

Opioid Abuse: The Managed Care Perspective

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Background

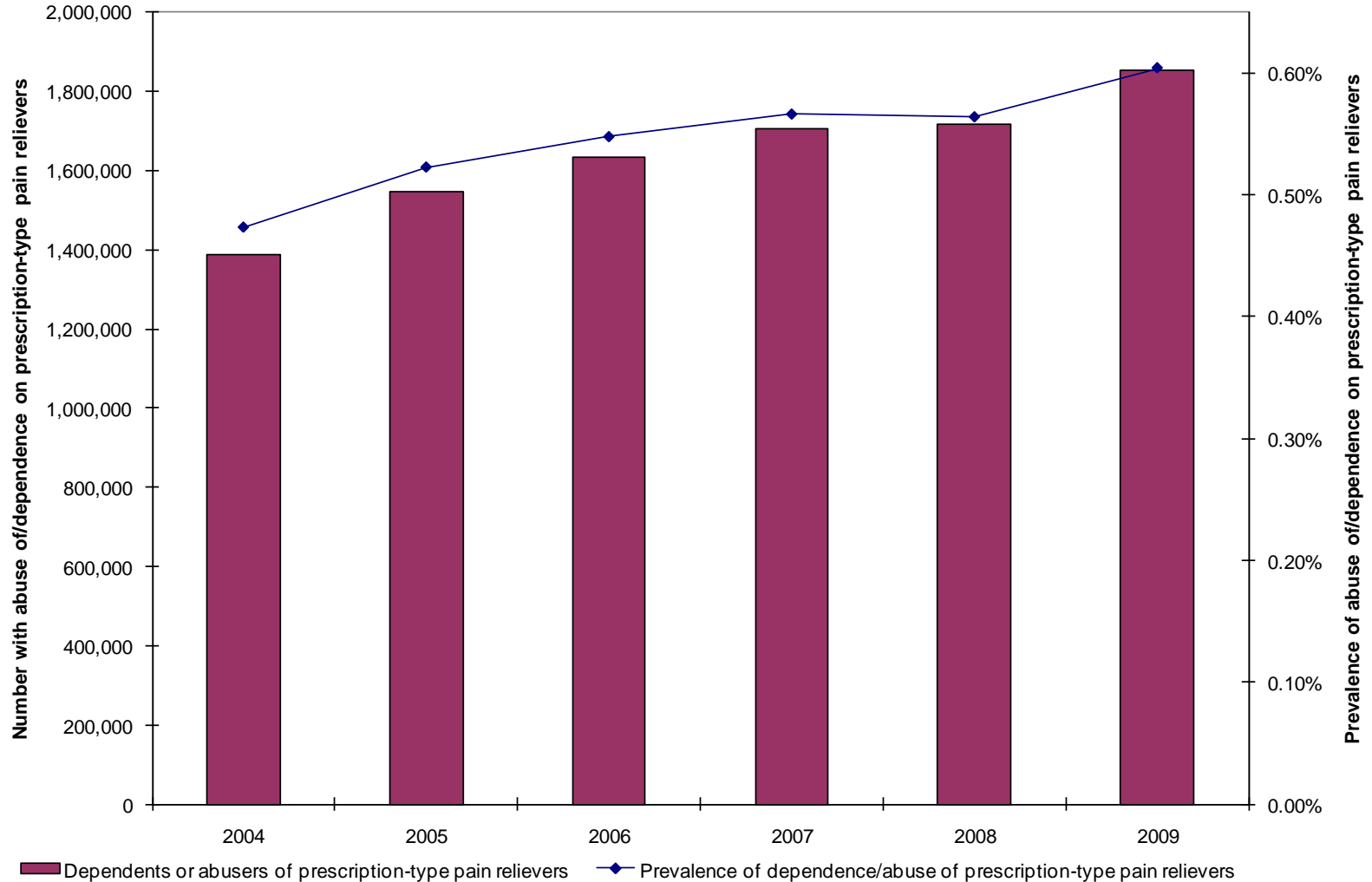
Background

- The latest National Survey on Drug Use and Health reports that 12.4 million Americans used prescription-type pain relievers (i.e., opioids) for non-medical purposes in 2009, up from 11.0 million in 2002¹
 - The 2009 figure represents a 6% increase over 2002, even after controlling for population growth

- Of this population, 1.9 million met the DSM-IV criteria for abuse of or dependence on pain relievers, yielding a national abuse/dependence prevalence of 0.60% in the U.S.^{1,2}

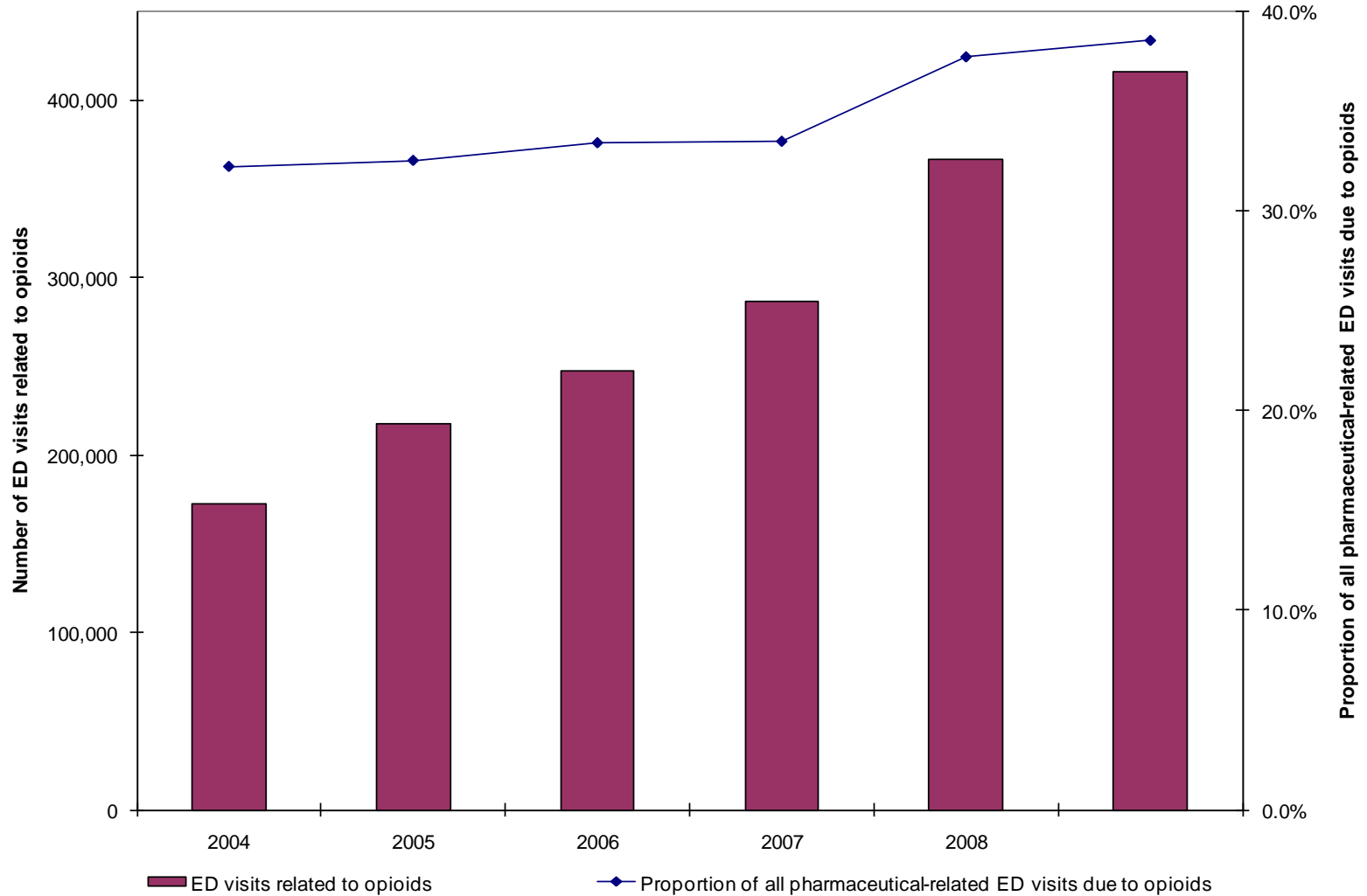
- During 2004-2009, the number of emergency department (ED) visits related to opioid abuse more than doubled from 170,000 to 420,000 according to the Drug Abuse Warning Network³
 - Opioids now account for 39% percent of all drug-related ED visits

Figure 1. Prescription pain reliever abuse/dependence in the U.S., 2004-2009



Source: National Survey on Drug Use and Health (NSDUH), 2004-2009; U.S. Census Bureau

Figure 2. Opioid-related ED visits in the U.S., 2004-2009



Source: Drug Abuse Warning Network (DAWN), 2004-2009

Impact on Managed Care Organizations

Opioid Abuse Impact on Managed Care Organizations (MCOs)

- Opioid abuse, dependence, and misuse imposes a significant monetary burden on MCOs
 - Opioid abusers have substantial direct medical and pharmacy costs
 - Caregivers for abusers face an additional economic burden

- Key considerations facing MCOs in the wake of opioid abuse concerns
 - Assess the cost savings impact of introducing opioids designed to deter abuse and ease of extraction
 - Use of internal medical and drug claims data to identify patients who may be at risk for opioid abuse

- AG research provides insights into key considerations facing MCOs
 - Budget impact model of potential cost savings of abuse-deterrent formulations
 - Claims-based predictive risk model of abuse-type behavior

Costs of Opioid Abuse

Opioid abuse has become a major social problem in the United States

- Annual health care costs per patient diagnosed with opioid abuse, dependence, and misuse (“opioid abuse”) are considerably greater than those of similar patients without any such diagnoses⁴
 - Privately-insured excess costs: \$20,546 per patient and \$1,010 per caregiver
 - Florida Medicaid excess costs: \$15,183 per patient

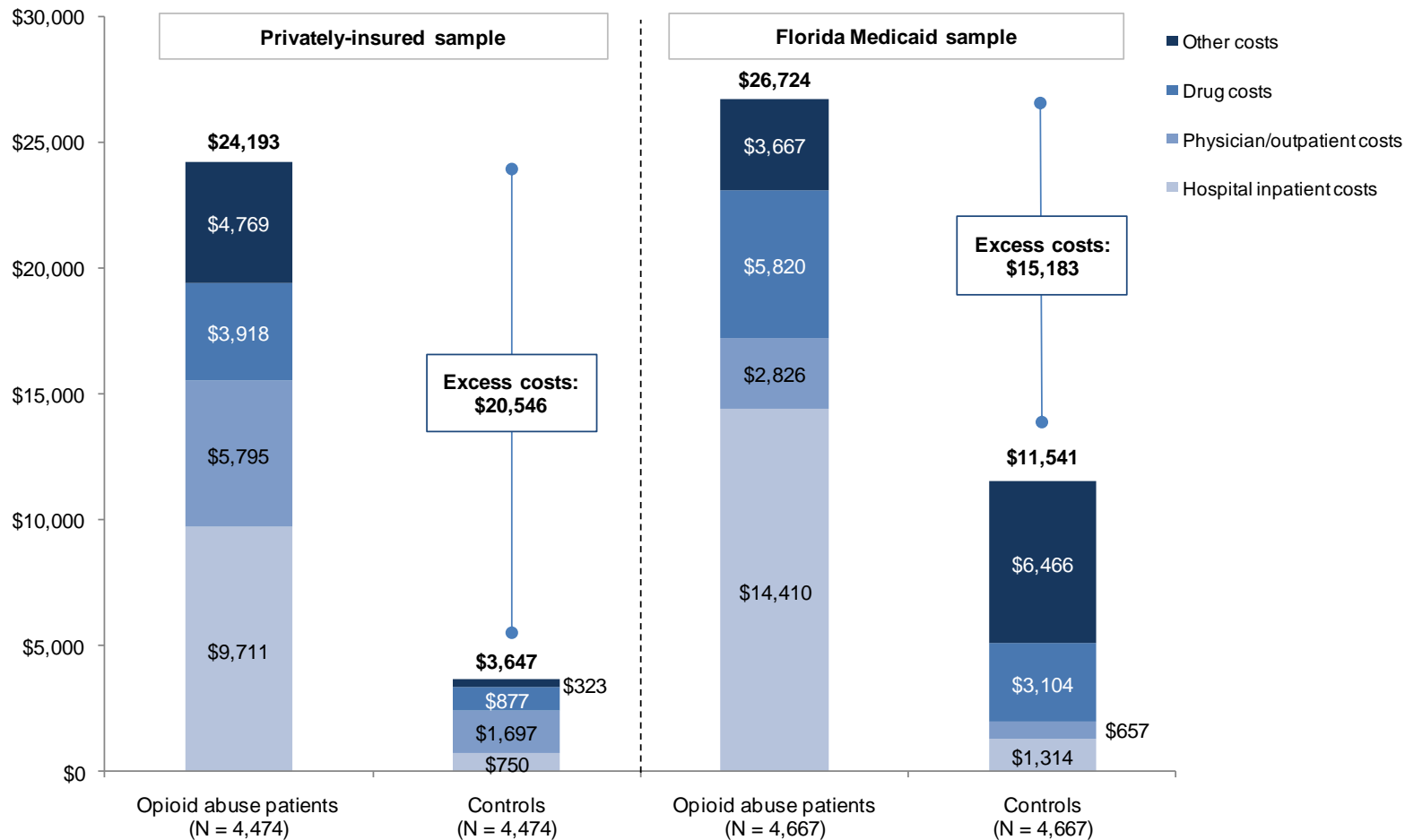
- Estimated societal costs of opioid abuse in the U.S. are substantial⁵
 - Total societal costs: \$55.7 billion
 - Health care costs: \$25.0 billion (45% of total costs)

- Key issues include
 - Abuse and diversion of prescription opioids
 - Undertreatment of pain for those with legitimate need for opioids

- Risk management approaches must balance maximization of the benefits of prescription opioids with minimization of risks associated with abuse⁶

Note: All costs reported in 2009 US\$.

Figure 3. Annual direct costs per opioid abuse patient



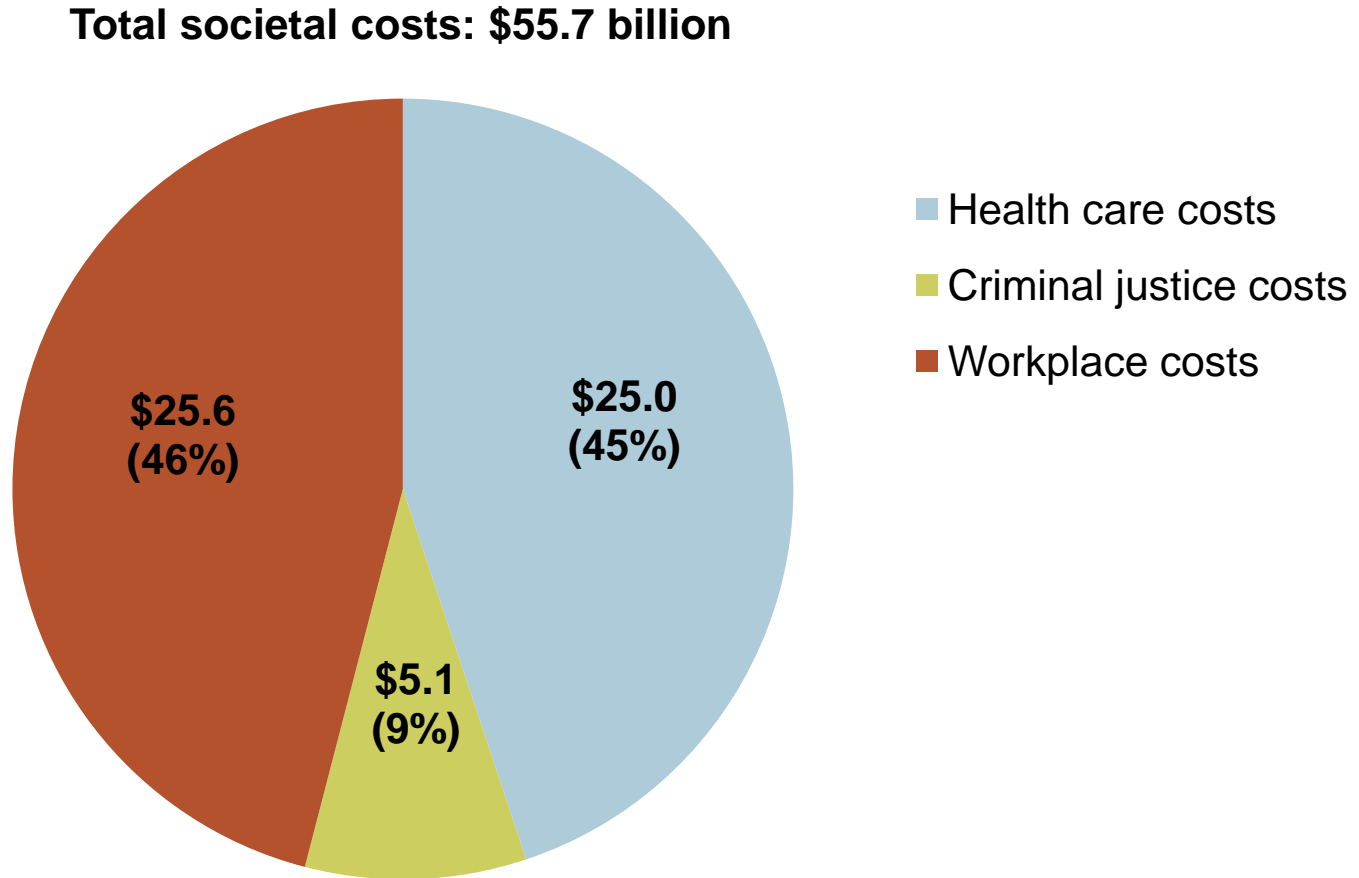
Note.

^aCosts were measured over a 12-month period (the 6 months before and after the index date).

^bOther costs include Emergency Department visits, lab services, and treatment at other places of services.

Source: White AG, Birnbaum HG, Schiller M, et al. The economic impact of opioid abuse, dependence, and misuse. *Am J Pharm Benefits*. 2011 Jun [forthcoming].

Figure 4. Annual societal costs of opioid abuse



Source: Birnbaum HG, White AG, Schiller M, et al. Societal costs of opioid abuse, dependence, and misuse in the United States. *Pain Med.* 2011 [Epub ahead of print].

AG research has examined two key initiatives that may reduce opioid abuse and help curb its costs

1. Design of tamper-resistant opioid formulations
 - Opioids designed to deter abuse or ease of extraction may help reduce prevalence of certain kinds of abuse/misuse (e.g., snorting or injecting)
 - As a result, these new formulations may help reduce costs associated with abuse/misuse including ED visits and hospitalizations

2. Estimation of models to identify patients at risk for opioid abuse
 - Claims data, such as those available to MCOs or prescription drug monitoring programs (PDMPs), can help identify patients who may be at risk
 - Important risk factors for opioid abuse include
 - Unusual prescription-related behavior (e.g., filling prescriptions at multiple pharmacies)
 - Comorbidities (e.g., non-opioid substance abuse, depression)
 - Demographics (e.g., male gender, 18-24 year old age group)

Budget Impact Model: Estimating Cost Savings of Opioids Designed to Deter Abuse

AG recently designed a budget impact model (BIM) with several objectives in mind

1. Assess the potential **cost savings to third-party payers** (e.g., MCOs, pharmacy benefits managers) that may be realized from the introduction of opioids designed to deter abuse
2. Quantify **health care impact of market entry** of opioids designed to deter abuse (e.g., reduced hospitalizations and ED visits)
3. Estimate **annual cost savings** resulting from health care impact
 - Direct medical cost savings (i.e., from a plan perspective)
 - Disability and absenteeism cost savings (i.e., from an employer perspective)
 - Drug cost offsets (i.e., from a pharmacy benefit manager perspective)
4. Evaluate the impact for **different populations** and under **various scenarios**
 - E.g., different assumptions regarding market share captured

BIMs can examine key prescription drug and medical-related outcomes associated with the abuse of prescription opioids

- Direct medical services
 - ED visits
 - Hospitalizations
 - Outpatient care
 - Substance abuse-related drug treatment (e.g., buprenorphine)
 - Diseases associated with injection (e.g., HIV, hepatitis, endocarditis, skin infection/abscess, cellulitis, phlebitis)

- Prescription drugs
 - Non-opioid prescription drug use
 - Opioids filled for purposes of abuse/misuse

BIMs can be designed with the flexibility to generate plan-specific estimates

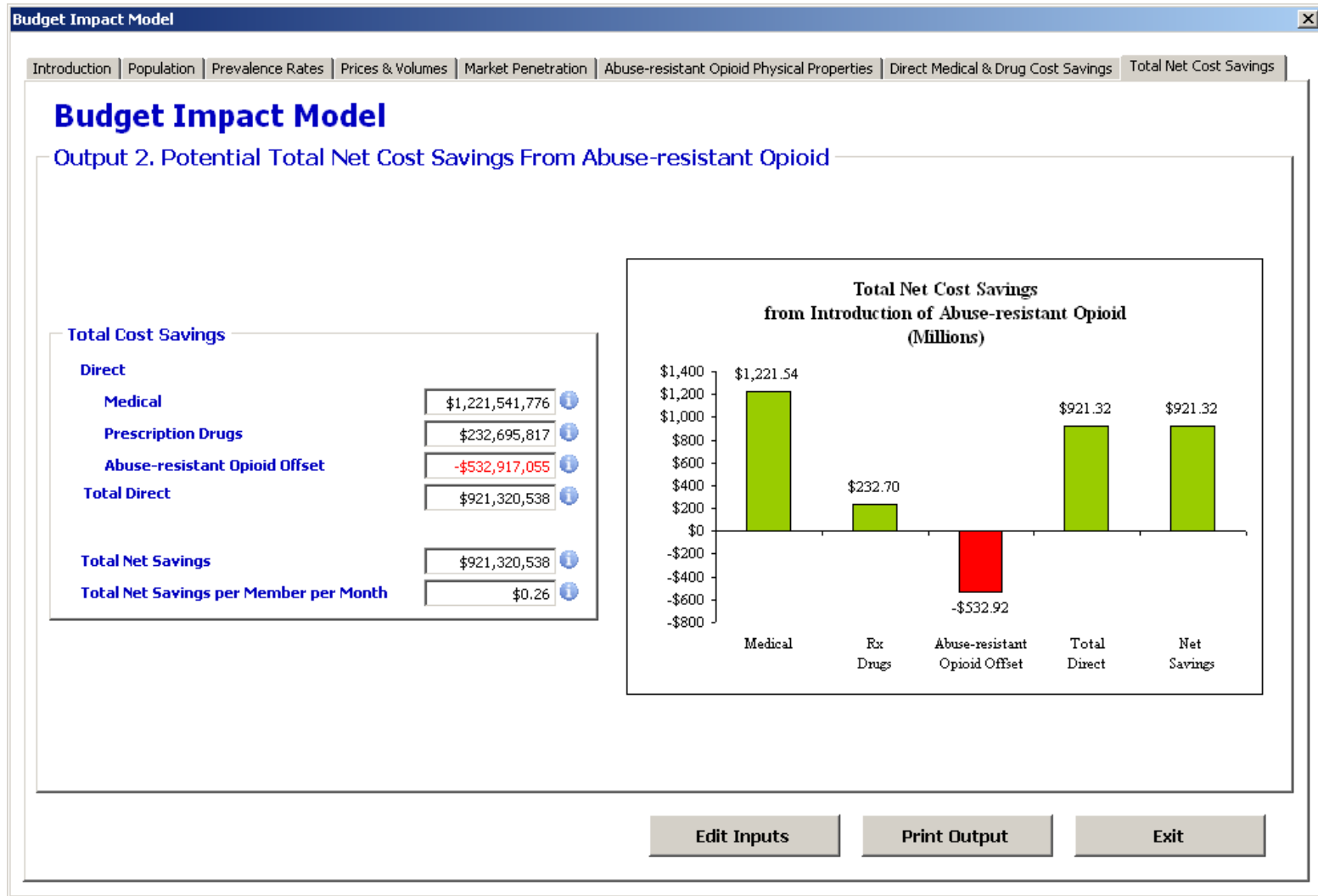
- User-defined model inputs include
 - Number of insured lives
 - Age distribution of insured lives
 - Prevalence of opioid abuse
 - Amount reimbursed for a 30-day supply of existing branded and generic opioids as well as for abuse-deterrent formulation
 - Number of 30-day opioid prescriptions (existing branded or generics) reimbursed per year
 - Market share captured from existing branded and generic opioids by abuse-deterrent formulation
 - Methods of abuse potentially prevented by abuse-deterrent formulation

AG's BIM estimated cost savings under three main scenarios

Scenario #1	Scenario #2	Scenario #3
<p>Abuse-resistant opioid captures:</p> <ul style="list-style-type: none"> • 100% of branded formulations of oxycodone ER • 15% of branded and 15% of generic formulations of methadone, transdermal fentanyl, morphine ER and oxymorphone ER <p>Proportion of opioid abusers who continue to abuse after shifting to abuse-resistant opioid:</p> <ul style="list-style-type: none"> • 0% injection • 0% snorting • 0% chew and swallow • 100% swallow • 100% other method of abuse <p>Abuse-resistant opioid priced at parity to branded oxycodone ER</p>	<p>Abuse-resistant opioid captures:</p> <ul style="list-style-type: none"> • 68% of branded formulations of oxycodone ER • 20% of branded and 20% of generic formulations of methadone, transdermal fentanyl, morphine ER and oxymorphone ER <p>Proportion of opioid abusers who continue to abuse after shifting to abuse-resistant opioid:</p> <ul style="list-style-type: none"> • 5% injection • 5% snorting • 20% chew and swallow • 100% swallow • 100% other method of abuse <p>Abuse-resistant opioid priced at parity to branded oxycodone ER</p>	<p>Abuse-resistant opioid captures:</p> <ul style="list-style-type: none"> • 52% of branded formulations of oxycodone ER • 10% of branded and 10% of generic formulations of methadone, transdermal fentanyl, morphine ER and oxymorphone ER <p>Proportion of opioid abusers who continue to abuse after shifting to abuse-resistant opioid:</p> <ul style="list-style-type: none"> • 20% injection • 20% snorting • 50% chew and swallow • 100% swallow • 100% other method of abuse <p>Abuse-resistant opioid priced at parity to branded oxycodone ER</p>
Cost Savings	Cost Savings	Cost Savings
Direct medical	Direct medical	Direct medical
\$1.9 billion	\$1.2 billion	\$711 million
Prescription drug	Prescription drug	Prescription drug
\$365.6 million	\$232.6 million	\$141.1 million
Drug cost offset	Drug cost offset	Drug cost offset
-\$798 million	-\$532.9 million	-\$267.7 million
Total	Total	Total
\$1.5 billion	\$0.9 billion	\$584.4 million

Reproduced from “White AG, Birnbaum HG, Rothman DB, Katz NP. Development of a budget-impact model to quantify potential cost savings from prescription opioids designed to deter abuse or ease of extraction. Appl Health Econ Health Policy. 2009;7(1):61-70.” with permission from Adis, a Wolters Kluwer business (© Adis Data Information BV 2009. All rights reserved.)

Figure 5. Screenshot of BIM output based on scenario #2



Risk Models: Identifying Patients At Risk for Opioid Abuse Using Claims Data

A data-driven approach to identifying at-risk patients is important to multiple stakeholders

- Payers (e.g., MCOs, PBMs)
 - Identification of at-risk individuals can help control costs, reduce fraud, and improve quality of care

- State public health and controlled substance authorities
 - Public health authorities need evidence-based methods to characterize and identify at-risk individuals and communities
 - PDMP administrators need validated cutoffs for threshold reports

- Federal government
 - National prescription monitoring legislation requires a rational, evidence-based implementation

- Clinicians
 - “External” outcome measures are critical for assessing clinical outcomes

AG research assessed the feasibility of using different mixes of claims data to identify patients at risk for opioid abuse

1. Drug claims model

- Based on prescription drug data (i.e., similar to what is available to PDMPs)

2. Medical claims model

- Based on data regarding medical services utilization and comorbidities

3. Integrated model

- Based on a combination of medical and prescription drug claims (i.e., similar to what may be available to MCOs)

Using privately-insured claims data from the state of Maine, several important risk factors were identified

Risk Factors from Drug Claims

- Demographics
 - Age (e.g., 18-24 years)
 - Gender (e.g., male)
- Utilization parameters
 - Number of opioid prescriptions
- Atypical prescription-related behavior
 - Receiving opioids from multiple pharmacies or multiple physicians
 - Refilling prescriptions early*
 - Consecutive, large (>50%) increases in dosage

Risk Factors from Medical Claims

- Demographics
 - Age (e.g., 18-24 years)
 - Gender (e.g., male)
- Medical diagnoses
 - Non-opioid substance abuse, depression, PTSD, hepatitis, cancer, fibromyalgia
- Medical treatment facility visits
 - Hospitalizations
 - Mental health outpatient care

*Based on days supply (i.e., filling a second prescription for the same drug with >10% of the first prescription remaining)

Source: White AG, Birnbaum HG, Schiller M, et al. Analytic models to identify patients at risk for prescription opioid abuse. Am J Manag Care. 2009;15(12):897-906.

Conclusion

Conclusion

- Prevalence of opioid abuse and related health care events continues to grow

- Opioid abuse imposes substantial costs on MCOs
 - At the patient level, both abusers and their caregivers have substantial excess costs
 - At the societal level, opioid abuse costs over \$50 billion annually

- Two potentially fruitful strategies for addressing opioid abuse are
 - Introduction of opioids designed to deter abuse or ease of extraction
 - Evidence-based analysis to better identify patients who may be at risk for opioid abuse

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