Louisiana Department of Health and Hospitals

Medicaid Pharmaceutical And Therapeutics Committee

August 11, 2010

Attachment 5

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Overview of Affordable Care Act and Impact on the Pharmaceutical Rebate Program

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Background of Federal Rebate Program

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- Manufacturers must agree to participate in the Federal Rebate program and provide a minimum level of Federal Rebate for Medicaid Fee-for-Service population.
- Non-participating manufacturers and their drugs are not a covered expense for Medicaid population.
- States and Federal government share Federal Rebates based on the Federal Medical Assistance Percentages (FMAP) which varies from state to state.[1]
- Supplemental Rebates are negotiated above and beyond Federal Rebates.

1. Available at: http://aspe.hhs.gov/health/fmap.htm

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Affordable Care Act

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- Increased Federal rebate percentages for covered outpatient drugs dispensed to Medicaid patients.
  - Federal government to receive the additional rebates.
- These changes were effective January 1, 2010.

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Federal Rebate Changes

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- For Brand name drugs, the minimum rebate percentage is increased from 15.1% of the average manufacturer price (AMP) to 23.1% of AMP
  - The additional 8% rebate goes entirely to the Federal government
- For clotting factors and drugs approved by the FDA exclusively for pediatric indications, the minimum rebate percentage is increased from 15.1% of AMP to 17.1% of AMP.
  - The additional 2% rebate goes entirely to the Federal government

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Federal Rebate Changes

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- For generic drugs, the minimum rebate percentage is increased from 11% of AMP to 13% of AMP
  - All additional rebates go entirely to the Federal government
- For new formulations (line extension) of a brand name drug that is an oral solid dosage form, the Federal rebate will increase.
  - CMS has not yet provided detailed guidance about line extension products
  - Products likely impacted include extended release oral dosage forms
  - Federal rebate will likely be tied to the innovator product
  - Affected products may be more expensive to the state as the rebates are not returned to the state but to the Federal government.

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Additional Federal Rebate Changes

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- Drug manufacturers that participate in the drug rebate program will now pay rebates for drugs dispensed to patients enrolled in Medicaid Managed Care Organizations (MCO).
  - Previously Federal Rebates were not paid to Medicaid MCOs.
  - Supplemental rebates do not apply to the MCO utilization.

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What do the Federal Rebate changes mean?

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- Contracts with manufacturers are written for a Guaranteed Net Unit Price (GNUP)
    - Per the GNUP calculation, Federal rebates and supplemental rebates are inversely proportional; therefore, if Federal rebates increase, then supplemental rebates decrease on a penny-for-penny basis.
- Federal rebates will increase.
- Therefore, supplemental rebates will decrease; projections are by an *average* of 33%
    - CMS has not yet provided detailed guidance about line extension products
- Overall, states are expected to experience a total reduction in all rebates of approximately 4% to 5%.

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New Business

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- Explanation of TOP$, monographs, and cost sheets

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The Optimal PDL $olution (TOP$)

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- In 2005, Louisiana was 1 of the first 3 states to join the TOP$ program.
- In 2010, Louisiana is 1 of 7 states participating in the multi-state purchasing pool
- States maintain ability to make own PDL decisions while belonging to TOP$

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TOP$ Medicaid PDL States

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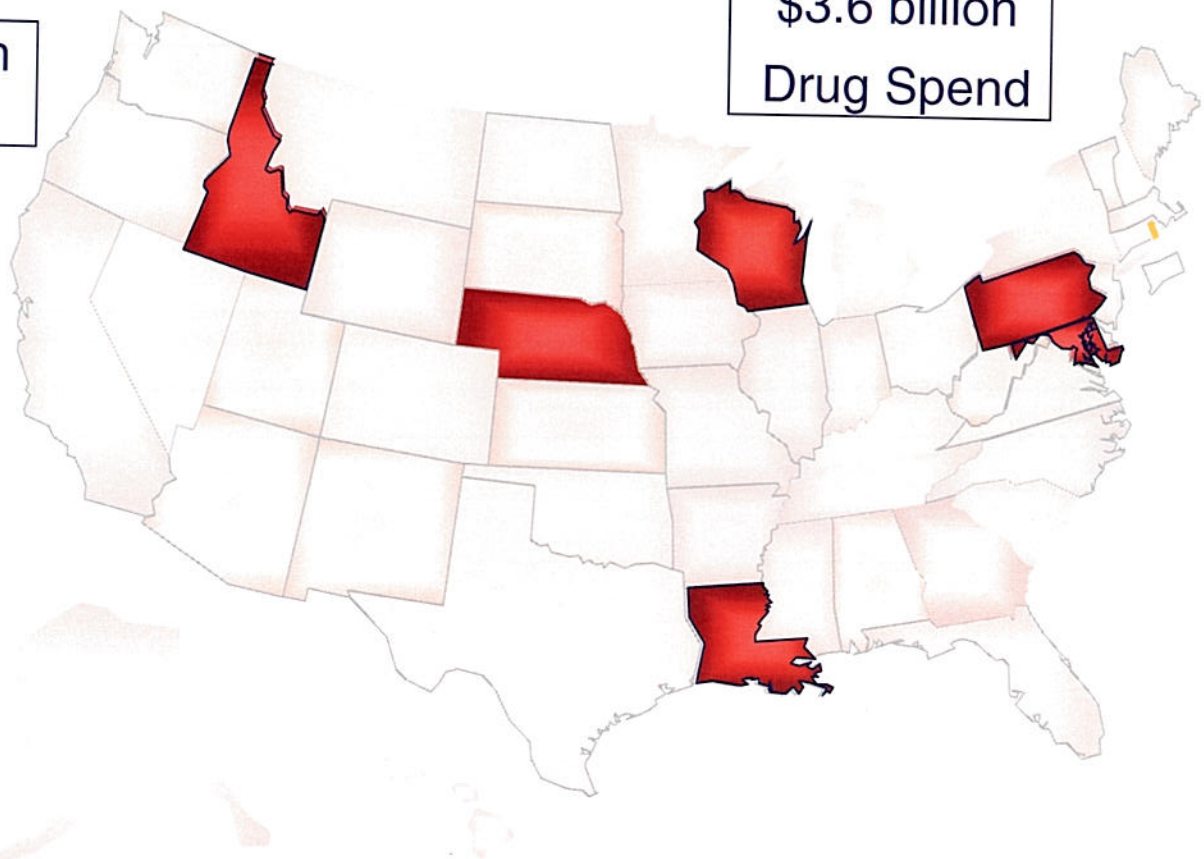
4 million lives

$3.6 billion Drug Spend



TOP$

Delaware

Idaho

Louisiana

Maryland

Nebraska

Pennsylvania

Wisconsin

62 Participating Manufacturers

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TOP$ Program Goals

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- Maintain clinical integrity
- Focus on net cost rather than rebates
- Establish price protection (eliminate/attenuate inflation)
- Provide a framework that includes a competitive component for manufacturers

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Define Market Basket

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- Grouping of products by therapeutic use
- TCRs
  - Comprehensive clinical reviews of market baskets
  - Data inclusion criteria
  - Highlighted information is new information added since the last review of the category

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Recommendation process

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- Clinical component
  - Efficacy
    - Peer-reviewed literature evaluation
  - Safety

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Recommendation process

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- Financial analysis
  - Average net-net cost of prescription to state
    - Claims cost less all supplemental rebates and federal rebates
    - This is the amount the state is paying for the prescriptions
  - Estimated savings are generated by:
    - Supplemental rebates
    - Market share shifts / disruption
  - Final recommendations

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Market Share Shift / Disruption

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- Example: Hypoglycemics, Insulins
- PDL decision implemented October 1, 2006
- Both Lilly and Novo Nordisk products ON PDL prior to October 2006
- Lilly product line ON PDL after October 1, 2006
  - ON PDL: Humulin, Humalog, Humalog Mix
  - ON PDL: Lantus, Levemir

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Example

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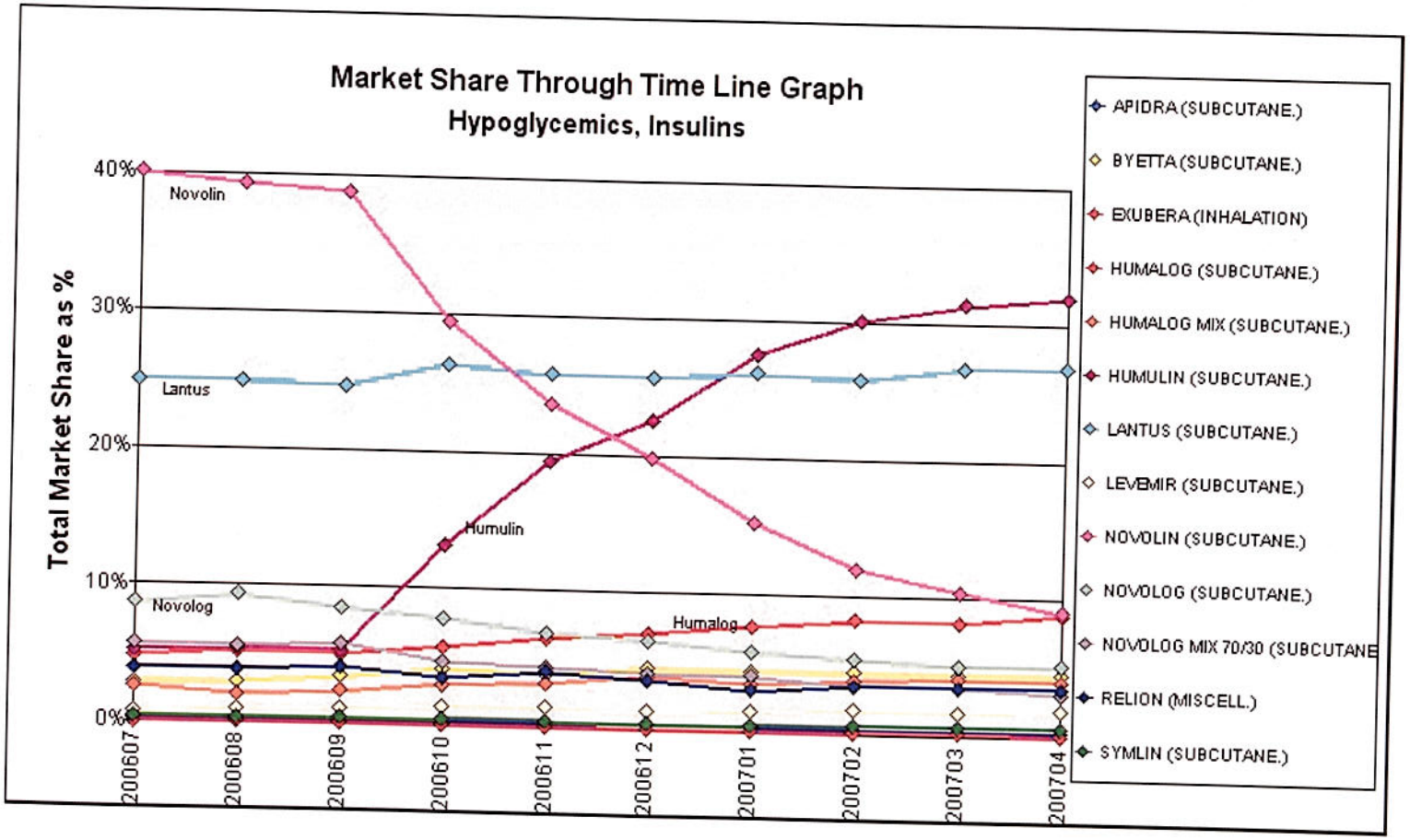

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Supplemental Rebates

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- Supplemental rebate solicitation
  - Listing of drugs in therapeutic drug classes scheduled for review
    - 71 Therapeutic Classes reviewed in 2010
  - Sent to each manufacturer that has drug being reviewed in a market basket

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Supplemental Rebates

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- Supplemental rebate contract terms and conditions
  - One-year contracts
  - GNUP – Guaranteed Net Unit Price
  - WAC-based formula
    - GNUP = WAC – federal rebate – supplemental rebate

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Supplemental Rebates

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- Supplemental rebate offers
  - Manufacturers offer GNUP for each tier
    - Tiers determined by number of states with drug on PDL
  - May provide enhanced offers for positioning (1-of-1, 1-of-2, etc.)
  - May define sub-classes
  - May make offers that allow for clinical edits
  - Best and final offers

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Louisiana PDL Program Savings

- Savings from PDL program
  - Fiscal Year 2010: $35.6 million

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Cost Sheets

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- Used as a tool to explain relative cost and savings projections for a therapeutic category
- All figures are stated on a per quarter basis

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Cost Sheets Highlights

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- Utilization data from 1Q09
  - Current Rx, Current Market Share
- Projected Rx column is estimated market share after PDL recommendations are fully implemented
  - Market share shift ("switch") savings are estimated for drugs moving to non-preferred status
  - For non-preferred products remaining non-preferred, stable market share is assumed
  - Range of PDL compliance FY'10: 89.7-92.3%

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Cost Sheets Highlights

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- Relative Cost Symbols
  - Explain the relative cost of products per prescription *within a class*
- Baseline
  - Lowest cost product in the class is assigned a symbol
- Increasing cost
  - Additional symbols are assigned based on comparison of product cost to baseline cost
    - Symbology changes after a certain level of pricing

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Cost Sheets Highlights

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- Current PDL Status vs. PDL Recommendation
- Total Savings with Recommendations is the estimated cost savings with the PDL recommendations fully implemented.
- Total incremental savings from current PDL represents a comparison to last year's savings
  - Zero incremental savings = no additional savings over last year

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THERAPEUTIC CLASS REVIEWS

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Alzheimer's Agents

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- Recommendations for the Preferred Drug List (PDL):
  - Aricept / Aricept ODT
  - Exelon capsules
  - Exelon Transdermal
  - Namenda

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Analgesics – Anesthetics, Topical

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- Recommendations for the Preferred Drug List (PDL):
  - Lidoderm
  - Voltaren

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Androgenic Agents

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- Recommendations for the Preferred Drug List (PDL):
  - Androderm
  - Androgel

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Antibiotics, Inhaled

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- Recommendations for the Preferred Drug List (PDL):
  - TOBI

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Antibiotics, Vaginal

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Recommendations for the Preferred Drug List (PDL):

- clindamycin
- metronidazole
- Cleocin ovules
- Vandazole

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Antidepressants, Other

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- Recommendations for the Preferred Drug List (PDL):
  - bupropion IR
  - bupropion SR
  - mirtazapine
  - trazodone
  - venlafaxine ER tablets (generic and brand)

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Antidepressants, SSRIs

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- Recommendations for the Preferred Drug List (PDL):
  - citalopram
  - fluoxetine
  - fluvoxamine
  - paroxetine
  - sertraline
  - Lexapro

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Antiemetics

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- Recommendations for the Preferred Drug List (PDL):
  - ondansetron and ondansetron ODT
  - Marinol (brand only)

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Antifungals, Oral

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- Recommendations for the Preferred Drug List (PDL):
  - fluconazole
  - griseofulvin suspension
  - ketoconazole
  - nystatin
  - terbinafine
  - Gris-Peg tablets

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Antifungals, Topical

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- Recommendations for the Preferred Drug List (PDL):
  - clotrimazole (RX)
  - clotrimazole-betamethasone
  - ketoconazole
  - ketoconazole shampoo
  - nystatin
  - nystatin-triamcinolone
  - Naftin

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Antihyperuricemics, Oral

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- Recommendations for the Preferred Drug List (PDL):
  - allopurinol
  - colchicine
  - probenecid / colchicine
  - probenecid

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Antiparasitics, Topical

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- Recommendations for the Preferred Drug List (PDL):
  - permethrin
  - Eurax
  - Ovide (brand only)
  - Ulesfia

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Antiparkinsons Agents

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- Recommendations for the Preferred Drug List (PDL):
  - benztropine
  - carbidopa / levodopa
  - ropinirole
  - pramipexole
  - selegiline
  - trihexyphenidyl
  - Stalevo

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Antipsychotics

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- Recommendations for the Preferred Drug List (PDL):
  - generics
  - Fanapt
  - Moban
  - Orap
  - Geodon (oral and injectable)
  - Seroquel
  - Seroquel XR
  - Risperdal Consta

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Antivirals, Topical

- Recommendations for the Preferred Drug List (PDL):
  - Denavir

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Atopic Dermatitis

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- Recommendations for the Preferred Drug List (PDL):
  - Elidel
  - Protopic

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Bile Salts

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- Recommendations for the Preferred Drug List (PDL):
  - ursodiol
  - Actigall

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Bone Resorption Suppression and Related Agents

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- Recommendations for the Preferred Drug List (PDL):
  - alendronate tablets
  - calcitonin salmon
  - Miacalcin

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Bronchodilators, Anticholinergics

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- Recommendations for the Preferred Drug List (PDL):
  - ipratropium
  - Atrovent HFA
  - Combivent
  - Spiriva

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Bronchodilators, Beta-Agonists

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- Recommendations for the Preferred Drug List (PDL):
  - albuterol (oral)
  - albuterol (nebulizer)
  - terbutaline (oral)
  - Maxair
  - ProAir HFA
  - Proventil HFA
  - Ventolin HFA
  - Xopenex

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Cephalosporins and Related Antibiotics

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- Recommendations for the Preferred Drug List (PDL):
  - amoxicillin / clavulanate suspension and tablets
  - Augmentin 125 and 250 suspension
  - cephalexin
  - cefaclor
  - cefadroxil
  - cefprozil
  - cefuroxime tablets
  - Suprax

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Cytokines and CAM Antagonists

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- Recommendations for the Preferred Drug List (PDL):
  - Cimzia
  - Enbrel
  - Humira

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Fluoroquinolones, Oral

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- Recommendations for the Preferred Drug List (PDL):
  - ciprofloxacin tablets
  - Avelox

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Glucocorticoids, Inhaled

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- Recommendations for the Preferred Drug List (PDL):
  - Advair / Advair HFA
  - Aerobid / Aerobid M
  - Asmanex
  - Flovent / Flovent HFA
  - QVAR
  - Symbicort

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Hypoglycemics, Incretins Mimetics/Enhancers

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- Recommendations for the Preferred Drug List (PDL):
  - Byetta pens
  - Januvia
  - Janumet
  - Onglyza
  - Symlin and Symlin pens

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Hypoglycemics, Insulins

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- Recommendations for the Preferred Drug List (PDL):
  - Humulin and Humulin pens
  - Humalog and Humalog pens
  - Humalog Mix and Humalog Mix pens
  - Lantus and Lantus pens

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Intranasal Rhinitis Agents

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- Recommendations for the Preferred Drug List (PDL):
  - Astelin
  - Astepro
  - fluticasone nasal
  - ipratropium nasal
  - Nasacort AQ
  - Nasonex
  - Patanase

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Leukotriene Modifiers

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- Recommendations for the Preferred Drug List (PDL):
  - Accolate
  - Singulair

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Macrolides - Ketolides

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- Recommendations for the Preferred Drug List (PDL):
  - azithromycin
  - erythromycin

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NSAIDs

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- Recommendations for the Preferred Drug List (PDL):
  - etodolac
  - diclofenac
  - flurbiprofen
  - ibuprofen RX
  - indomethacin (oral/rectal)
  - ketoprofen
  - ketorolac
  - meloxicam
  - naproxen RX
  - piroxicam
  - oxaprozin
  - sulindac
  - Vimovo

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Oncology Agents, Oral

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- Recommendations for the Preferred Drug List (PDL):
  - Xeloda
  - Iressa
  - Tarceva
  - Gleevec
  - Tykerb
  - Nexavar
  - Sprycel

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Ophthalmic Antibiotics

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- Recommendations for the Preferred Drug List (PDL):
  - erythromycin
  - gentamicin
  - bacitracin/polymyxin
  - neomycin-polymyxin-gramicidin
  - polymyxin/trimethoprim
  - tobramycin
  - Tobrex ointment
  - triple antibiotic
  - Vigamox
  - sulfacetamide

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Ophthalmics for Allergic Conjunctivitis

- Recommendations for the Preferred Drug List (PDL):
  - Alrex
  - cromolyn sodium
  - Pataday
  - Patanol

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Ophthalmic Anti-inflammatories

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- Recommendations for the Preferred Drug List (PDL):
  - dexamethasone
  - diclofenac
  - fluorometholone
  - flurbiprofen
  - Flarex
  - FML Forte
  - FML S.O.P
  - Lotemax
  - Maxidex
  - Pred Mild

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Ophthalmics, Glaucoma Agents

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- Recommendations for the Preferred Drug List (PDL):
  - generics (<u>except</u> brimonidine P, dorzolamide, and dorzolamide/timolol)
  - Alphagan P (brand only)
  - Azopt
  - Betimol
  - Betoptic S
  - Combigan
  - Cosopt (brand only)
  - Istalol
  - Propine
  - Travatan / Travatan Z
  - Trusopt (brand only)
  - Xalatan

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Pancreatic Enzymes

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- Recommendations for the Preferred Drug List (PDL):
  - pancrelipase
  - Creon
  - Zenpep

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Platelet Aggregation Inhibitors

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- Recommendations for the Preferred Drug List (PDL):
  - dipyridamole
  - Aggrenox
  - Plavix

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Steroids, Topical High

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- Recommendations for the Preferred Drug List (PDL):
  - betamethasone valerate
  - triamcinolone acetonide
  - fluocinonide
  - fluocinonide-e
  - fluocinonide emollient

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Steroids, Topical Low

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- Recommendations for the Preferred Drug List (PDL):
  - alcometasone dipropionate
  - hydrocortisone
  - desonide
  - Capex shampoo

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Steroids, Topical Medium

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- Recommendations for the Preferred Drug List (PDL):
  - fluocinolone acetonide
  - hydrocortisone butyrate
  - hydrocortisone valerate
  - mometasone furoate
  - prednicarbate
  - fluticasone propionate
  - Locoid Lipocream
  - Pandel

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Steroids, Topical Very High

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- Recommendations for the Preferred Drug List (PDL):
  - clobetasol emollient
  - clobetasol propionate
  - halobetasol propionate

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Stimulants and Related Agents

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- Recommendations for the Preferred Drug List (PDL):
  - generics (<u>except</u> amphetamine salt combo ER and methamphetamine)
  - Concerta
  - Daytrana
  - Focalin / Focalin XR
  - Intuniv
  - Metadate CD
  - Methylin chewable and solution
  - Procentra
  - Vyvanse

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Tetracyclines

PROVIDER SYNERGIES L.L.C.
Together, we can do more.

- Recommendations for the Preferred Drug List (PDL):
  - doxycycline hyclate
  - doxycycline hyclate DR
  - doxycycline monohydrate
  - minocycline capsules and tablets
  - tetracycline

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New Drug Reviews

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Analgesics, Narcotic Long Acting – Exalgo

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- Recommendations for the Preferred Drug List (PDL):
  - Do Not Add Exalgo

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Analgesics, Narcotics – Short Acting - Rybix ODT

- Recommendations for the Preferred Drug List (PDL):
  - Do Not Add Rybix ODT

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Multiple Sclerosis Agents – Ampyra

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- Recommendations for the Preferred Drug List (PDL):
  - Do Not Add Ampyra

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Other Business

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Proposed Therapeutic Classes at Next Meeting

PROVIDER SYNERGIES L.L.C.
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- Angiotensin Modulators/ Calcium Channel Blockers Combinations
- Analgesics, Narcotics (Short and Long Acting)
- Angiotensin Modulators
- Antibiotics, GI
- Antibiotics, Topical
- Anticoagulants, Injectable
- Antihistamines, Minimally Sedating
- Antimigraine Agents
- Beta-Blockers
- Bladder Relaxant Preparations
- BPH Treatments
- Calcium Channel Blockers
- Erythropoiesis Stimulating Proteins
- Growth Hormones
- Hepatitis C Agents
- Hypoglycemics, Meglitinides
- Hypoglycemics, TZDs

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Proposed Therapeutic Classes at Next Meeting

PROVIDER SYNERGIES L.L.C.
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- Lipotropics, Other
- Lipotropics, Statins
- Multiple Sclerosis Agents
- Otic Antibiotics
- PAH Agents
- Phosphate Binders
- Proton Pump Inhibitors
- Sedative Hypnotics
- Skeletal Muscle Relaxants
- Ulcerative Colitis Agents

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Next Meeting Date

PROVIDER SYNERGIES L.L.C.
Together, we can do more.

- Next meeting date – May 4 or May 11, 2011

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Public Testimony

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Louisiana Department of Health and Hospitals

Medicaid Pharmaceuticals And Therapeutics Committee

August 11, 2010

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