Connecticut Medicaid and Pharmacy

A Presentation to the Connecticut Healthcare Cabinet
February 14, 2017

Medicaid and Pharmacy

- Reflections on past recommendations to the Health Care Cabinet
- The problems we see from our window
- Reference Materials:
  - Overview of Connecticut Medicaid's Pharmacy Programs

Bailitt Pharmacy Recommendations
October, 2016

- Strategies to better understand drug pricing
- Strategies to maximize state purchasing and regulatory powers to reduce pharmaceutical costs
- Strategies to optimize safe and effective use of medications

Strategies to better understand drug pricing

Rising drug costs are a matter of deep concern to the Department. We, too, seek solutions to these trends and appreciate the opportunity to add our recommendations to the expert's proposals from past meetings.

The Department respectfully cautions the Cabinet about an approach that examines drug costs outside of the context of other health costs and health needs. Such an approach fails to account for the substantial clinical and financial benefits generated by medications and related treatments.

Let's not just look at cost

Medications save money and lives.

PhARMA is correct in its assertion that medications are largely why heart disease rates decreased 46% in the U.S. between 1991 and 2011.

Other examples:

- Epiglottitis and the HIB vaccine
- Children's cancer
- And many others

Let's not look at cost out of context – Hepatitis C medications

- NASHP and Bailitt discussed the high cost of medications, highlighting the new hepatitis C treatments and Massachusetts' suit over high prices.
- Yes, these medications are costly, but these costs must be considered in the context of overall medical costs.

- Previous medications and treatments were:
  - Also very costly to purchase, ineffective and were taken for years
  - Only available by IV and had significant side effects,

so we paid long term health care costs for infusions, progressive liver and other organ disease and failure, including diabetes (another major epidemic), and then paid for a liver transplant

- Whereas the new medications are oral, short term, and curative
- Research suggests these medications are cost effective in 5-7 years.

Connecticut Medicaid's Answer

- Connecticut's Preferred Drug List currently treats all hepatitis C medications as 'preferred' because CT Medicaid is self-insured, so our coverage decisions are different from those of many MCOs and other programs.

CT Medicaid's self-insured model allows us to view this coverage as a worthwhile investment in our members and in our state.

Therefore Connecticut Medicaid focuses our attention on making sure our members are not re-infected with hepatitis C virus, primarily through intensive care management and referral to behavioral health services.

Strategies to better understand drug pricing

Both the Bailitt Proposal and the NASHP Report offer several suggestions which we would like to explore further, including:

- Strategies to maximize state purchasing.
- Strategies to address the rapidly rising costs of specialty pharmaceuticals.
- Pricing and incentive design based upon efficacy, performance and comparative effectiveness research.
- Alternative Medicaid pricing strategies.

Bailitt: Strategies to Maximize State Purchasing

"As a participant in a purchasing coalition, Medicaid should work with the coalition to … align their program formularies and their pharmacy benefit programs to maximize the coalition's purchasing power. The formularies should be based on maximizing pharmaceutical effectiveness, rather than maximizing rebates."

DSS: Joint Purchasing Coalitions

Medicaid is a Federal/State Partnership. Per the Medicaid State Plan, which defines service coverage, provider credentials, and beneficiary eligibility:

- The state pays claims (>10 million prescriptions annually)
- The federal government reimburses the state between 50 - 95% fee for service (the "federal match" or FFP)
- In return for FFP, federal law requires:
  - Payment only for medications whose manufacturers participate in the federal drug rebate program (Omnibus Budget Reconciliation Act of 1990)

DSS: Joint Purchasing Coalitions

Twice in the recent past, the Connecticut Department of Social Services consulted with the Centers for Medicare and Medicaid Services (CMS) to investigate joint purchasing with other non-Medicaid entities within state government. Twice, CMS strongly asserted that:

- The purchasing power of the U.S. Government (federal rebate) is not transferrable.
- Medicaid must enroll 'any willing provider' so that the provider competition strategies used by pharmacy benefit vendors are unavailable to Medicaid programs.

DSS: Joint Purchasing Coalitions

DSS is very cost conscious and seeks to minimize its purchase price for pharmaceuticals. Our pharmacy spend after rebate **decreased** by $55.8 million between 2015 and 2016.

- Connecticut Medicaid maximizes federal and state supplemental rebates, and participates in joint rebate negotiation arrangements with other state's Medicaid programs.
- We cannot responsibly turn our back on rebate arrangements that generate over $750 million annually in favor of an unproven alternative which may not offer similar success.
- Such an arrangement is unlikely to receive required federal approval and would require significant changes to state statutory authority.

Strategies to better understand drug pricing

Both NASHP and the Bailitt proposal call for implementation of strategies to increase drug price transparency, create or better enforce unfair trade and consumer protection laws.

Bailitt specifically recommended that drug manufacturers be required "to disclose to the Attorney General the following pricing information for up to a specified number of high-expenditure drugs (including) discounts and rebates provided to insurers and PBMs, including Medicaid providing coverage to Connecticut residents through Medicaid, private insurance programs, the state exchange and 340B programs."

CT Medicaid applauds these ideas, however:

- Negotiations of rebate, both federal and state supplemental rebates, are based upon manufacturer's business interests balanced with the purchasing power of the largest health care payer and consumer – the U.S. Government.
- We further negotiate supplemental rebate in a cooperative arrangement with 12 other states.
- Rebates are negotiated with an understanding that they will remain confidential and not shared with others.
- As a result of the above, Connecticut's rebate revenue is substantial.
- Again, we hesitate to turn our back on a proven revenue stream in favor of an unproven, untested construct.

A level playing field must truly be level:

- Efforts to increase price transparency must not add to costs, recognizing that rebate and other such arrangements assume a large degree of confidentiality.
- Public purchasing and regulatory models must be consistent with federal match and rebate requirements unless new arrangements can promise state revenues greater than those already recouped by the Department.
- Consumer and other protections, unfair trade laws etc. should be deployed against all unscrupulous health care marketing and trade practices.

Both Bailitt and NASHP Report offered several other creative suggestions which we hope to explore:

- Strategies to address the rapidly rising costs of specialty pharmaceuticals.
- Pricing and incentive design based upon efficacy, performance and comparative effectiveness research.
- Alternative Medicaid pricing strategies.

Addressing Specialty Drug Price Increases

We absolutely agree that specialty drug prices are a growing concern. Part of the challenge is that there is no agreed upon definition of specialty drugs – definitions vary – widely.

Therefore strategies to address their use and costs begs for an agreed upon definition.

- The Bailitt recommendations appear to define 'specialty drug' based upon high cost.
- But also separately seemed to link "specialty drugs" to biologics and biosimilars.
- Other authors/studies define specialty drugs as those that require parenteral administration (IM or IV)

Cost Remains a Major and Growing Challenge -

- The department implemented its first specialty pharmacy authorization requirement on a biologic, palivizumab (Synagis) 10 years ago, because at the time, it was expensive at over $2,000/dose.
- Per your previous experts, looming on the horizon are:
  - Biologics/biosimilars
  - New personalized cancer treatments
  - Genetic therapies
- Per DSS – already here:
  - An epidemic of opioid abuse
  - Growing bacterial resistance to antibiotics

Biologics and Biosimilars

- A biologic is a product manufactured in a living system such as a microorganism, or plant or animal cells.
- Very large and complex molecules.
- Many use recombinant DNA technology.
- A biosimilar is a product that is approved based on a showing that it is highly similar to an FDA-approved biological product.
- Biosimilars are not generic medications. Generic medications are exact copies of small molecules; biologics are too large and too complex to be exactly copied. Biosimilars are clinically similar.

Biologics and Biosimilars

- Biologics are not new – vaccines and insulin are biologic products.
- The complexity and the cost of these products are what is new.
- Bailitt and NASHP offer several recommendations for biologics and biosimilars, as well as other high-cost drugs:
  - Performance purchasing – “money back guarantee”
  - Indication specific pricing – how well a drug performs for a specific illness
  - Bulk purchasing arrangements for public health
  - Enable states to act as Pharmacy Benefit Managers

Performance Pricing

- Bailitt admits that performance pricing is difficult because most drugs do not show long term results within the year or two that most payers require an ROI.
- Fortunately, CT Medicaid doesn't think one year at a time and therefore find the performance pricing idea intriguing.
- DSS agrees that indication-specific pricing would be difficult given the granularity of claims and the rapid increase in medical disease-specific knowledge.
- The FDA needs to set national policy on biosimilars; states cannot do it alone.

Effectiveness Pricing Studies

- Both Bailitt and NASHP mentioned ICER (the Institute for Clinical and Economic Research) as a source of research support for coverage decisions:
  - To evaluate the magnitude of the difference in 'net health benefit' (or, the balance between the clinical benefits the drug offers in relation to the risks or side effects someone might experience from the drug), and
  - The level of certainty that you have in your estimate of net health benefit, based on the evidence available.

DSS Agrees: PCSK9 Inhibitors

DSS' Medical Director has participated on ICER's Comparative Effectiveness Public Advisory Council (CEPAC) since 2012. ICER recommendations helped shape CT Medicaid coverage on topics such as sleep apnea treatment, breast cancer imaging and, most recently, Proprotein Convertase Subtilisin/Kexin Type 9 inhibitors.

- PCSK9 inhibitors were FDA approved in late 2015 as medications to dramatically decrease LDL-cholesterol (the 'bad' kind').
- They were offered as an example of medications that could 'break the bank' but haven't. PhARMA and NASHP offered reasons and thoughts about this, we'd like to offer our thoughts and how ICER's recommendations became coverage policy.

PCSK9i Recommendations:

- ICER's PCSK9i recommendations were both cautious and limited because FDA approval was on the basis of successful lowering of LDL cholesterol
- Impact on cardiac and other diseases remains unproven
- Why is this important?
  - Torcetrapib and related medications –
    - Greatly lowered LDC-cholesterol also, but increased cardiac events

DSS PCSK9i Coverage

- Coverage is available therefore only for those with demonstrated
  - Severe familial hypercholesterolemia
  - Statin intolerance
  - Failure of control with statins, ezetimibe
- So far only 50 requests for coverage
- We suspect that the reason the utilization remains low is that prescribers are waiting to see evidence of efficacy (and pay taxes, too)

DSS: Comparative Effectiveness

To the extent it is available, DSS uses comparative effectiveness research in its coverage decisions, however:

- This science is in its infancy.
- Most research, especially drug research, is supported by manufacturers and therefore effectiveness of the drug is compared against placebo and not against alternative drugs or treatments.
- Comparative effectiveness research must compete with manufacturer marketing, provider and other stakeholder pressures.

Strategies to optimize the safe and effective use of medications

- Bailitt recommended strategies to increase drug adherence, citing numerous reasons why medications are not used as prescribed, further recommending strategies such as the use of financial incentives to increase drug adherence.

- Although commercial payers and employer (including the Comptroller's HEP Program) experience supports this recommendation, Connecticut Medicaid's experience is that such incentives are only marginally effective. Our members have not participation in incentivized medication adherence programs and tobacco cessation programs remains modest.

Strategies to optimize the safe and effective use of medications

What Bailitt, NASHP and PhARMA did not do is comment on the role and responsibility of the FDA.

The bureau that predates the FDA was the result of the Pure Food and Drug Act of 1906, that among other things required that drugs be safe and effective and that later greatly limited direct to consumer advertizing of medications.

- **Per the FDA:**

  "The FDA oversees the advertising of prescription drug products under the Federal Food, Drug, and Cosmetic Act and related regulations. That means the agency must ensure that prescription drug information provided by drug firms is truthful, balanced, and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement, and education program, and by fostering better communication of labeling and promotional information to both health professionals and consumers"

The FDA:

- Is largely silent on biosimilars leaving the states to individually regulate and control them.
- Approves most new medications coming on the market as orphan drugs, with less rigorous efficacy and safety standards required for approval.
- Approves a larger number of new drugs that in past years which later go on to be recalled for safety reasons that initial research and review failed to identify.
  - Vioxx
  - Seldane

Medicaid Pharmacy: Looming Challenges – DSS' Approach

Many of the concerns raised or discussed by representatives from Bailitt, the National Association of State Health Programs (NASHP) and by PhARMA last month are also concerns for Medicaid,

But we would like to offer one of our own...

Opioids – A National Epidemic

- Since 2000, 165,000 people died from an overdose related to opioids in the U.S., a 200% increase in drug overdose deaths due to opioids
- There were 47,055 overdose deaths just in 2014 – a 6.7% increase over 2013
- Heroin-related deaths increased 26% in 2014 and more than tripled since 2010
- Death rates from natural/semisynthetic opiates increased 9%, heroin 26%, and synthetic opioids (other than methadone) 80% respectively, from 2013 to 2014
- In 2013, 1.9 million Americans had an opioid dependency per DSM IV criteria
- This epidemic does not discriminate. Deaths are increased among:
  - Both genders
  - All racial and ethnic groups
  - In most areas of the nation (including the Northeast)
- States experiencing the greatest increases in deaths are those with the highest use of illicit fentanyl including several states in the Northeast
  - MMWR 64(50); 1378-82 (January 1, 2016)

The Epidemic Costs a Lot of Money, too

- Estimated annual direct and indirect costs per the CDC in 2014:
  - $57.7 billion for abuse, dependence, and non-medical use of prescription opiates
  - $20.4 billion for the treatment of overdoses

This epidemic reaches across health plans

- Between 2011 and 2015, commercial plan's payments for opioid-related claims rose 1300% from $3435 to $19,333 per member per year (not including lab data)

Some context…

- In 2002, there was the equivalent one bottle of opioids prescribed per capita for every citizen in the US
- More individuals died from drug overdoses in 2014 than in any other year on record
- Drug overdoses cause more deaths than any other cause of injury and poisoning. They are 1.5 times as frequent as the next leading cause (motor vehicle collisions)
- 1 of every 550 patients prescribed an opioid dies from an opioid-related overdose at a median of 2.6 years from their first opioid prescription (1 of 32 die when using a dosage >200 MEDs)

We mention this because of how we got here…

This epidemic is almost entirely the responsibility of the healthcare industry.

- FDA-approved unique labeling of oxycontin said that it is *less addictive* than other opioids
- Label further warned against crushing the tablet to avoid releasing "*a potentially toxic amount of the drug*" or instructions for abuse
- Increased usage of opioids corresponds directly with marketing efforts for long acting/sustained release opioids beginning in the 1990s.
- Among heroin users in the 1960s, their first use of an opiate was heroin; 75% of current heroin users report their first use of an opioid was one prescribed to them
- Marketed and detailed as "virtually non-addicting" with a risk of "less than 1 percent"

- Where did the “less than 1 percent” come from?

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients' who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had a history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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N.Engl. J. Med, 1980 vol 302(2) pp 123

The Reality:

No high-quality, long term clinical trials demonstrating the efficacy and safety of opiates for chronic non-cancer pain have ever been conducted.

DSS' Opioid Crisis Initiatives

- Provider notification concerning Section 7 of Public Act 16-43 which instructs prescribers to limit opioid RXs to a 7 day supply
- Increase in refill % to limit premature refills
- Increased Behavioral Health intervention
- Long Acting Opioid Prior Authorization
- MME
- Narcan
- Prescriber outreach and education
- Client outreach and Intensive Case Management

In Summary

- Medicaid cannot participate in joint purchasing or other arrangements without facing the loss of substantial federal and rebate revenue.
- Looking at cost and efficacy through comparative effectiveness research is very promising, but faces its own challenges
- Focusing on pharmaceutical costs without context is unwise and dismisses the crucial benefits many of these agents bring.
- Such a narrow focus missed the epidemic in our neighborhoods and in our homes.

Pharmacy Unit

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CADAP Unit
Left to Right: Antonia Ortega, Michael Leary, Jan Washburn
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Questions?

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Connecticut Medical Assistance Program
Pharmacy Program

Reference Materials

Medicaid - Overview

- Title XIX of the Social Security Act
- Enacted 1965 with Medicare (title XVIII)
- Medicaid was enacted as a compromise in order to gather the votes to enact Medicare
- There was originally no long-term plan for financial stability, therefore delegated to the states to administer

Connecticut Medical Assistance Program and Pharmacy

- We serve over 750,000 members (21% of the state residents)
- >10 million prescriptions annually
- 774 enrolled Medicaid pharmacies
- $1.3 billion spent annually

Connecticut Medical Assistance Program and Pharmacy

- HUSKY Program
  - HUSKY A – family coverage
  - HUSKY B – Children's Health Insurance Program (not Medicaid)
  - HUSKY C – 'aged, blind, disabled'
  - HUSKY D – single adults (expansion)
- Special coverage groups/programs:

  Tuberculosis-limited benefit group

  Family Planning-limited benefit group

  CT AIDS Drug Assistance Program (CADAP)

Program Goals

- Positive health outcomes
- Less morbidity and mortality
- Healthier when treated early

  - Decreased overall costs through better medicine
  - Increased provider and client satisfaction

Preferred Drug List

- Created with the advice of the P & T Committee
- It is not a formulary
- Includes only certain classes of drugs
- Coverage decisions based upon many factors, including
  - Efficacy
  - Market share
  - Availability of multiple forms of medications (i.e. liquid medications for kids
  - Cost after rebate
- (Seemingly) odd coverage decisions – brand > generics
- "Non-preferred" medications are still available via prior authorization

Pharmaceutical &Therapeutics Committee

- The Pharmaceutical and Therapeutics Committee ("P&T Committee") for the Connecticut Medical Assistance Program is established under the authority of section 17b-274d of the Connecticut General Statutes. The purpose of the P&T Committee is to adopt one or more PDLs (Preferred Drug List) for use in the Connecticut Medical Assistance Program. As necessary and appropriate, the P&T Committee will **review and evaluate medical criteria, standards, and educational intervention methods concerning the establishment of one or more PDLs and make recommendations to the Department.** The P&T Committee may also make recommendations to the Department regarding prior authorization of any prescribed drug covered by the Connecticut Medical Assistance Program.

P&T Composition and Membership

- Members of the P&T Committee are **appointed by the Governor**. There will be sixteen (16) members as follows: Seven (7) members shall be **physicians** licensed pursuant to Chapter 370 of the Connecticut General Statutes, including one (1) general practitioner, one (1) pediatrician, one (1) geriatrician, one (1) psychiatrist, one (1) child psychiatrist, one (1) oncologist, and one (1) specialist in family planning; four(4) members shall be **pharmacists** licensed pursuant to Chapter 400j of the Connecticut General Statutes; two (2) members shall be visiting **nurses**, one (1) specializing in adult care and one (1) specializing in psychiatric care; one (1) member shall be a clinician designated by the Commissioner of Mental Health and Addiction services; one (1) member shall be a **representative of pharmaceutical manufacturer**; and one (1) member shall be a **consumer representative.**

PDL and Rebate

- OBRA 1990-President George H.W. Bush
  - Prospective Drug Utilization Review
    - Drug/Disease Interactions-edits/audits
  - Patient Counseling Standards
    - Directions/information
  - Maintaining Patient Records
    - Mandatory client information

TOP$

- CT is part of the Provider Synergies L.L.C. TOP$ program
- Multi state pool for administering the PDL
- Includes DE, ID, LA, MD, NE, PA and WI
- Achieve quality pharmaceutical care while achieving optimal state savings

Drug Utilization Review Board

- The Board membership is composed of actively practicing, independently-thinking **pharmacy and medical professionals** and has the responsibility to establish criteria for retrospective review of medication prescribing and dispensing to Medical Assistance recipients. Through their expertise, the board develops retrospective interventions regarding medication usage by Medical Assistance recipients. The Board's mission is to facilitate the appropriate and cost effective delivery of pharmaceutical care.

Patient Safety First!

- Alerts to pharmacy providers-examples
  - Drug-Drug interaction (DD)
  - Drug-Age –Geriatric alert (GR)
  - Overutilization Alert (ER)
  - High Dose Alert (HD)
  - Ingredient Duplication (ID)
  - Therapeutic Duplication (TD)
  - Drug Pregnancy Alert (PG)

Other Utilization Review/Clinical Programs or Innovations

- Step therapy
- Optimal Dose
- Prior Authorization-
  - Hep C
  - PCSK9i
  - LAO
- Morphine Milliequivalent
- OTC coverage

CT Aids Drug Assistance Program (CADAP)

- Partnership with Department of Public Health
- Provide medications related to HIV/AIDS
- Formulary overseen by DPH
- 400%FPL
- Federal oversight via grant-HRSA (Health Resources and Services Administration)