the Chairman and a senior member and former Chairman of the Committee, we have a responsibility to the more than 100 million Americans who receive health care coverage under these programs to oversee their proper administration and ensure the taxpayer dollars are appropriately spent. This report describes the investigative work, findings, and recommendations of the Minority Staff of the Senate Committee on the Judiciary and the Majority Staff of the Senate Committee on Finance regarding the corporate practice of dentistry in the Medicaid program. The issues are analyzed primarily in the context of one company, Small Smiles. We received whistleblower complaints about the company, it has been the subject of a False Claims Act lawsuit, and it has been under a corporate integrity agreement with independent monitoring by the Department of Health and Human Services Office of Inspector General since January 2010. In addition, we briefly examined complaints received regarding ReachOut Healthcare America (ReachOut).

At the outset of this investigation, Church Street Health Management (CSHM), the parent company of Small Smiles, cooperated with Committee staff until it emerged from bankruptcy. After emerging from bankruptcy and hiring new counsel, CSHM ceased cooperating. Under the old ownership, Committee staff was able to obtain reports by the Independent Monitor, a private, independent oversight entity whose services were mandated as part of CSHM's settlement agreement with the U.S. Department of Justice (DOJ). However, the new owners and counsel refused to give Committee staff access to on-going reports from the Independent Monitor. ReachOut cooperated with the Committees' investigation. More than 10,000 pages of documents were obtained from CSHM, ReachOut, whistleblowers, and Federal entities. The Committee staff conducted six meetings with Small Smiles, six meetings with the U.S. Department of Health and Human Services Office of Inspector General, one site visit, and various stakeholder meetings throughout the course of the investigation. Likewise, the Committee staff met with ReachOut three times in addition to meeting with various stakeholders.

## II. Executive Summary

Across the country, there are companies that identify themselves as dental management companies. These organizations are typically organized as a corporation or limited liability company. They work with dentists in multiple states and purport to provide general administrative management services. In late 2011, whistleblowers and other concerned citizens came forward with information that some of these companies were doing more than providing



management services. In some cases, dental management companies own the dental clinics and have complete control over operations, including the provision of clinical care by clinic dentists.

While there is no Federal requirement that licensed dentists, rather than corporations, own and operate dental practices, many states have laws that ban the corporate practice of dentistry. In those states where owners of dental practices must be dentists licensed in that state, the ownership structure used by some dental management companies is fundamentally deceptive. It hides from state authorities the fact that all rights and benefits of ownership actually flow to a corporation through contracts between the company and the "owner dentist." These contracts render the "owner dentist" an owner in name only.

Notably, these clinics tend to focus on low-income children eligible for Medicaid. However, these clinics have been cited for conducting unnecessary treatments and in some cases causing serious trauma to young patients; profits are being placed ahead of patient care.

In one case, the corporate structure of a dental management company appears to have negatively influenced treatment decisions by over-emphasizing bottom-line financial considerations at the expense of providing appropriate high-quality, low-cost care. As a consequence, children on Medicaid are ill-served and taxpayer funds are wasted.

Our investigation into these allegations began by examining five corporate dental chains which were alleged to be engaged in these practices:

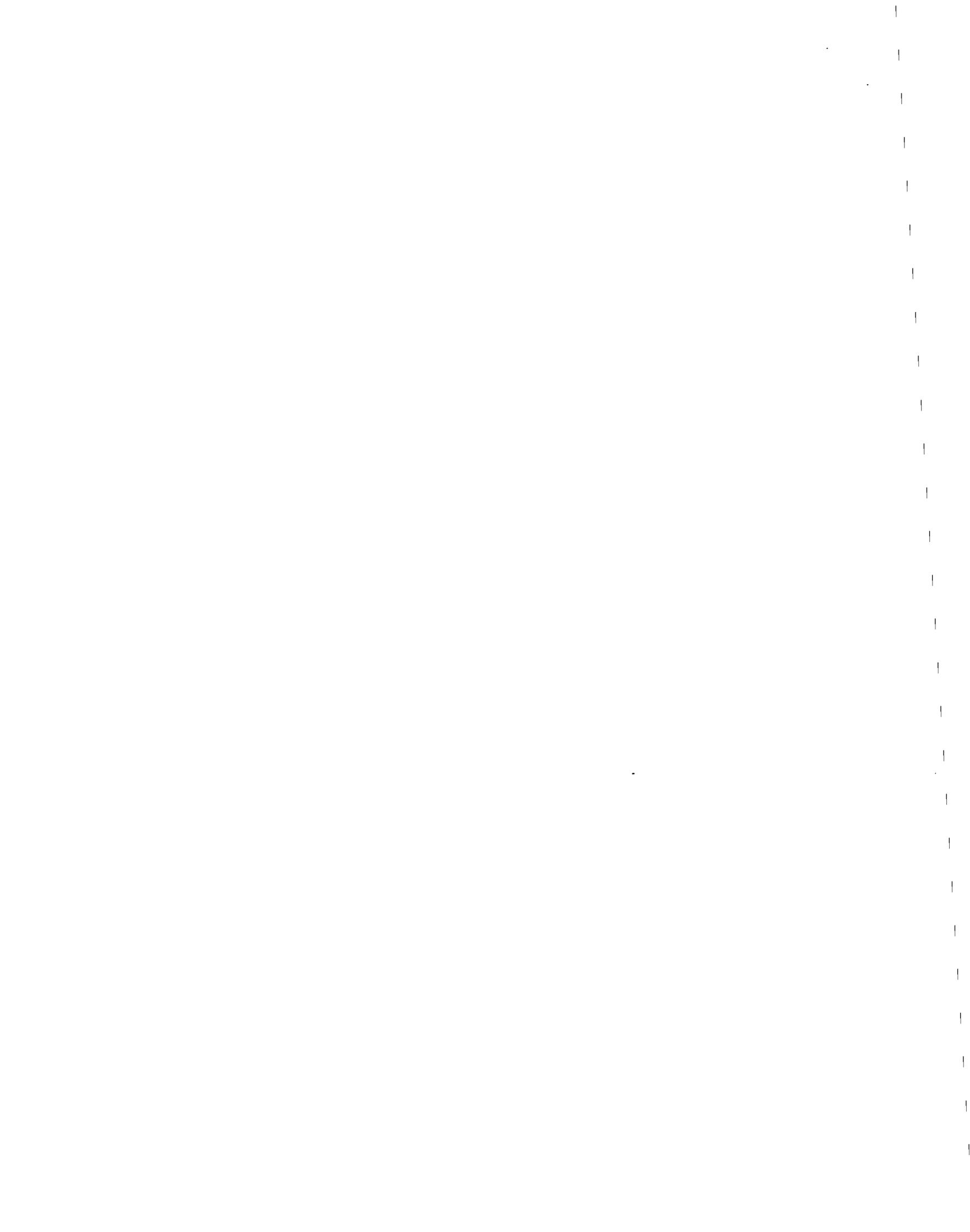
- Church Street Health Management (CSHM), which at the time owned 70 Small Smiles dental clinics in 22 states and the District of Columbia;
- NCDR, LLC, which owns 130 Kool Smiles clinics in 15 states and the District of Columbia;
- ReachOut Healthcare America (ReachOut) which operates mobile clinics that treat children at schools in several states;
- Heartland Dental Care, Inc. (Heartland), which operates more than 300 clinics in 18 states; and
- Aspen Dental Management, Inc., (Aspen) which operates more than 300 Aspen Dental clinics in 22 states.

While we initially looked broadly at all five companies, the focus shifted primarily to CSHM and ReachOut, due to similarities between the patient populations of these two companies. Both treat Medicaid-eligible children almost exclusively and therefore are reimbursed using taxpayer dollars.

#### **A. CSHM**

CSHM has management services agreements with dental clinics which extend far beyond providing typical management services. Through its agreements, CSHM assumes significant control over the practice of dentistry in Small Smiles clinics and is empowered to take substantially all of a clinic's profits.

CSHM has management services agreements with "owner dentists" who typically work at one of the Small Smiles clinics and also "own" several clinics nearby. These "owner dentists" are paid a sal-



that the two pulpotomies (root canals) and two silver crowns administered were both unnecessary, and in the case of the former, performed incorrectly.<sup>8</sup>

Another troubling case occurred in December 2011. Nevada's Clark County School District, with a student population of almost 400,000, severed contractual ties with ReachOut after receiving complaints from parents who alleged ReachOut did not give proper notification before proceeding with serious procedures such as fillings and crowns.<sup>9</sup> According to Amanda Fulkerson, spokesperson for the Clark County School District, "They [ReachOut] were going well beyond what we consider preventive care."<sup>10</sup>

The allegations against ReachOut that its dental practices were abusing children and billing Medicaid for unnecessary procedures were serious and disturbing, but we found that those practices were not necessarily widespread. Unlike CSHM, ReachOut's management services agreements truly provide only administrative and scheduling support, and do not constitute *de facto* ownership and control of its mobile dental clinics.<sup>11</sup>

In its Administrative Agreements with dentists, ReachOut uses language similar to the following example, which ensures that the sole authority to practice dentistry remains with the licensed dentist:

*Sole Authority to Practice.* Notwithstanding any other provision of this Agreement, Provider shall have exclusive authority and control over the healthcare aspects of Provider and its practice to the extent they constitute the practice of a licensed profession, including all diagnosis, treatment and ethical determinations with respect to patients which are required by law to be decided by a licensed professional.<sup>12</sup>

ReachOut maintains administrative services agreements with local dentists, or principal shareholders (PCs), who largely provide mobile services to schools, but also the military and in some states, nursing homes.<sup>13</sup> At the time of this report, ReachOut has contracts with 23 dental practices in 22 states. The contracts between ReachOut and dental practices relate only to nonclinical aspects.<sup>14</sup> ReachOut is paid set fees by the dentists for facilitating the mobile dentistry services. These services include providing equipment and supplies, maintaining inventory, and providing information systems, financial planning, scheduling, reporting, analysis, and customer service.<sup>15</sup>

<sup>8</sup> See *id.*

<sup>9</sup> See Ken Alltucker, *Mobile dental clinics drawing scrutiny*, AZCentral.com (Aug. 18, 2012) <http://www.azcentral.com/business/articles/20120810mobile-dental-clinics-scrutiny.html>.

<sup>10</sup> *Id.*

<sup>11</sup> See, e.g., Administrative Agreement between ReachOut and [REDACTED] DDS, PC (July 2, 2006) (bates RHA 0000007-0000021) (Exhibit 32).

<sup>12</sup> Administrative Agreement between ReachOut and [REDACTED], DDS at 9 (Apr. 23, 2009) (bates RHA 0000030) (Exhibit 33). Small Smiles has what is arguably similar language to that found in ReachOut's administrative agreement. However, ReachOut's language appears to be focused more on limiting its liability. Moreover, our investigation found that Small Smiles' contractual language is at odds with actual practice. See report Section IV(a); see Management Services Agreement, Small Smiles Dentistry for Children, Albuquerque, PC and FORBA, LLC at 2 (Oct. 1, 2010) (Exhibit 6).

<sup>13</sup> See Administrative Agreement between ReachOut and Big Smiles Colorado at 2-3 (July 1, 2009) (bates RHA 0000051-0000065) (Exhibit 34).

<sup>14</sup> See Letter from Reginald Brown, Attorney at WilmerHale, to Senators Baucus and Grassley at 2 (Feb. 23, 2012) (Exhibit 31).

<sup>15</sup> See *id.*



The basic plan behind the Administrative Agreement between ReachOut and the mobile dentists is “to provide *administrative and financial services* as set forth herein, so that the PC can focus on *furnishing high-quality dental care* directly and through third-party dentists to needy, primarily low-income, children in schools and out-of-home placement agencies needing mobile dentistry through the services of the PC’s dentist(s).”<sup>16</sup> The compensation for ReachOut is divided into two categories: direct expenses and administrative services. Administrative services are billed at a fee of \$500 per visit for all services provided.<sup>17</sup> Direct expenses are billed at the actual cost plus 15% of the entire professional corporation (PC)’s employee salaries and expenses paid from the PC’s account.<sup>18</sup>

Before children can receive treatment during school hours, they must obtain parental approval. ReachOut America maintains that all offered services must be pre-approved by the child’s parents or legal guardians. Verification of the legal guardianship of the child is the responsibility of the school. However, per contractual agreement, ReachOut facilitates the delivery of the Provider consent forms and coordinates the completion of the consent forms:

- Arrange for the delivery of the Provider consent forms to the proper school employee in each school for each student to take home.
- Coordinate that each school obtains completed consent forms by the students and that they are provided to the Administrator [ReachOut].<sup>19</sup>

In ReachOut’s case, the reported problems of unnecessary procedures, lack of parental consent, and patient abuse appear to be the result of ReachOut having management agreements with several unscrupulous dentists. Given the administrative nature of their arrangement, ReachOut lacks ability to police such bad actors. As of last year, the company had no standards for dentists with whom they contract to obtain parental consent for treatment—leaving each mobile clinic to devise its own forms and procedures. While these factors appear to have contributed to many of the problems reported to us involving the company, it is also evidence that ReachOut does not significantly control the operations of clinic dentists, and simply contracts with dentists to provide support services.

<sup>16</sup> Administrative Agreement between ReachOut and [REDACTED] DDS, PC at 1 (July 2, 2006) (bates RHA 0000007–0000021) (emphasis added) (Exhibit 32).

<sup>17</sup> See *id.* at 9.

<sup>18</sup> See *id.*

<sup>19</sup> Administrative Agreement between ReachOut and [REDACTED] D.D.S., Big Smiles Maryland PC, at 5 (Apr. 1, 2009) (bates RHA 0000246) (Exhibit 35).



### III. Key Findings

1. Through management services agreements with dentists, CSHM is the *de facto* owner of all Small Smiles clinics. It retains all the rights of ownership, employs all staff, recruits all staff, makes all personnel decisions, and receives all income from each Small Smiles clinic.

2. CSHM entered into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) as part of the company's settlement with the U.S. Department of Justice (DOJ). As part of the agreement, an Independent Monitor (IM) conducts extensive audits of CSHM's clinics. During the last 3 years, the IM has found massive amounts of taxpayer dollars being recklessly spent on unnecessary procedures on children in the Medicaid program by Small Smiles clinics.

3. After 2 years of intense scrutiny by HHS OIG through the CIA, and attempting to follow newly prescribed rules, CSHM went bankrupt.

4. After 3 years of monitoring by the HHS OIG and emerging from bankruptcy with new ownership and leadership changes, CSHM has repeatedly failed to meet quality and compliance standards set forth in the CIA with HHS OIG. Breaches in quality and compliance include: (1) unnecessary treatment on children; (2) improper administration of anesthesia; (3) providing care without proper consent; and (4) overcharging the Medicaid program.

5. Despite CSHM's repeated violations of the CIA, resulting in both monetary fines and an HHS OIG-issued Notice of Intent to Exclude the company from Medicaid, HHS OIG has allowed Small Smiles to continue to participate in the program.

6. Despite state laws against the corporate practice of dentistry, numerous states have allowed companies such as CSHM to operate dental clinics under the guise of management services agreements. These practices appear contrary to the purpose of state law requiring clinics to be owned and operated by licensed dentists. The result is poor quality of care, billing Medicaid for unnecessary treatment, and disturbing consumer complaints.

7. Access to dental care is a problem in certain parts of the country, particularly rural areas for the dual reasons of fewer employment opportunities and lower reimbursement rates than urban counterparts. It is also a problem for some patients served by the Medicaid program due to the number of dentists who are unwilling to accept patients on Medicaid. Access is complicated by the burden of extremely high student loans of dentists graduating from dental school that makes serving rural or Medicaid populations problematic.



**OWNERSHIP OF DENTAL PRACTICES  
EMPLOYMENT OF DENTISTS  
INTERFERENCE WITH THE PROFESSIONAL JUDGMENT OF A DENTIST**

There has been a growth of dental management companies in the country and an expanding list of administrative services they offer to provide dentists. These companies enter into management agreements (contracts) with dentists that define a relationship. State dental boards are finding it challenging to understand and be definitive as to what provisions of these agreements and activities of these companies result in managing, controlling and perhaps interfering with a dental practice to the point of essentially owning the practice.

States regulate who can own and operate a dental practice, what entities may employ a dentist, and what level of control non-dentist owners and managers may have over a dental practice. An area of particular concern to practicing dentists is the succession of ownership in the event of the death or disability of the dentist. Several states have addressed this concern with laws allowing the surviving spouse or legal representative of the dentist's estate to continue ownership of the dental practice for a time in order to sell or liquidate the practice.

This summary classifies states into broad categories depending on the type of regulation related to several aspects of the ownership of dental practices. There may also be dental board policies, court rulings, or attorney general opinions that impact how a particular state interprets and regulates in these areas. For specific details on a particular state please contact the state dental board.

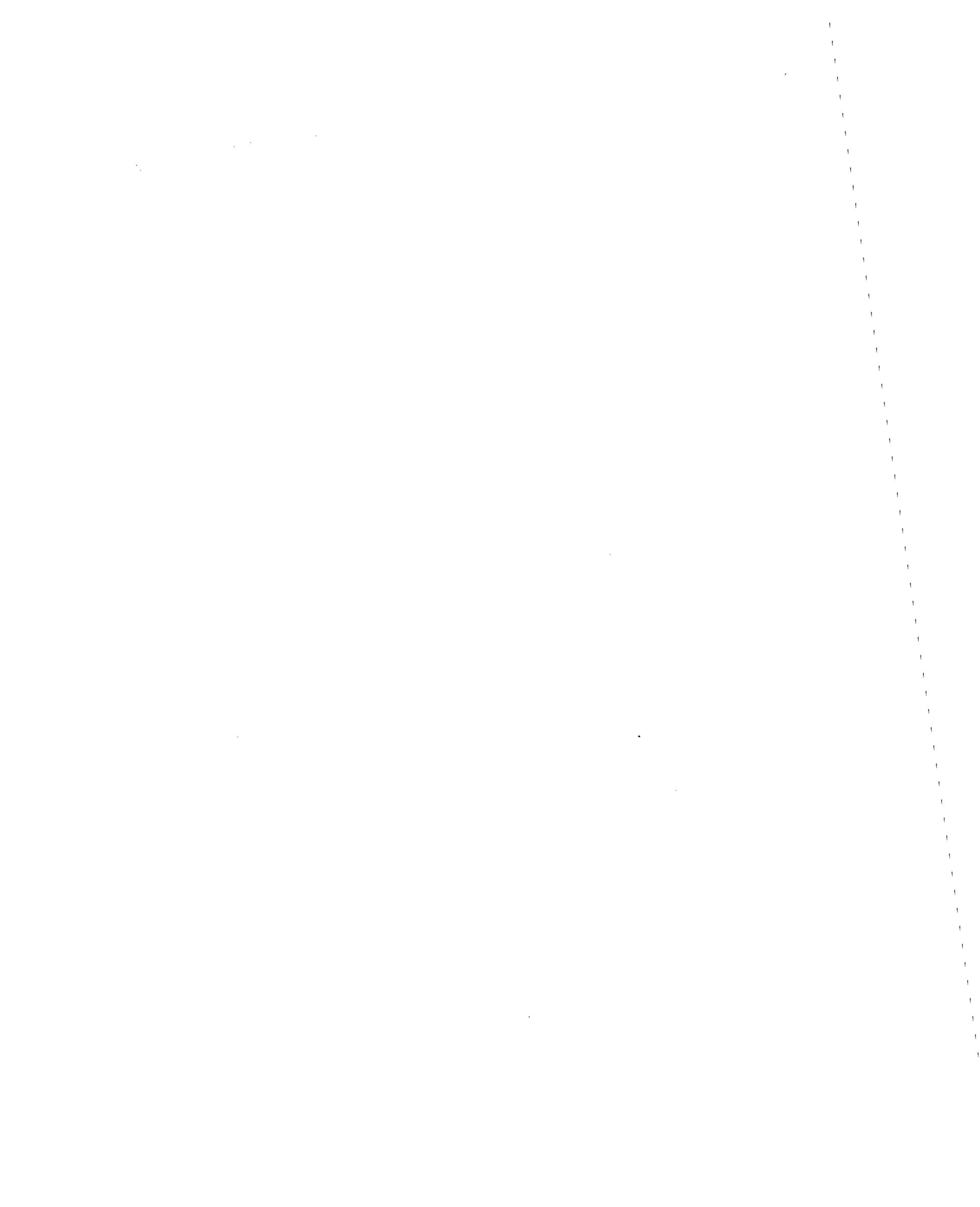
ADA policy <http://www.ada.org/currentpolicies.aspx>  
Ownership of Dental Practices (2000:462)

Resolved, that the Association supports the conviction long held by society that the health interests of patients are best protected when dental practices and other private facilities for the delivery of dental care are owned and controlled by a dentist licensed in the jurisdiction where the practice is located, and be it further

Resolved, that, in the case of a deceased or incapacitated dentist, in order to protect the interests and the oral health of the patients in that practice, the dentist's non-dentist surviving spouse, heir(s), or legal representative(s), as appropriate, should be allowed to maintain ownership of the dental practice for two years to allow for continuity of care during the orderly transition to a new owner

**Ownership defined as dentistry**

An examination of the dental practice laws and regulations reveal that, as a general rule, states attempt to restrict non-dentist interference or ownership by making the act of owning (managing, operating, leasing, etc.) a dental practice, a defining element of practicing dentistry.



The District of Columbia and twenty-five (25) states define the ownership of a dental practice as an element of practicing dentistry.

<b>Alabama</b>	<b>Minnesota</b>	<b>Oklahoma</b>
<b>California</b>	<b>Missouri</b>	<b>Rhode Island</b>
<b>Colorado</b>	<b>Montana</b>	<b>South Dakota</b>
<b>Connecticut</b>	<b>Nebraska</b>	<b>Tennessee</b>
<b>Delaware</b>	<b>New Hampshire</b>	<b>Utah</b>
<b>Hawaii</b>	<b>New Jersey</b>	<b>Vermont</b>
<b>Illinois</b>	<b>North Carolina</b>	<b>Washington</b>
<b>Maine</b>	<b>Ohio</b>	<b>Wyoming</b>
<b>Maryland</b>		

#### **Non-dentist operation of a dental practice prohibited**

Four (4) states, **Massachusetts, New York, North Carolina,** and **Vermont** prohibit non-dentists from operating dental practices. The New York State Dental Association reports that the statutory exceptions to this provision and the enforcement policies of the attorney general have eroded the law's effectiveness.

#### **Uncertain Status**

Four (4) states, **Iowa, Louisiana, Michigan,** and **Pennsylvania**<sup>6f</sup> either have no laws addressing the issues of ownership and control, or have provisions that provide no guidance on how to classify those states within this summary. For example, **Louisiana** has a provision preventing dentists from sharing fees with non-dentists.

#### **Non-dentists Participation in Ownership of Private Practices**

Twelve (12) states, **Arizona, California, Colorado, Indiana**<sup>2f</sup>, **Kentucky, Maine, Minnesota, Nevada, New Mexico, North Dakota, Washington**<sup>1f</sup> and **Wisconsin**, allow person or legal entity not licensed as a dentist in the state to participate in the ownership of a private dental practice. **California-2003** law allows physicians, surgeons, hygienists, and assistants to own up to 49% of a practice.

**Colorado** - The CDA reports that the dental practice act is preempted by a law allowing nondentist ownership if the dental practice is part of a provider network. **Kentucky's** Board of Dentistry interprets the Dental Practice Act as permitting a non-dentist to own a dental practice. **Maine** allows denturists to hold a non-controlling stockholder interest in an incorporated dental practice. **Minnesota** allows health care professionals to form a corporation for the provision of multidisciplinary services. **North Dakota** permits non-dentists to own and control up to 49% of a private, as opposed to non-profit, dental practice. **Wisconsin**, however, does prohibit interference with the professional judgment of a dentist per WDA.

#### **Exceptions to Ownership / Operation Restrictions upon Dentist's Death or Disability**

The District of Columbia and twenty-eight (28) states, **Alabama, Alaska, Arizona, California, Colorado, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Maine, Missouri, Montana, Massachusetts, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island**<sup>5f</sup>, **Tennessee, Texas,** and **Vermont** permit the estate or spouse of a deceased or incapacitated dentist to own or operate a dental practice, or to employ a dentist for a specified, limited period of time. **Montana**, for example, limits the period of such



ownership to 12 months, **Ohio** limits it to 90 days, **Kansas** limits it to 18 months with extensions in 6 month increments if needed up to an additional year. **New Mexico** allows spouses or hygienists to own the dental practice for up to a year after the death of the dentist.

### **Enforcement of Ownership Restrictions**

Despite statutory or regulatory restrictions on ownership, there is little case law to provide guidance on the subject. In some states, there is a lack of enforcement, for a variety of reasons; in other states, the restrictions are interpreted differently. The **Ohio** Attorney General issued an opinion stating that Ohio law does not prohibit a non-dentist from furnishing certain business and management services in operating a dental practice. The **Maryland** Attorney General concluded that a non-dentist is prohibited from owning or operating a dental practice, but that some forms of business arrangements may be permissible.

Many states also have restrictions on the use of trade names, such as "Smiling Dentistry," for a dental practice. They require the name of individual dentist(s) to appear prominently in the name of the practice. The effect of the trade-name regulation is to prevent public deception as to the identity of the responsible owner.

### **Non-dentists Ownership of Dental Facilities & Employment of Dentists**

In an effort to increase access to dental care, there has been a trend in recent years to allow facilities, other than dental schools or governmental entities, to own and operate dental practices and employ dentists. The most common types of these facilities are federally qualified health centers and nonprofit corporations that provide dental care to underserved populations. The District of Columbia and twenty (20) states, **Alabama, Alaska, California, Colorado, Connecticut, Florida, Kansas, Louisiana, Maine, Missouri, Montana, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, South Carolina, South Dakota<sup>3/</sup>, Texas, and Washington<sup>1/</sup>**, allow dentists to be employed by non-profit health facilities owned and operated by non-dentists. The **Alabama, Florida, New Mexico** and **Texas** Boards of Dentistry have authority to approve or disapprove entities that employ dentists. These entities must register with the dental board and, in **Missouri**, are expressly subject to the same disciplinary rules as dentists.

Seven (7) states, **Connecticut, Hawaii, Illinois, Kansas, Maine, Virginia**, and **Washington**, allow dentists to be employed by employers who provide health care services for employees at work. **Alaska** and **Oregon** allows labor organizations to own and operate dental practices to treat its members.

In one (1) state, **Colorado**, dental hygienists who own and operate dental hygiene practices may rent equipment and office space in the same facility to dentists<sup>4/</sup>.

**Georgia** law expressly provides that working as an employee of anyone or entity that is not owned by a licensed dentist is cause for disciplinary action.

### **Interference with the Professional Judgment of a Dentist**

Twenty-two (22) states, **Alaska, Arizona, Arkansas, California, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, North Carolina, Oklahoma, Rhode Island, South Carolina, Texas, and Utah**, prohibit non-dentists from interfering with the professional judgment of a dentist.



**Florida** expressly regulates the relationship between dentists and dental managed services organizations. The **Mississippi** Board of Dentistry is not concerned with the form or type of business arrangements entered into by dentists as long as there is no interference with clinical judgment. The **Indiana** attorney general has issued an opinion that the Dental Practice Act provides that non-dentists may not be involved in the direction, control, and treatment of patients but are not prohibited from owning dental practices. **Texas** - a 1999 law prohibits interference and expressly prohibits the board of dentistry from prohibiting dentists from contracting with DMSOs.

Some states like Kansas require companies that provide dental office administrative services and dental practice management services to register with the dental board.

<sup>1/</sup> Washington-dentists may join partnerships or other business association with, and be employed by denturists provided that there is no impairment of independent professional judgment.

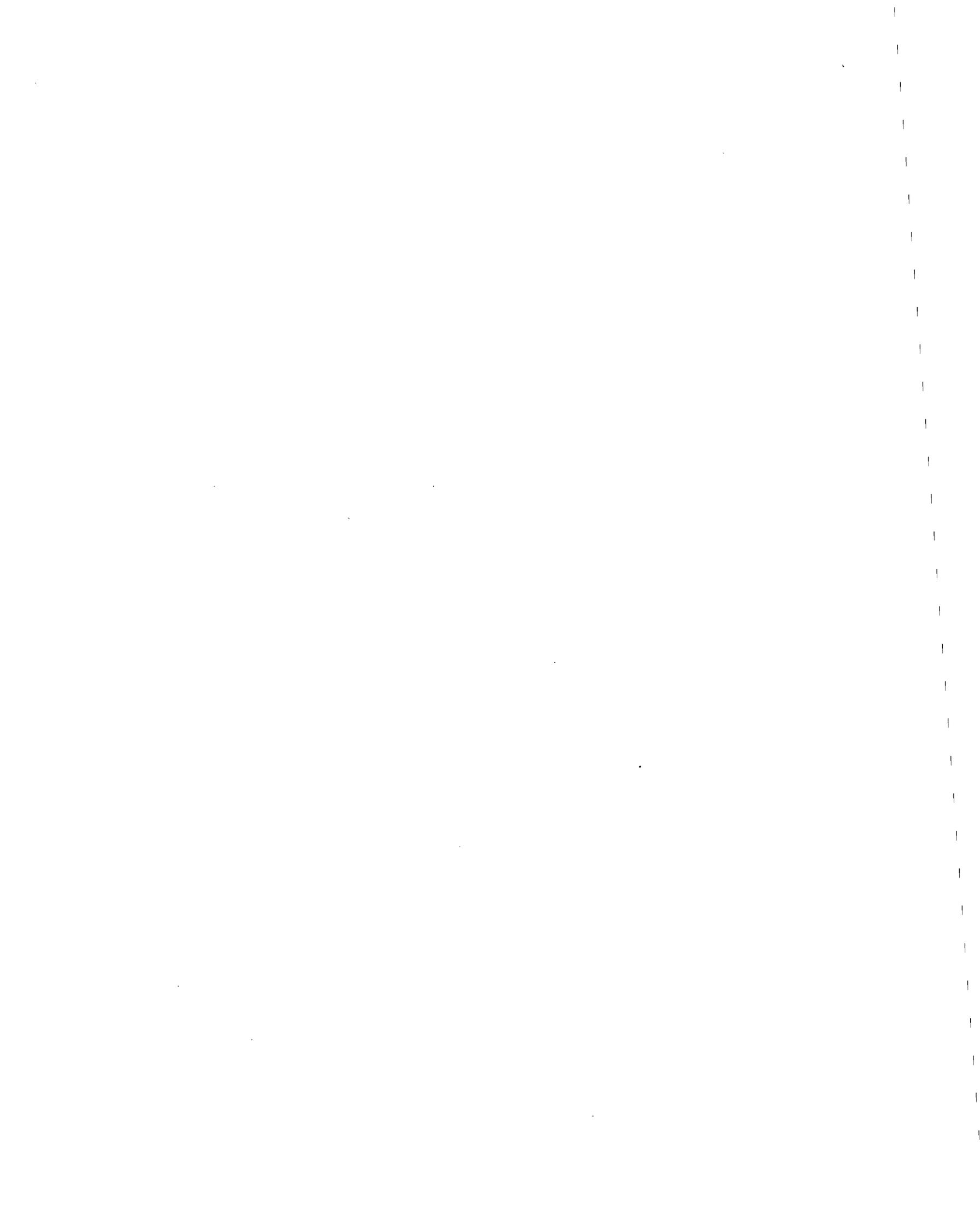
<sup>2/</sup> Indiana-an Attorney General Opinion may be construed as allowing non-dentists to own dental practices if there is no interference with the professional opinion of the dentist.

<sup>3/</sup> South Dakota permits nonprofit entities affiliated with nonprofit dental service organizations to own and operate mobile dental units. Community Health Centers (CHCs) and Migrant Health Centers may also employ dentists.

<sup>4/</sup> In such a scenario, professional responsibility for the dental patient, all dental services, patient records and payment remains with the dentist. In order to make it clear to the patient who is responsible for the services, dental hygienist owners must inform patients if there is any supervisory relationship between them and the dentists who rent equipment and space from them.

<sup>5/</sup> Applies only to an incorporated dental practice.

<sup>6/</sup> The Pennsylvania Board of Dentistry's Practice Ownership Committee and Board Chair hold the opinion, based on a particular law and Supreme Court ruling that only a licensed dentist may own a practice and have called for clarifying legislation.



## FINAL REPORT

### **Health Finance Commission**

#### **I. STATUTORY AND LEGISLATIVE COUNCIL DIRECTIVES**

The Indiana General Assembly enacted legislation (IC 2-5-23) establishing the Health Finance Commission to study health finance in Indiana. The Commission may study any topic:

- (1) directed by the chairperson of the Commission;
- (2) assigned by the Legislative Council; or
- (3) concerning issues that include: the delivery, payment, and organization of health services, rules that pertain to health care delivery, payment, and services that are under the authority of any board or agency of state government, the implementation of long term care services, the state Medicaid program, and the Children's Health Insurance Program.

The Legislative Council assigned the Commission the following additional issues to study:

- (1) health care reform;
- (2) the disposal of unused prescription drugs;
- (3) biosimilar biological products;
- (4) whether to amend statutes to allow certified registered nurse anesthetists to be classified as advanced practice nurses;
- (5) issues concerning ambulatory outpatient surgical centers;
- (6) Medicaid false claims and whistle-blower protection;
- (7) issues concerning dental care;
- (8) electronic medical records; and
- (9) immunizations.

See Legislative Council Resolution 13-01, available on the Legislative Services Agency website: <http://www.in.gov/legislative/>

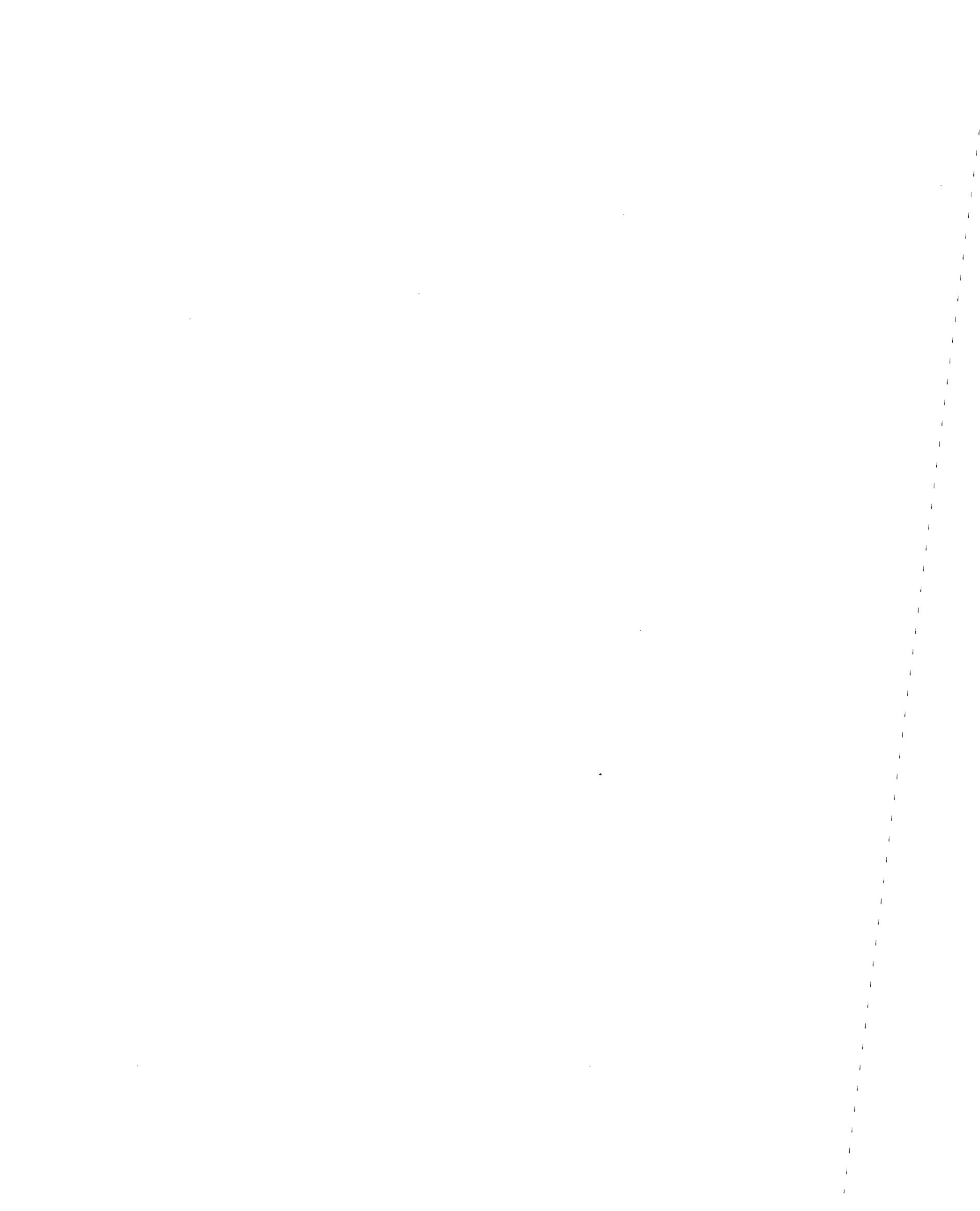
#### **III. SUMMARY OF WORK PROGRAM**

The Commission met five times over the interim: June 25, 2013; July 22, 2013; August 21, 2013; September 16, 2013; and October 22, 2013. For more detailed information concerning the testimony at a meeting, please see the Commission's minutes which are available on the Legislative Services Agency website: <http://www.in.gov/legislative/>

##### June 25, 2013

Secretary Debra Minott, Family and Social Services Administration (FSSA), briefed the Commission on enrollment statistics for the Healthy Indiana Plan (HIP) and FSSA's request to the federal government to extend HIP past its December 31, 2013 expiration. Secretary Minott stated that FSSA is focusing first on the extension of HIP before negotiation on the expansion of Medicaid. FSSA provided an update on Indiana's Medicaid waivers and each waiver's waiting list status. FSSA and the Office of the Attorney General provided information about each agency's role in preventing and investigating Medicaid fraud.

##### July 22, 2013



Mr. Logan Harrison, Indiana Department of Insurance, provided information concerning Indiana insurance rate projections for the 2014 plan year and other individuals testified concerning the importance of providing health insurance coverage for certain services. Information was provided concerning fraud and the School Free and Reduced Price Lunch Program. Testimony was provided concerning ambulatory outpatient surgical centers, the scope of practice for Certified Registered Nurse Anesthetists, and Indiana's use of electronic health data.

#### August 21, 2013

Testimony was given regarding the lack of traumatic brain injury services, specifically post-acute care facilities, available in Indiana. Dr. Virginia Caine, Marion County Department of Health, provided recommendations to increase the number of Indiana residents who are immunized. The Commission also heard testimony concerning the regulations governing ambulatory outpatient surgical centers, the use of tanning beds by minors, concerns with the disposal of unused prescription drugs, and follow-up information concerning the School Free and Reduced Price Lunch Program. Mr. Lance Rhodes, FSSA, updated the Commission on a programming error by a contractor that resulted in the unauthorized release of personal information of some individuals who participate in programs administered by FSSA.

#### September 16, 2013

Secretary Debra Minott, FSSA, provided an update on negotiations with the federal government that resulted in a one-year renewal of the Healthy Indiana Plan (HIP). Commission members also heard testimony concerning food handling and entities that are exempt from food handling requirements, the use of telehealth and telemedicine, various midwifery issues, and a report from the Division of Mental Health and Addiction concerning Indiana Methadone clinics.

#### October 22, 2013

### **IV. COMMITTEE ACTION**

The Commission made the following recommendations:

- The Commission recommends that the issue concerning the disposal of unused prescription drugs continue to be considered and that any necessary action be taken once the federal government finalizes regulations in this area.
- The Commission recommends that the Office of the Attorney General and stakeholders continue to work on reaching an agreement on language to address Medicaid fraud and whistleblower matters.
- The Commission recommends that the Legislative Council grant permission for Dr. Jack Shonkoff of Harvard University to present to a joint meeting of the standing Health and Education committees of both Houses concerning the subject of brain development.

The Commission considered the following Preliminary Drafts (PD):

#### PD



## WITNESS LIST

Dr. Jerome Adams, Anesthesiologist  
Mr. Tom Arkins, Indy EMS  
Ms. Mary Helen Ayres, Certified Professional Midwife  
Mr. John Barnes, Department of Education  
Mr. John Barth, MHS  
Ms. Lisa Brooking, Tanning bed provider  
Dr. Virginia Caine, Marion County Department of Health  
Mr. Vince Caponi, St. Vincent Health  
Mr. John Cardwell, Indiana Homecare Task Force  
Ms. Libby Cierzniak, Indiana Society of Anesthesiologists, Indianapolis Public Schools  
Dr. Carrie Davis, Indiana Academy of Dermatology  
Mr. John Dickerson, Arc of Indiana  
Ms. Katie Donnar, Melanoma survivor  
Ms. Susan Fitt, parent  
Mr. Tony Gillespie, Indiana Minority Health Coalition  
Mr. Scott Gilliam, Indiana State Department of Health  
Ms. Mary Ann Griffin, Certified Professional Midwife  
Ms. Nancy Griffin, advocate  
Ms. Candice Hager, Ft. Wayne Community Schools  
Ms. Christina Hamby, CRNA  
Ms. Cornelia Hammerly, CRNA  
Mr. Logan Harrison, Indiana Department of Insurance  
Ms. Patty Hebenstreit, MDwise  
Dr. John Hinton, Advantage Health Solutions  
Ms. June Holt, parent  
Mr. Randy Hountz, Purdue Healthcare Advisors  
Dr. Dick Huber, parent  
Mr. John Kansky, Indiana Health Information Exchange (IHIE)  
Mr. Jeff Kidd, family member  
Ms. Faith Laird, FSSA  
Mr. Joe Levy, American Suntanning Association  
Dr. Lisa Lombard, Rehabilitation Hospital of Indiana  
Mr. David McCormick, Indiana State Department of Health  
Ms. Pat McGuffey, Indiana State Chiropractic Association  
Ms. Kristen Metzger, Anthem  
Mr. Chris Mickens, Indiana State Department of Health  
Mr. Eric Miller, Advance America  
Secretary Debra Minott, FSSA  
Dr. Charles Miramonti, Indy EMS  
Mr. Kevin Moore, FSSA  
Mr. Alan Neuenschwander, parent  
Dr. Jonathan Neufeld, Upper Midwest Telehealth Resource Center  
Ms. Nicole Norvell, FSSA  
Dr. Pat O'Neil, Indiana Society of Anesthesiologists  
Mr. Greg Pachmayr, Indiana Board of Pharmacy  
Ms. Nancy Penn, Indiana Federation of Ambulatory Surgical Centers  
Dr. Charles Poland, DDS  
Mr. Alan Pope, Office of the Attorney General



Mr. Lance Rhodes, FSSA  
Mr. Mike Rinebold, Indiana State Medical Association  
Mr. Mark Scherer, Indiana Association of Nurse Anesthetists  
Ms. Roberta Schmidt, Neuro Restorative  
Dr. Keeter Sechrist, Dermatologist  
Ms. Adrienne Shields, FSSA  
Mr. Dan Skinner, Advocate  
Ms. Julie Sutton, Department of Education  
Mr. Eric Thieme, IHIE  
Dr. Drew Trobridge, Anesthesiologist  
Mr. Andrew VanZee, FSSA  
Ms. Connie Vickery, Indiana Restaurants and Lodging Association  
Mr. Shawn Walters, FSSA  
Ms. Susan Waschevski, FSSA  
Mr. Terry Whitson, Indiana State Department of Health  
Mr. Jim Zieba, Indiana Optometry



BILL NUMBER: Final Report

DATE: Oct. 22, 2013

COMMITTEE: Health Finance Commission

AUTHORS/SPONSORS: \_\_\_\_\_

ATTORNEY: \_\_\_\_\_

PHONE # \_\_\_\_\_

**AMEND**

AMT #		AMT #		AMT #			
Yes	No	Yes	No	Yes	No	Yes	No

**COMMITTEE MEMBERS**

DO PASS		DO PASS	
Yes	No	Yes	No

								Rep. Ed Clere, V-Ch	✓				
								Rep. Steven Davisson	✓				
								Rep. Ronald Bacon					
								Rep. Robert Behning					
								Rep. Suzanne Crouch	✓				
								Rep. David Frizzell	✓				
								Rep. Donald Lehe					
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								Rep. Dennis Zent	✓				
							→	Rep. Charlie Brown	✓				
								Rep. B. Patrick Bauer					
								Rep. Gregory Porter					
								Rep. Robin Shackelford					
								Sen. Ryan Mishler	✓				
								Sen. Vaneta Becker	✓				
								Sen. Rodric Bray	✓				
								Sen. Ed Charbonneau	✓				
								Sen. Ron Grooms	✓				
								Sen. Jean Leising	✓				
								Sen. Pete Miller	✓				
							→	Sen. Jean Breaux	✓				
								Sen. Frank Mrvan	✓				
								Sen. Mark Stoops	✓				
								Sen. Greg Taylor	✓				
								Sen. Patricia Miller, Ch	✓				

FINAL VOTE TOTAL

18	0		
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CHAIRPERSON





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**PRELIMINARY DRAFT  
No. 3352**

**PREPARED BY  
LEGISLATIVE SERVICES AGENCY  
2014 GENERAL ASSEMBLY**

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DIGEST

**Citations Affected:** Noncode.

**Synopsis:** Study concerning the costs of dental education. Requires the commission for higher education of the state of Indiana to study and make recommendations concerning the issue of the high cost of dental education.

**Effective:** Upon passage.



A BILL FOR AN ACT concerning professions and occupations.

*Be it enacted by the General Assembly of the State of Indiana:*

- 1           SECTION 1. [EFFECTIVE UPON PASSAGE] (a) As used in this  
2 SECTION, "commission" refers to the commission for higher  
3 education of the state of Indiana established by IC 21-18-2.  
4           (b) Before November 1, 2014, and in consultation with the state  
5 board of dentistry and the Indiana University School of Dentistry,  
6 the commission shall study and make recommendations concerning  
7 the issue of the high cost of dental education and the high level of  
8 debt incurred by an individual attending dental school.  
9           (c) This SECTION expires December 31, 2014.  
10          SECTION 2. An emergency is declared for this act.



BILL NUMBER: PD 3352

DATE: \_\_\_\_\_, 2013

COMMITTEE: \_\_\_\_\_

AUTHORS/SPONSORS: \_\_\_\_\_

ATTORNEY: \_\_\_\_\_

PHONE # \_\_\_\_\_

**AMEND**

AMT #		AMT #		AMT #		COMMITTEE MEMBERS		DO PASS		DO PASS	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No

								Rep. Ed Clere, V-Ch	✓			
								Rep. Steven Davisson	✓			
								Rep. Ronald Bacon				
								Rep. Robert Behning				
								Rep. Suzanne Crouch	✓			
								Rep. David Frizzell	✓			
								Rep. Donald Lehe				
								Rep. Eric Turner				
								Rep. Dennis Zent	✓			
								→ Rep. Charlie Brown	✓			
								Rep. B. Patrick Bauer				
								Rep. Gregory Porter				
								Rep. Robin Shackelford				
								Sen. Ryan Mishler	✓			
								Sen. Vaneta Becker	✓			
								Sen. Rodric Bray	✓			
								Sen. Ed Charbonneau	✓			
								Sen. Ron Grooms	✓			
								Sen. Jean Leising	✓			
								Sen. Pete Miller	✓			
								→ Sen. Jean Breaux	✓			
								Sen. Frank Mrvan	✓			
								Sen. Mark Stoops	✓			
								Sen. Greg Taylor	✓			
								Sen. Patricia Miller, Ch	✓			

FINAL VOTE TOTAL

180			
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CHAIRPERSON





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**PRELIMINARY DRAFT**  
**No. 3296**

**PREPARED BY**  
**LEGISLATIVE SERVICES AGENCY**  
**2014 GENERAL ASSEMBLY**

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DIGEST

**Citations Affected:** Noncode.

**Synopsis:** Department of health matters. Requires, before September 1, 2014, the state department of health to: (1) adopt rules concerning the regulation of facilities for treatment of traumatic brain injuries; and (2) make recommendations to the legislative council and health finance commission concerning food handling law changes.

**Effective:** Upon passage.



A BILL FOR AN ACT concerning health.

*Be it enacted by the General Assembly of the State of Indiana:*

- 1           SECTION 1. [EFFECTIVE UPON PASSAGE] (a) As used in this  
2 SECTION, "department" refers to the state department of health.  
3           (b) Before September 1, 2014, the department shall adopt rules  
4 that establish a license and provide regulations for a facility that  
5 provides specialized treatment and services for traumatic brain  
6 injuries.  
7           (c) Before September 1, 2014, the department shall make to the  
8 legislative council and health finance commission  
9 recommendations concerning changes to the food handling laws.  
10          (d) This SECTION expires December 31, 2014.  
11          SECTION 2. An emergency is declared for this act.



BILL NUMBER: PP 3296

DATE: \_\_\_\_\_, 2013

COMMITTEE: \_\_\_\_\_

AUTHORS/SPONSORS: \_\_\_\_\_

ATTORNEY: \_\_\_\_\_

PHONE # \_\_\_\_\_

AMEND

AMT #		AMT #		AMT #			
Yes	No	Yes	No	Yes	No	Yes	No

COMMITTEE MEMBERS

DO PASS		DO PASS	
Yes	No	Yes	No

								Rep. Ed Clere, V-Ch	✓				
								Rep. Steven Davisson	✓				
								Rep. Ronald Bacon					
								Rep. Robert Behning					
								Rep. Suzanne Crouch	✓				
								Rep. David Frizzell	✓				
								Rep. Donald Lehe					
								Rep. Eric Turner					
								Rep. Dennis Zent	✓				
								Rep. Charlie Brown	✓				
								Rep. B. Patrick Bauer					
								Rep. Gregory Porter					
								Rep. Robin Shackelford					
								Sen. Ryan Mishler	✓				
								Sen. Vaneta Becker	✓				
								Sen. Rodric Bray	✓				
								Sen. Ed Charbonneau	✓				
								Sen. Ron Grooms	✓				
								Sen. Jean Leising	✓				
								Sen. Pete Miller	✓				
								Sen. Jean Breaux	✓				
								Sen. Frank Mrvan	✓				
								Sen. Mark Stoops	✓				
								Sen. Greg Taylor	✓				
								Sen. Patricia Miller, Ch	✓				

FINAL VOTE TOTAL

180		
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CHAIRPERSON

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**PRELIMINARY DRAFT**  
**No. 3364**

**PREPARED BY**  
**LEGISLATIVE SERVICES AGENCY**  
**2014 GENERAL ASSEMBLY**

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DIGEST

**Citations Affected:** IC 25-8-15.4-15; IC 25-8-15.4-16.

**Synopsis:** Minors and tanning devices. Prohibits a person less than 16 years of age from using a tanning device in a tanning facility. Repeals a provision requiring a person less than 16 years of age to be accompanied by a parent or guardian when using a tanning device in a tanning facility. Requires the state department of health to adopt standards concerning the safe use of tanning devices by individuals.

**Effective:** Upon passage; July 1, 2014.



A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

*Be it enacted by the General Assembly of the State of Indiana:*

- 1           SECTION 1. IC 25-8-15.4-15 IS REPEALED [EFFECTIVE JULY  
2 1, 2014]. ~~Sec. 15: A person who is less than sixteen (16) years of age~~  
3 ~~must be accompanied by a parent or guardian when using a tanning~~  
4 ~~device in a tanning facility.~~
- 5           SECTION 2. IC 25-8-15.4-16 IS AMENDED TO READ AS  
6 FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 16. **(a) A person who**  
7 **is less than sixteen (16) years of age may not use a tanning device**  
8 **in a tanning facility.**
- 9           **(b) A person who is at least sixteen (16) years of age but** less than  
10 **eighteen (18) years of age may not use a tanning device in a tanning**  
11 **facility unless the parent or guardian of the person has also signed the**  
12 **written statement under section 11 of this chapter in the presence of the**  
13 **operator of the tanning facility.**
- 14           SECTION 3. [EFFECTIVE UPON PASSAGE] **(a) As used in this**  
15 **SECTION, "department" refers to the state department of health**  
16 **established by IC 16-19-1-1.**
- 17           **(b) Before September 1, 2014, the department shall adopt**  
18 **standards concerning the safe use of tanning devices by individuals**  
19 **in Indiana.**
- 20           **(c) This SECTION expires December 31, 2014.**
- 21           SECTION 4. An emergency is declared for this act.



BILL NUMBER: PD 3364

DATE: 10/22, 2013

COMMITTEE: \_\_\_\_\_

AUTHORS/SPONSORS: \_\_\_\_\_

ATTORNEY: \_\_\_\_\_ PHONE # \_\_\_\_\_

**AMEND**

AMT #		AMT #		AMT #		COMMITTEE MEMBERS		DO PASS		DO PASS	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No

								Rep. Ed Clere, V-Ch	✓			
								Rep. Steven Davisson	✓			
								Rep. Ronald Bacon				
								Rep. Robert Behning				
								Rep. Suzanne Crouch		✓		
								Rep. David Frizzell	✓			
								Rep. Donald Lehe				
								Rep. Eric Turner				
								Rep. Dennis Zent	✓			
								Rep. Charlie Brown	✓			
								Rep. B. Patrick Bauer				
								Rep. Gregory Porter	✓			
								Rep. Robin Shackelford				
								Sen. Ryan Mishler	✓			
								Sen. Vaneta Becker		✓		
								Sen. Rodric Bray	✓			
								Sen. Ed Charbonneau	✓			
								Sen. Ron Grooms	✓			
								Sen. Jean Leising	✓			
								Sen. Pete Miller	✓			
								Sen. Jean Breaux	✓			
								Sen. Frank Mrvan	✓			
								Sen. Mark Stoops	✓			
								Sen. Greg Taylor	✓			
								Sen. Patricia Miller, Ch	✓			

Don't determine oppor. age  
Sen Breaux  
withdrawn

FINAL VOTE TOTAL

17	16	2		
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CHAIRPERSON





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**PRELIMINARY DRAFT**  
**No. 3341**

**PREPARED BY**  
**LEGISLATIVE SERVICES AGENCY**  
**2014 GENERAL ASSEMBLY**

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DIGEST

**Citations Affected:** IC 16-18-2; IC 16-42.

**Synopsis:** Biosimilar products. Allows a pharmacist to substitute an interchangeable biosimilar product for a prescribed biological product if certain conditions are met. Requires the board of pharmacy to maintain an Internet web site that lists the biosimilar biological products that are determined to be interchangeable. Allows the board of pharmacy to adopt rules. Provides that a written or electronic prescription for a biological product must comply with the existing prescription form requirements.

**Effective:** July 1, 2014.



A BILL FOR AN ACT to amend the Indiana Code concerning health.

*Be it enacted by the General Assembly of the State of Indiana:*

1 SECTION 1. IC 16-18-2-35.8 IS ADDED TO THE INDIANA  
2 CODE AS A **NEW SECTION** TO READ AS FOLLOWS  
3 [EFFECTIVE JULY 1, 2014]: **Sec. 35.8. "Biological product", for**  
4 **purposes of IC 16-42-25, has the meaning set forth in**  
5 **IC 16-42-25-1.**

6 SECTION 2. IC 16-18-2-36.2 IS ADDED TO THE INDIANA  
7 CODE AS A **NEW SECTION** TO READ AS FOLLOWS  
8 [EFFECTIVE JULY 1, 2014]: **Sec. 36.2. "Biosimilar", for purposes**  
9 **of IC 16-42-25, has the meaning set forth in IC 16-42-25-2.**

10 SECTION 3. IC 16-18-2-191.2 IS ADDED TO THE INDIANA  
11 CODE AS A **NEW SECTION** TO READ AS FOLLOWS  
12 [EFFECTIVE JULY 1, 2014]: **Sec. 191.2. "Interchangeable", for**  
13 **purposes of IC 16-42-25, has the meaning set forth in**  
14 **IC 16-42-25-3.**

15 SECTION 4. IC 16-18-2-288 IS AMENDED TO READ AS  
16 FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 288. (a) "Practitioner",  
17 for purposes of IC 16-42-19, has the meaning set forth in  
18 IC 16-42-19-5.

19 (b) "Practitioner", for purposes of IC 16-41-14, has the meaning set  
20 forth in IC 16-41-14-4.

21 (c) "Practitioner", for purposes of IC 16-42-21, has the meaning set  
22 forth in IC 16-42-21-3.

23 (d) "Practitioner", for purposes of IC 16-42-22 **and IC 16-42-25,**  
24 has the meaning set forth in IC 16-42-22-4.5.

25 SECTION 5. IC 16-42-22-8, AS AMENDED BY P.L.204-2005,  
26 SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE  
27 JULY 1, 2014]: Sec. 8. (a) For substitution to occur for a prescription  
28 other than a prescription filled under the Medicaid program (42 U.S.C.  
29 1396 et seq.), the children's health insurance program established under  
30 IC 12-17.6-2, **the biosimilar biological products requirements under**  
31 **IC 16-42-25,** or the Medicare program (42 U.S.C. 1395 et seq.):



1 (1) the practitioner must:

2 (A) sign on the line under which the words "May substitute"  
3 appear; or

4 (B) for an electronically transmitted prescription,  
5 electronically transmit the instruction "May substitute."; and

6 (2) the pharmacist must inform the customer of the substitution.

7 (b) This section does not authorize any substitution other than  
8 substitution of a generically equivalent drug product.

9 SECTION 6. IC 16-42-25 IS ADDED TO THE INDIANA CODE  
10 AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE  
11 JULY 1, 2014]:

12 **Chapter 25. Drugs: Biosimilar Biological Products**

13 **Sec. 1. As used in this chapter, "biological product" means:**

14 (1) a virus;

15 (2) a therapeutic serum;

16 (3) a toxin;

17 (4) an antitoxin;

18 (5) a vaccine;

19 (6) blood;

20 (7) a blood component;

21 (8) a blood derivative;

22 (9) an allergenic product;

23 (10) a protein (except any chemically synthesized  
24 polypeptide);

25 (11) a product analogous to a product described in  
26 subdivisions (1) through (10);

27 (12) arsphenamine;

28 (13) an arsphenamine derivative; or

29 (14) any other trivalent organic arsenic compound;

30 applicable to the prevention, treatment, or cure of a disease or  
31 condition for human beings.

32 **Sec. 2. As used in this chapter, "biosimilar" refers to a  
33 biological product that:**

34 (1) has been licensed as a biosimilar product under 41 U.S.C.  
35 262(k); and

36 (2) is highly similar to the reference product, with:

37 (A) no clinically meaningful differences between the  
38 biological product and the reference product in terms of  
39 safety, purity, and potency of the product; and

40 (B) only minor differences in clinically inactive  
41 components.

42 **Sec. 3. As used in this chapter, "interchangeable" means a  
43 determination by the federal Food and Drug Administration that  
44 a biosimilar product may be substituted for a reference biological  
45 product without the intervention of the health care provider that  
46 prescribed the biological product.**



1           **Sec. 4. A pharmacist may substitute a biosimilar product for a**  
2 **prescribed biological product if the following conditions are met:**

3           **(1) The biosimilar product has been determined by the federal**  
4 **Food and Drug Administration to be interchangeable with the**  
5 **prescribed biological product.**

6           **(2) The prescribing practitioner has:**

7           **(A) for a written prescription, signed on the line under**  
8 **which the words "May substitute." appear; or**

9           **(B) for an electronically transmitted prescription,**  
10 **electronically transmitted the instruction "May**  
11 **substitute."**

12           **(3) The pharmacist has informed the customer of the**  
13 **substitution.**

14           **(4) The pharmacist notifies the prescribing practitioner,**  
15 **orally, in writing, or electronically, within five (5) calendar**  
16 **days of the substitution.**

17           **(5) The pharmacy and the prescribing practitioner retain a**  
18 **written or electronic record of the interchangeable biosimilar**  
19 **substitution for at least five (5) years.**

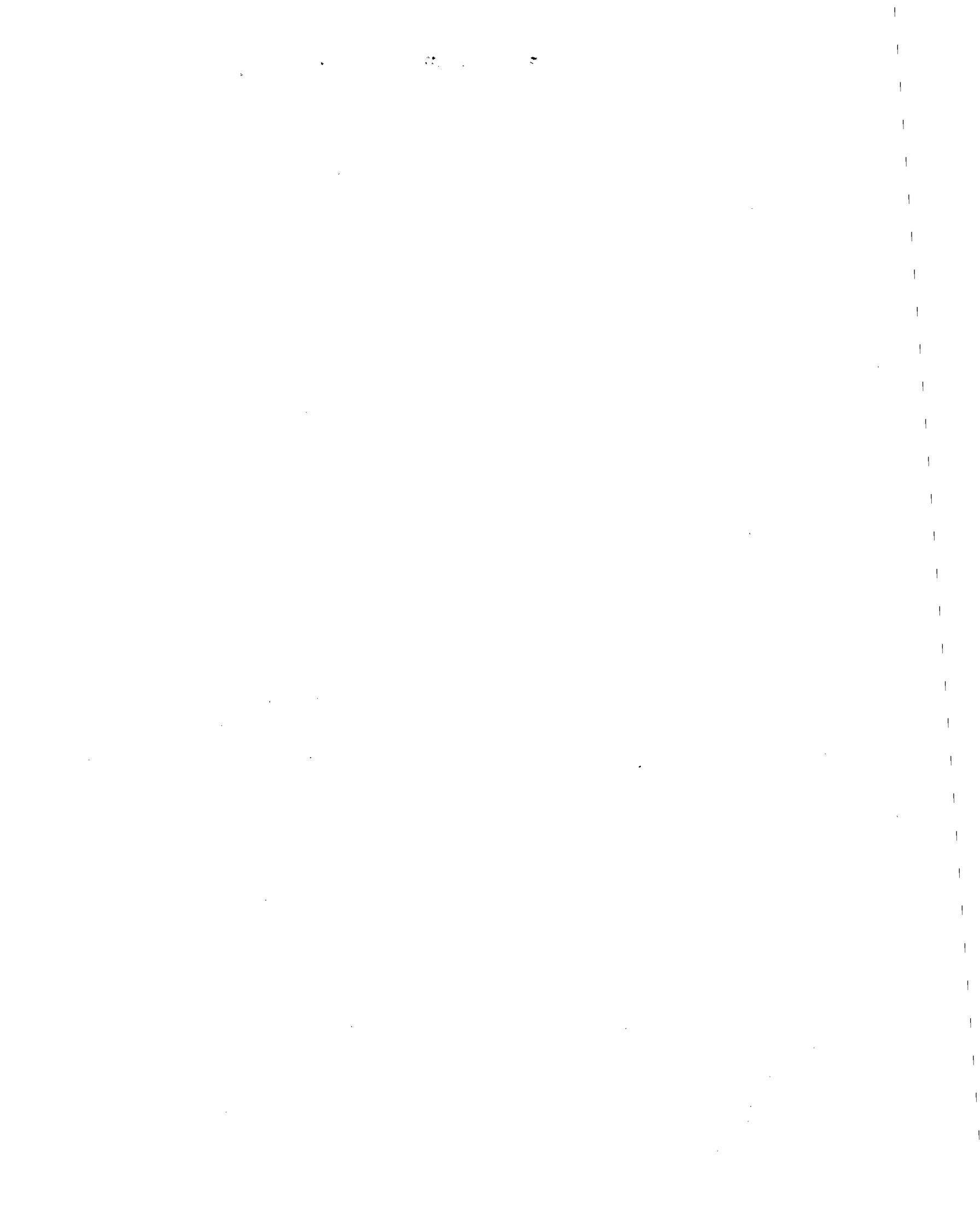
20           **Sec. 5. (a) The Indiana board of pharmacy shall maintain a**  
21 **public Internet web site that contains a current list of biosimilar**  
22 **biological products that the federal Food and Drug Administration**  
23 **has determined to be interchangeable.**

24           **(b) The Indiana board of pharmacy may adopt rules under**  
25 **IC 4-22-2 necessary to implement this chapter.**

26           **Sec. 6. A written or electronic prescription for a biological**  
27 **product must comply with the requirements under IC 16-42-22-6.**









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**PRELIMINARY DRAFT**  
**No. 3361**

**PREPARED BY**  
**LEGISLATIVE SERVICES AGENCY**  
**2014 GENERAL ASSEMBLY**

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DIGEST

**Citations Affected:** Noncode.

**Synopsis:** Electronic health data work group. Requires the state department of health and the office of the secretary of family and social services to establish a work group to study uniform access to electronic health data by health providers.

**Effective:** Upon passage.



A BILL FOR AN ACT concerning health.

*Be it enacted by the General Assembly of the State of Indiana:*

- 1           SECTION 1. [EFFECTIVE UPON PASSAGE] (a) As used in this  
2 SECTION, "state department" refers to the state department of  
3 health.  
4           (b) The state department and the office of the secretary of  
5 family and social services shall establish a work group to study the  
6 issue of uniform access to electronic health data by health  
7 providers in Indiana.  
8           (c) Before October 1, 2014, the state department shall report to  
9 the health finance commission with the findings of the work group  
10 described in this SECTION. The findings must include the cost for  
11 any recommendation.  
12           (d) This SECTION expires December 31, 2014.  
13           SECTION 2. An emergency is declared for this act.



BILL NUMBER: PD 3361

DATE: \_\_\_\_\_, 2013

COMMITTEE: \_\_\_\_\_

AUTHORS/SPONSORS: \_\_\_\_\_

ATTORNEY: \_\_\_\_\_

PHONE # \_\_\_\_\_

**AMEND**

AMT #		AMT #		AMT #		COMMITTEE MEMBERS		DO PASS		DO PASS	
Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
						Rep. Ed Clere, V-Ch		✓			
						Rep. Steven Davisson		✓			
						Rep. Ronald Bacon					
						Rep. Robert Behning					
						Rep. Suzanne Crouch		✓			
						Rep. David Frizzell		✓			
						Rep. Donald Lehe					
						Rep. Eric Turner					
						Rep. Dennis Zent		✓			
						Rep. Charlie Brown		✓			
						Rep. B. Patrick Bauer		✓			
						Rep. Gregory Porter		✓			
						Rep. Robin Shackelford					
						Sen. Ryan Mishler		✓			
						Sen. Vaneta Becker		✓			
						Sen. Rodric Bray		✓			
						Sen. Ed Charbonneau		✓			
						Sen. Ron Grooms		✓			
						Sen. Jean Leising		✓			
						Sen. Pete Miller		✓			
						Sen. Jean Breaux		✓			
						Sen. Frank Mrvan		✓			
						Sen. Mark Stoops		✓			
						Sen. Greg Taylor		✓			
						Sen. Patricia Miller, Ch		✓			

FINAL VOTE TOTAL

190		
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CHAIRPERSON



### Response to Representative Porter's HIP Questions

**Question #1: "How specifically are the approximately 10,500 individuals currently receiving HIP coverage to be effectively transitioned to the Exchange so there is not a gap or lapse in their healthcare coverage? (i.e., they have health insurance now, but come midnight December 31, their coverage under HIP ends entirely)."**

The Family and Social Services Administration has developed a comprehensive transition plan for the approximately 10,500 individuals currently covered under HIP who will be eligible for federal premium tax credits to purchase Marketplace coverage in 2014. The transition plan is designed to ensure that beneficiaries undergoing the transition understand how to enroll in Marketplace coverage, and obtain the new premium tax credits. The State has identified these transitioning individuals and will provide a series of notifications (one phone call and two letters) that will be delivered throughout September and October. The notices are designed to inform them of the changes and give information about Marketplace open enrollment and affordability provisions. FSSA will also inform individuals that if their eligibility circumstances have changed and they would like to be considered for HIP benefits in 2014, they need to re-apply by no later than November 30, 2013. The notice will also describe their appeal rights.

**Question #2: "Has FSSA been able to look at these 10,500 HIP recipients who are going to lose HIP coverage on January 1, 2014 and been able to determine how many will be able to continue to receive coverage through their current medical providers (even though insurance will now be obtained through the Exchange instead of HIP) and how many will not?"**

The three Managed Care Entities (MCEs) that administer HIP—Anthem, MDWise, and Managed Health Services—will also offer plans on the federal Marketplace in Indiana. Therefore, those individuals transferring from HIP to Marketplace coverage have the option of purchasing a plan from the same MCE under which they are covered by HIP to increase chances of maintaining their current providers.

**Question #3: "Has FSSA been able to analyze what type of services that these 10,500 individuals currently receive through HIP, but may not be able to receive through the insurance packages available through the Exchanges because they do not cover the services or are realistically out of the affordability range because they are only available in the higher tier Silver, Gold, or Platinum plans?"**

The benefits offered in HIP are based on a commercial market plan and these benefits do not differ substantially from the benefits designated as Essential Health Benefits (EHB) in the commercial market. Due to the EHB requirements, all health plans sold on the federal Marketplace cover the EHB. These benefits include:

- Ambulatory patient services;
- Emergency services;
- Hospitalization;
- Maternity and newborn care;
- Mental health and substance abuse disorder services, including behavioral health treatment;
- Prescription drugs;
- Rehabilitative and habilitative services and devices;
- Laboratory services;



- Preventive and wellness services and chronic disease management;
- Pediatric services, including oral and dental.

The exact benefits and services covered under each of these benefit categories are set by an EHB benchmark plan. Indiana’s EHB benchmark plan is the Anthem Blue Cross Blue Shield PPO plan. For individuals over 100% FPL who are transitioning from HIP to Marketplace coverage, there will be minor differences in benefits between HIP and commercial coverage. These benefit differences are shown in the below table.

**Table 1: HIP and Marketplace Coverage Benefit Differences**

<b>Benefit</b>	<b>HIP</b>	<b>Marketplace Coverage</b>
<b>Home Health Care Visits</b>	Covered, no limit	Covered, 100 visit limit per year
<b>Bariatric Surgery</b>	Covered if medically necessary	Not covered. Benefit may be able to be purchased as an addition to the primary health plan.
<b>Skilled nursing facility</b>	Covered, 60 days per year limit	Covered, 90 days per year limit
<b>Maternity Care</b>	Not Covered, pregnant individuals covered on Medicaid	Covered
<b>Physical Therapy, Occupational Therapy, Speech Therapy</b>	Covered, 25 visits per year	Covered, 20 visits per year
<b>Chiropractic Care</b>	Not covered	Covered, 12 visits per year
<b>Hearing Aids</b>	Covered for 19 and 20 year olds	Not covered
<b>Vision correction after accident or injury</b>	Not Covered	Covered
<b>Dental services after accident or injury</b>	Not covered	Covered

For plans sold on the federal Marketplace, the base level of benefits will be the same regardless of the metal level of coverage purchased (bronze, silver, gold, or platinum). Individuals may be able to buy additional benefits, but all individuals are guaranteed to have coverage for at least the EHB benefits as designated by the benchmark plan. The difference between a bronze plan and a platinum plan on the Marketplace is not a benefit discrepancy, but rather a variation in the ratio of premium costs to enrollee cost sharing.

**Question 4: “Has FSSA been able to do any analysis of what the net out-of-pocket costs will be for those (i.e., the average amount) who will receive coverage under the Exchange after they leave HIP? Has any analysis been done on how many of the transitioned 10,500 HIP recipients will drop coverage and revert to “uninsured status” (especially the population increment between 100% and 138% of FPL who could obtain Medicaid if Indiana was to pursue a Medicaid expansion)?”**

FSSA has conducted analysis of what average premium expenses will be for former HIP members when they transition to plans sold on the federal Marketplace. HIP members are accustomed to paying a



monthly contribution to their POWER accounts, which for individuals between 100 and 200% of the FPL, was an average of \$51.57 in 2012. The table below shows the premiums that individuals can expect for federal Marketplace plans compared to the HIP required monthly contribution. In most cases, former HIP members' premium costs will decrease when switching to Marketplace coverage.

**Table 2: Premium Costs for Marketplace plans and HIP POWER Account Contributions**

FPL	Single Individual Estimated Annual Income (2013)	Marketplace Required % of Income Contribution	Estimated Contribution: Marketplace plan <sup>1</sup>	Required % of Income Contribution for HIP	Estimated Contribution: HIP POWER Account
100-125%	\$11,171- \$13,963	2%	Annual: \$223-\$279 Monthly: \$19-\$24	3%	Annual: \$336- \$420 Monthly: \$28- \$35
125-138%	\$13,964- \$15,083	2-4%	Annual: \$279-\$603 Monthly: \$24 -\$51	4%	Annual: \$558- \$603 Monthly: \$47- \$51

Current HIP members transitioning to Marketplace coverage will also be eligible for Cost-Sharing Reductions (CSRs) if they purchase a silver plan. CSRs decrease out-of-pocket costs by requiring insurers to reduce deductibles, copayments, and coinsurance amounts for low-income individuals enrolled in marketplace silver plans. The specific amount of beneficiary cost-sharing depends on income level and healthcare utilization behaviors.

**Question 5: “As it relates to the potential to cover 45,000 individuals under HIP under the Waiver Extension, where specifically is the 45,000 person number derived from?”**

The HIP authorizing legislation specifies clearly that HIP “is not an entitlement program. The maximum enrollment of individuals who may participate in the plan is dependent on the funding appropriated for the plan”.<sup>2</sup> Therefore, the estimate of HIP’s potential to cover 45,000 individuals under the waiver extension is derived by determining the HIPs average annual cost and the projecting annual cigarette tax revenues. Consideration of projections of the cigarette tax revenue in future years alongside average enrollee costs in current and past years facilitate estimates of the number of enrollees HIP will be able to cover per the legislative requirements.

**Question 6: Can you clarify what is meant by having to submit an “amendment” to CMS to lower eligibility to 100% of FPL for HIP when enrollment approaches 45,000 since the HIP program already, and since inception, allows those between 23% and 200% of poverty to be eligible for HIP.**

In 2012, in preparation for the Affordable Care Act, the Indiana General Assembly passed a bill which included a provision to reduce the HIP income eligibility threshold from its current level, 200% of the

<sup>1</sup>Estimated Contribution is based on election of the second lowest cost silver plan. Individuals’ actual contribution may be more or less depending on the cost of the plan selected.

<sup>2</sup> House Enrolled Act No. 1678 of 2007, codified as amended at Ind. Code § 4-22-2-37.1 (available at <http://www.in.gov/legislative/bills/2007/PDF/HE/HE1678.1.pdf>)



FPL, to 138% of the FPL, effective January 1, 2014<sup>3</sup>. The Centers for Medicare and Medicaid Services (CMS) was notified of this legislative change in the 2011 HIP Waiver Renewal Application.

As part of the response to the 2014 HIP Extension Waiver application, CMS issued Special Terms and Conditions (STC), which is the document that governs the operation of the program. The STCs stipulated that the HIP eligibility threshold be lowered to 100% of the Federal Poverty Level, effective January 1, 2014. Indiana retains the ability to further lower the eligibility threshold should cigarette tax revenue projections indicate that the program will not be able to support additional enrollees. In the event the state needs to exercise this defacto cap on enrollment to maintain alignment with HIP legislation, the State will submit an amendment to CMS through the waiver amendment process to reflect the lowered income threshold.

**Question #7** “Although FSSA has said there is the potential to increase HIP enrollments to make up for the 10,500 individuals leaving HIP to go to the Exchanges how is this different from what the actual enrollment situation is now? What is stopping FSSA from immediately processing those Caretaker adults (still eligible and wanting coverage) on the 56,000-plus HIP waiting list to get them into HIP as soon as possible? Why has this not been done already since the funding and capacity currently exist to do this?”

Specifically and for instance, Caretaker adult enrollment is not capped by the federal government and the only restraint on caretaker adults is how much money the state has to accommodate their enrollment (i.e., which should not be an immediate problem because HIP has an over \$300 million surplus with a continued decline in enrollment). In contrast, non-Caretaker adults are “capped” by the federal government at approximately 36,500 enrollees. But the fact of the matter is that only 10,681 (FSSA numbers) individuals currently in HIP are caretaker adults. So even under the existing program we have the capacity to immediately serve 26,000 more caretaker adults without getting any additional federal approval.”

There is currently no cap on caretaker adult enrollment. Caretaker adults that apply for HIP are not placed on a waitlist and if they qualify they are automatically enrolled in HIP. Current caretaker adult enrollment in HIP reflects those caretaker adults that have applied for HIP coverage. Caretaker adults are not currently placed on the waitlist.

The advent of the Affordable Care Act will likely encourage applications for HIP and Medicaid and an increase in participation is expected. The state will evaluate the potential for additional non-caretaker enrollment based on overall HIP enrollment and projected cigarette tax revenues for 2014.

**Question #8:** “How specifically is FSSA going to ramp up the enrollment of non-Caretaker adult population into the HIP program when one looks at past attempts by FSSA to increase the non-caretaker adult population and sees there a total lack of meaningful effectiveness. For instance, in July 2011, FSSA announced that they were opening up 8,000 additional slots for caretaker adults and at that time the caretaker adult population in the HIP program was well over 13,000 people. However, today the caretaker adult population for HIP has plummeted to only 10,000 people. If these 8,000 “additional” people had been added in 2011 (or 2012 or 2013 for that matter) to the 13,000 non-Caretaker adult population in 2011, the non-caretaker adult population should today be close to 25,000 people with 10,000 MORE non-caretaker adults eligible for enrollment before the federal caps

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<sup>3</sup> Senate Enrolled Act No. 461 of 2010 (available at <http://www.in.gov/legislative/bills/2011/SE/SE0461.1.html>).



**were hit (i.e. non-caretaker adult numbers are even more comparatively disturbing because in November of 2008, just ten months into the HIP program we had 22,792 non-Caretaker adults in the program, 64.1% of total enrollment!)**

**How will FSSA make sure this time that the slots WE ALREADY HAVE for non-caretaker adults will be filled? Is there a real plan this time to do this now?"**

In the first quarter of 2012, the State made an effort to enroll more non-caretaker adults who were on the waitlist into the program, mailing 18,800 letters. As a result of this effort, only 1,578 of those on the waitlist (8.4%) gained coverage under HIP. This low number is likely due to the fact that many people become eligible for another Medicaid category or gained coverage through other venues. In April 2012, program enrollment was closed for non-caretakers as the State waited for CMS guidance on the future of HIP. HIP enrollment has never been closed for caretaker adults and caretaker adult enrollment reflects the number of qualified caretakers that apply for HIP.

Overall, the uncertainty around the future of HIP has likely impacted enrollment, as media reports have highlighted the potential closing. Even now, CMS has not given the State clear direction as to whether HIP will be allowed to continue past December 31, 2014. Without long-term assurance of HIP's existence, it is difficult for the State to plan for additional enrollees when coverage under the program might be very temporary. . Additionally, with the initiation of the Marketplace open enrollment period October 1, 2013 and the federal efforts to get individuals to apply for coverage, the State expects that HIP enrollment of both caretaker and non-caretaker adults will increase over the next year.

**Question #9: What plans is FSSA undertaking regarding the HIP program post December 31, 2014? Why for instance was only a one-year extension granted to the HIP program when it appeared FSSA was requesting a three-year extension?**

The State requested the maximum waiver extension period of three years in its waiver application. CMS only granted a one-year extension of HIP in response to Indiana's waiver application, through December 2014. The State continues to seek guidance from CMS about the future of the HIP program, and hopes that CMS can answer this question.

**Question #10: What more really needs to be "demonstrated" under the HIP waiver? For instance, FSSA continually reports a 95% satisfaction rate for those receiving HIP and less emergency room utilization. These factors, along with the fact that HIP costs more than Medicaid and can serve less individuals than Medicaid due to payment of Medicare rates has been successfully "demonstrated" for almost five years now? What new item and/or items are going to be "demonstrated" by a Medicaid extension for an additional year's duration?**

We agree that HIP is a successful program and should be continued. We look forward to CMS's response to the strong data regarding member satisfaction and emergency room utilization cited in the question above. In addition to the mentioned successes, there is evidence that the HIP model encourages utilization of preventive care and screening. In 2012, 39% of male HIP beneficiaries and 69% of female HIP beneficiaries received at least one preventative service. Additionally, a 2013 survey of HIP members indicated that 84.5% of enrollees had a routine check-up in the past year. HIP preventative use among caretakers is greater than similarly commercially-insured populations and use among non-caretakers is comparable to a similarly commercially-insured population.



Additionally, we are continuing to evaluate the willingness and ability of low-income beneficiaries to contribute to the cost of their healthcare coverage. Early data indicates that paying a fixed monthly amount into a POWER account, similar to a premium structure in a commercial plan, is an effective contribution strategy for this population. In the 2013 survey, 83% of HIP member respondents indicated they prefer this model (with the opportunity to receive unspent money back) over making a copayment each time they visited a health professional, pharmacy, or hospital. We will continue to gather more data on POWER account contribution rates over the next year of the demonstration.

**Question #11: HIP has been extended for one year, however, unless some momentous and heretofore undemonstrated immediate enrollment effects are undertaken, current HIP enrollment is set to drastically decline starting January 1, due to the transitioning of 10,500 HIP enrollees to the Exchanges (basically a 30% decline in enrollment in one day). What will the loss of this many individuals do to the current HIP revenue surplus of \$300 million? How much more is FSSA estimating that HIP will grow above the \$300 million level?**

The advent of the Affordable Care Act and the individual mandate is expected to have an impact on HIP enrollment. The federal government has indicated plans to promote coverage options and to this end, all States have predicted increases in enrollment for individuals that are eligible but not enrolled in Medicaid. When the federal Marketplace's open enrollment period ends (March 2014), the State will re-evaluate its HIP enrollment strategy.

**Question #12 The enrollment for caretaker adults (the uncapped cohort of the HIP population) has remained static at about the low – to-mid 20,000 number for a number of years and there has never been a waiting list for this segment of the HIP population. Why has the caretaker adult population not experienced any growth (it actually declined somewhat since 2011 when it exceeded 27,000) in HIP enrollment? Does FSSA have any estimates of what the potential caretaker adult population that could be eligible for HIP is? Has or is FSSA going to do any outreach to grow this segment of the HIP population?**

As indicated above, the uncertainty of HIP's future has had an impact on enrollment. The State has estimates of potential enrollment and monitors this routinely. The State relies on the three MCE's that administer the HIP program (Anthem, MDwise, and Managed Health Services) to conduct marketing, outreach, and enrollment activities and will continue to do so in 2014.

The plans engage in many types of activities to bolster enrollment. In 2012, Anthem's outreach staff participated in over 375 events statewide to provide information on HIP and Hoosier Healthwise. Anthem also regularly partners with faith-based organizations, Work Force One, the Indiana Minority Health Coalition, Covering Kids and Families, and other public resource agencies to educate potential beneficiaries about the HIP program and encourage potential beneficiaries to apply for coverage. In 2012, MDWise conducted outreach at over 100 school events (a particularly effective venue to promote HIP enrollment for caretakers), collaborated with School-Based Health Centers to promote HIP to uninsured parents, hosted 197 Q & A chats with individuals at Division of Family Resources Office and other agencies, presented on HIP at DFR IMPACT community presentations, offered presentations to seven companies where health insurance was not offered by employers, and distributed applications at various community events and presentations. Similarly, MHS participated in over 150 community events statewide in 2012, including community health fairs and faith-based healthy lifestyle programs. MHS also conducts online marketing.









**STATE OF INDIANA**

**Michael R. Pence  
Governor**

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**STATE BUDGET AGENCY**

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**Brian E. Bailey  
Director**

October 11, 2013

Senator Patricia Miller, Chairman  
Health Finance Commission

Dear Senator Miller,

FSSA Secretary Debra Minott provided an update on the Healthy Indiana Plan (HIP) renewal at the September 16, 2013 Health Finance Commission meeting. During the presentation, Secretary Minott was asked why HIP is limited to 45,000 individuals when there is a surplus in the HIP Trust Fund.

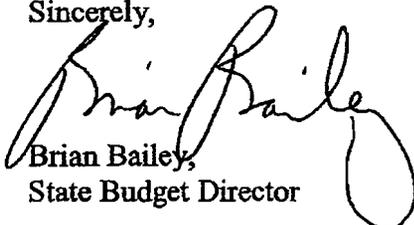
As of the end of FY 2013, the balance in the HIP Trust Fund was \$307 million. Much of this balance accumulated after the increase in the cigarette tax but before the program became operational. This amount represents about 2.75 times the annual revenues and expenses of the program.

If Indiana were to use this \$307 million balance to expand HIP enrollment to cover the current HIP waitlist, the program would quickly become unsustainable. After a little over two years, the balance would run out. Indiana then would be faced with the decision either: (1) to reallocate an additional \$114 million to HIP annually to cover the shortfall (through tax increases or cuts elsewhere), or (2) to remove thousands of individuals from the program.

Before increasing HIP enrollment or expanding Medicaid, it would be essential to have a long-term funding mechanism in place. It would not be fiscally responsible to rely on a one-time balance that would leave Indiana with a funding shortfall once those funds are depleted.

I hope this helps provide the information you requested. If you would like additional information or would like to discuss this, please do not hesitate to contact me.

Sincerely,



Brian Bailey,  
State Budget Director

Cc: Senator Luke Kenley, Representative Tim Brown

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October 11, 2013

