

A STUDY OF NEW JERSEY SENATE BILL 1313

*Mandated Health Benefits Coverage for Opioid
Analgesics with Abuse-Deterrent Properties*

The Mandated Health Benefits Advisory Commission
New Jersey Department of Banking and Insurance

Report to the New Jersey State Senate
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Introduction

The New Jersey Mandated Health Benefits Advisory Commission (MHBAC) has been asked to review Senate Bill 1313, which would require that health insurers provide coverage for prescribed abuse-deterrent opioid (ADO) analgesic drugs at a cost that "shall not exceed the lowest cost-sharing level applied to brand name non-abuse-deterrent opioid drugs...[or] to generic non-abuse-deterrent opioid drugs covered under the applicable contract." ⁱ The Mandated Health Benefits Advisory Commission Act (N.J.S.A. 17B:27D-1) tasks the Commission with providing an independent analysis of the social, medical, and financial impact of proposed legislation referred to it for review. ⁱⁱ

The MHBAC prepared this report using its own resources, including staff from the New Jersey Department of Banking and Insurance. Commission members contributed their professional expertise in helping to shape the presentation of this report, analyzing published research, and drafting and editing its various sections.

Social Impact

This section examines the potential social impact of mandating coverage of abuse-deterrent opioids in the context of an on-going national opioid abuse epidemic, which has not spared New Jersey.

Among the social consequences the MHBAC is asked to address is *the extent to which insurance coverage for the proposed mandated health benefit already exists or, if no coverage exists, the extent to which the lack of coverage results in inadequate health care or financial hardship for the affected population of New Jersey*. The Commission concludes that:

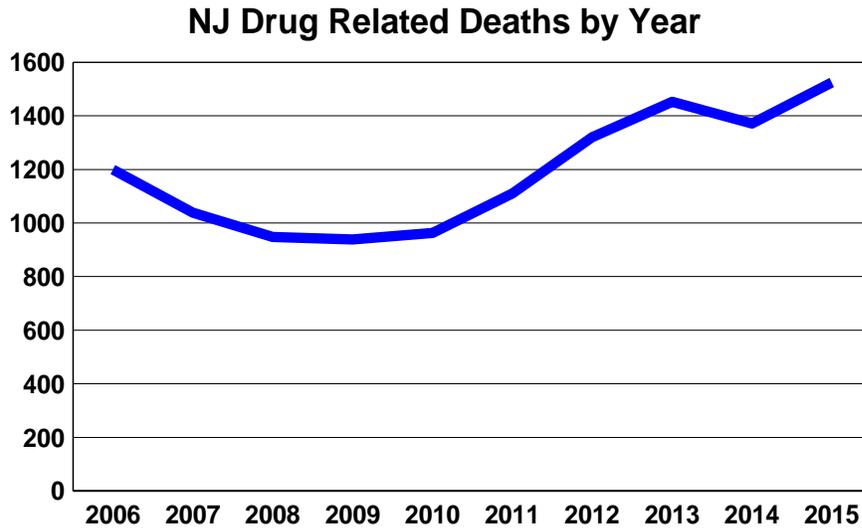
- The benefit already exists in the State; New Jersey Department of Banking and Insurance (NJDOBI) rules prohibit insurance carriers from having "closed formularies," in which a drug is not covered because it is not on the formulary; carriers can, however, designate preferred drugs on a formulary and institute differential cost sharing, based upon whether or not a drug is in the preferred category.
- Because NJDOBI rules put a ceiling on co-pays for all drugs, the financial hardship on New Jersey consumers may be more muted than it might otherwise be.
- Because this bill mandates that higher cost abuse-deterrent opioids will not experience higher cost-sharing than lower cost alternative opioids, it is expected to restrict the ability of carriers to negotiate costs from manufacturers. ⁱⁱⁱ, ^{iv}

Background

Opioid and opiate related morbidity and overdose mortality are, together, a major public health problem in New Jersey. Nationally, in 2014, "nearly 2 million Americans abused or were dependent on prescription opioids; another 10.3 million (had) used prescription opioids for a non-medical purpose in

the past year." ^v Drug-related deaths in New Jersey rose to 1,587 in 2015, a 21.7% increase over 2014 (see Figure 1 for the ten-year trend in drug-related deaths in New Jersey).

Figure 1. New Jersey Drug-Related Deaths, 2006-2015



Source: New Jersey Office of the State Medical Examiner (OSME)

Among the 1,587 drug-related deaths in 2015, 918 involved heroin and 417 involved fentanyl.^{vi} We define “fentanyl” throughout this analysis to include both the prescription compound Fentanyl and the synthetic, illicit drug fentanyl. (See Table 1 for a four-year comparison of drug-related deaths by the drugs involved in the deaths.)

Table 1. Drug-Related Deaths, by Drug, 2012-2015

Year	Total	Heroin	Fentanyl	Oxycodone
2012	1223	514	42	303
2013	1336	567	46	290
2014	1304	706	142	248
2015	1587	918	417	302

Source: New Jersey Office of the State Medical Examiner (OSME)

[N.B., Some of the drug-related deaths in this table tested positive for multiple drugs. If a single case tested positive for heroin, fentanyl, and oxycodone, for example, each respective column would include a count for each drug. The columns for specific drugs, therefore, will sum to a greater number than the total number of drug deaths in a given year.]

Between January 1, 2015 and December 31, 2015 there were 11,351 instances of naloxone deployment.^{vii} The generic drug, naloxone, also known by the brand name, Narcan, is administered to counteract the effects of opioid overdose. The number of naloxone doses administered cited above could include repeat administrations of the drug to the same person in 2015. In the same time period, the New Jersey Substance Abuse Monitoring System recorded 48,640 unduplicated admissions for substance abuse treatment.^{viii} Opioid abuse comes at an enormous economic cost to the country related to lost wages and economic productivity, healthcare expenses, and substance abuse treatment; this cost was estimated to be \$78.5 billion for the United States in 2013.^{ix}

Discussion

Opioid prescriptions are the gateway for three associated problems. The first problem is the unintended addiction of patients prescribed opioids for pain, whether they are an immediate-release, a sustained-release, or an abuse-deterrent formulation. While no data exist regarding the extent of this problem in New Jersey, a study of outpatients prescribed opioids for chronic, non-cancer-related pain at the Geisinger Clinic, determined that 26% met the criteria for current opioid dependence; age above 65 and concurrent depression, psychotropic medications and pain impairment all increased the risk of dependence.^x In a different study examining adolescent substance abuse, Vosburg and colleagues found that 17% of those addicted obtained their first opioid via a legal prescription for pain.^{xi}

The second problem is that opioids in the home lead to accidental ingestions. Between 1997 and 2012, pediatric hospitalizations for accidental opioid ingestion increased two-fold; the greatest risk of exposure occurred in young children and older adolescents.^{xii} Lovegrove and colleagues found that the drugs most commonly associated with childhood emergency hospitalization for accidental ingestion, nationally, between 2007-2011, were opioids and benzodiazepines; the most common drug ingredient in these cases was buprenorphine, a narcotic agonist used in the treatment of opioid addiction, and the most frequently hospitalized were children between one and two years of age.^{xiii} A related and burgeoning problem is the five-fold increase, over the past decade, of newborns born opioid-dependent to opioid-addicted mothers; SAMSHA (U.S. Substance Abuse, Mental Health and Addiction Services) reports that as of January 2017, about 21,000 pregnant women/month are using opioids for non-medical purposes.^{xiv}

The third problem is the diversion of prescription opioids into the street or illegal market. Among the participants in Vosburg's study of adolescent substance abuse, 56% were given prescription opioids by family or friends, 17% took them from family or friends, and 11% purchased them from a friend.^{xv} Between 2013 and 2014 (after abuse-deterrent opioid formulations were available for oxycodone, hydrocodone and morphine),^{xvi} the New Jersey Medical Examiner determined that there was a 14% reduction in opioid overdose deaths due to oxycodone, a 42% reduction in deaths from oxymorphone, and a 60% reduction in deaths due to morphine. At the same time there was a 9% rise in deaths due to hydrocodone, a 23% rise in deaths to heroin, and a staggering 208% rise in deaths due to fentanyl. This

reveals, overall, fewer deaths due to prescription opioids, and a parallel rise in the deaths due to illegal, cheaper heroin and fentanyl, either alone or in combination with heroin and prescription opioids.^{xvii} The numbers reported here are proportions, not rates, so it's possible for proportions to change without a change in rates.

Medical Evidence

This section reviews the medical literature for evidence of the impact of abuse-deterrent opioids, as demonstrated in well-designed, empirical studies. An examination of the New Jersey data for a four-year period shows an alarming trend in overdose deaths involving heroin and fentanyl. As presented in Table 1 above, between 2012 and 2015 heroin involvement as a percentage of drug overdose deaths increased nearly 38%, fentanyl involvement in overdose deaths increased 665% in the same period, while oxycodone involvement in overdose deaths decreased 23% between 2012 and 2015.

This begs the question: has the introduction of abuse-deterrent opioids (ADOs) reduced accidental exposure to or abuse of opioids? Extended-release opioids (EROs) are associated with a greater risk of abuse and overdose than immediate-release opioids (IROs).^{xviii} Currently, abuse-deterrent formulations exist only for EROs and not for IROs.^{xix} One study used data from the National Poison Control Data System (NPCDS) to compare outcomes for these different opioid formulations. It is important to note that the NPCDS data come from voluntary telephone calls to poison control centers and, therefore, do not represent a random sample of opioid poisonings and might not accurately reflect the population experience. In this study, the authors compared NPCDS data from two years before to two years after the introduction of an abuse-deterrent formulation of extended release oxycodone. The authors use the abbreviation ERO for extended-release opioids and SE for single-entity, immediate-release opioids. Coplan and colleagues found that:

"Abuse exposures for ERO decreased 36% (130 to 83), increased 20% for other SE oxycodone (229 to 273), and increased 42% (356 to 505) for heroin. Unintentional therapeutic errors affecting patients for ERO decreased 20% (161 to 129) and increased 19% (223 to 265) for other SE oxycodone. Unintentional general (accidental) exposures for ERO decreased 39% (75 to 46), changed 0% (189 to 189) for other SE oxycodone, and increased 21% for heroin (22 to 27). The majority (63%) of unintentional general exposures were among children 1 to 2½ years of age. In the age category of 12 to 29.9 months of age, accidental exposures decreased by 51% (95%CI: -60%, -40%) from before to after reformulation."^{xx}

Therapeutic errors are defined by the National Poison Data System as errors affecting patients resulting from unintentional deviation from a proper therapeutic regimen that results in a wrong dose, incorrect route of administration, administration to the wrong person, or administration of the wrong substance. (Coplan, *op.cit.*, p.3).

While there is some indication in the literature that the introduction of abuse-deterrent formulations decreased the abuse of extended-release opioids in the first years after their introduction, experts differ in their opinions as to whether or not ADOs have driven the increase in abuse of illicit opioids, like heroin and fentanyl.^{xxi}, ^{xxii} ADOs are resistant to crushing (and therefore snorting) and they are more expensive than non-abuse-deterrent formulations; switching to easier to use non-ADOs and cheaper alternatives (*i.e.*, illicit heroin and fentanyl) is widely reported^{xxiii}, ^{xxiv}. It is estimated that only about 4% of individuals abusing prescription opioid formulations move on to heroin abuse, but this constitutes a large population, because so many abuse the former.^{xxv}

The evidence from empirical studies is mixed. Compton and colleagues, for instance, conclude that a rise in heroin abuse began in 2006, before the introduction of ADOs, and has paralleled the rise in all non-medical opioid use. These authors assert that the introduction of ADO formulations and other abuse-deterrent strategies, like the mandated use of prescription monitoring programs in states, and institutionally-based policies limiting prescriptions for types and quantity of opioids, cannot be construed as causing the heroin epidemic.^{xxvi}

In sharp contrast, a January, 2017 National Bureau of Economic Research (NBER) working paper explicitly links the introduction of the abuse-deterrent formulation of OxyContin with a rise in the abuse of and overdose deaths due to heroin. While the working paper's authors acknowledge a reduction in the abuse of OxyContin itself in the first years after the introduction of its abuse-deterrent formulation, this was overcome by a switch to abuse of other prescription opioid formulations, to heroin, and most recently, to fentanyl.^{xxvii} The evidence on the causal relationship between the introduction of ADOs and the increased use of other drugs, such as heroin and fentanyl, is therefore contradictory and inconclusive.

The introduction of ADOs has been associated in some notable instances with unforeseen, unintended and negative consequences. Substance abusers driven by the high "likeability" (*i.e.*, positive effects/few negative effects)^{xxviii} of extended-release oxycodone, have successfully overcome the tamper-resistance of the abuse-deterrent formulation by melting it down and injecting it. Needle sharing, not uncommon among those injecting opioids, increases the risk of contracting HIV, as well as Hepatitis B and C. Additionally, ADOs continue to be abused in oral form.^{xxix} Twenty five percent of the teenagers in Vosburg's study claimed that ADOs might have reduced the likelihood that they would have begun to abuse them; data from that study also showed that the small subgroup of prescription opioid abusers most likely to move to heroin use were those who had manipulated extended-release opioids for chewing, snorting or injection.^{xxx}

When primary care physicians' knowledge about opioid abuse and diversion was assessed by national sample in 2014, 46% of doctors incorrectly answered that abuse-deterrent formulations were less addictive than other opioids.^{xxxi} The phrase "abuse-deterrent" is apparently associated with a false sense of security among a significant number of prescribers, underscoring the necessity of prescriber education to help address the on-going epidemic. Ironically, given this "misconception" that ADOs are

less addictive than other opioids, the availability of ADOs may lead to increased prescribing, which may lead to an increase in addiction.

In its 2016 "Guideline for Prescribing Opioids for Chronic Pain," the Centers for Disease Control and Prevention (CDC) exclude abuse-deterrent formulations, noting that: "The abuse-deterrent label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations."^{xxxii}

Summary

In summary, abuse-deterrent opioids are not the panacea for opioid addiction that their title might suggest, given their increased cost compared to other formulations, the fact that they are not fully abuse-resistant and can be abused orally, the unanticipated associated risks of increasing heroin and fentanyl abuse when individuals switch to these cheaper alternatives, and the potential for increased rates of diseases like HIV and Hepatitis B and C when they are melted down and injected with shared needles. Studies suggest that the most positive social impact that ADOs have had are on reducing immediate fatalities in children after accidental ingestion, and reducing prescribing errors by clinicians. These pros and cons are delineated in Table 2, below.

Table 2. Pros and Cons of Abuse-deterrent Opioid (ADO) Formulations

PROS	CONS
<ul style="list-style-type: none"> Resistant to immediate abuse by snorting or crushing 	<ul style="list-style-type: none"> Not fully abuse-resistant; can still be abused orally or melted for injection or snorting
<ul style="list-style-type: none"> Reduced rates of (immediate) fatalities from accidental ingestion by children, because pills are not chewable. 	<ul style="list-style-type: none"> Abuse-resistance properties and higher cost may lead some to switch to cheaper heroin and illicit fentanyl
<ul style="list-style-type: none"> Reduced rates of therapeutic errors by prescribers 	<ul style="list-style-type: none"> Higher lethality from heroin and fentanyl overdose
	<ul style="list-style-type: none"> Risk of HIV, Hepatitis B & C from injections of all opioids
	<ul style="list-style-type: none"> Prescribers' false sense of security about addiction- and abuse-potential might increase prescribing of ADOs, possibly leading to more addiction and an increased supply of opioids in the community
	<ul style="list-style-type: none"> Increased costs for all payors

Finally, Table 3 lists the major risk factors associated with opioid overdose:

Table 3: Opioid Overdose Risk Factors:

<ul style="list-style-type: none">• Male
<ul style="list-style-type: none">• Non-Hispanic white
<ul style="list-style-type: none">• Lower Socioeconomic status
<ul style="list-style-type: none">• Rural residence
<ul style="list-style-type: none">• Middle age
<ul style="list-style-type: none">• Mental illness
<ul style="list-style-type: none">• Medical condition involving chronic pain
<ul style="list-style-type: none">• High dose prescription for opioid
<ul style="list-style-type: none">• Concomitant prescription of benzodiazepine
<ul style="list-style-type: none">• Multiple prescriptions
<ul style="list-style-type: none">• Multiple prescribers
<ul style="list-style-type: none">• Community where higher than average number of opioid prescriptions being written

Adapted from: Paulozzi, L. (2012). Prescription drug overdoses: A Review. *Journal of Safety Research*. 43: 283-289.

Financial Impact

The MHBAC is tasked with evaluating the impact of the passage of S 1313 on the costs of health insurance and prescription coverage in New Jersey, as well as examining how those costs are likely to be allocated among the various payors. S 1313 requires coverage of at least one prescribed ADO per opioid analgesic active ingredient on a health plan's formulary or prescription drug list.^{xxxiii} This requirement is placed on the following:

- hospital/medical/health service corporation contracts,
- health maintenance organization contracts,
- individual and group health insurance policies,
- individual and small employer health benefit plans,
- State Health Benefits Commission, and
- School Employees Benefits Commission.

As a result, New Jersey's commercial health insurance markets, comprised of the Individual Health Coverage (IHC), Small Employer Health (SEH), and mid- and large-employer insured markets, are affected by S 1313. Approximately 1.7 million New Jersey lives are covered by insured health plans from these commercial markets.^{xxxiv}

In addition, S 1313 impacts New Jersey's State health plans - State Health Benefits Program (SHBP) and School Employees' Health Benefits Program (SEHBP). These programs are self-funded by the State and provide health benefits to New Jersey's state and school employees, retirees, and their dependents. The number of lives covered by the State's health prescription drug plans is approximately 700,000 as of 2016.^{xxxv}

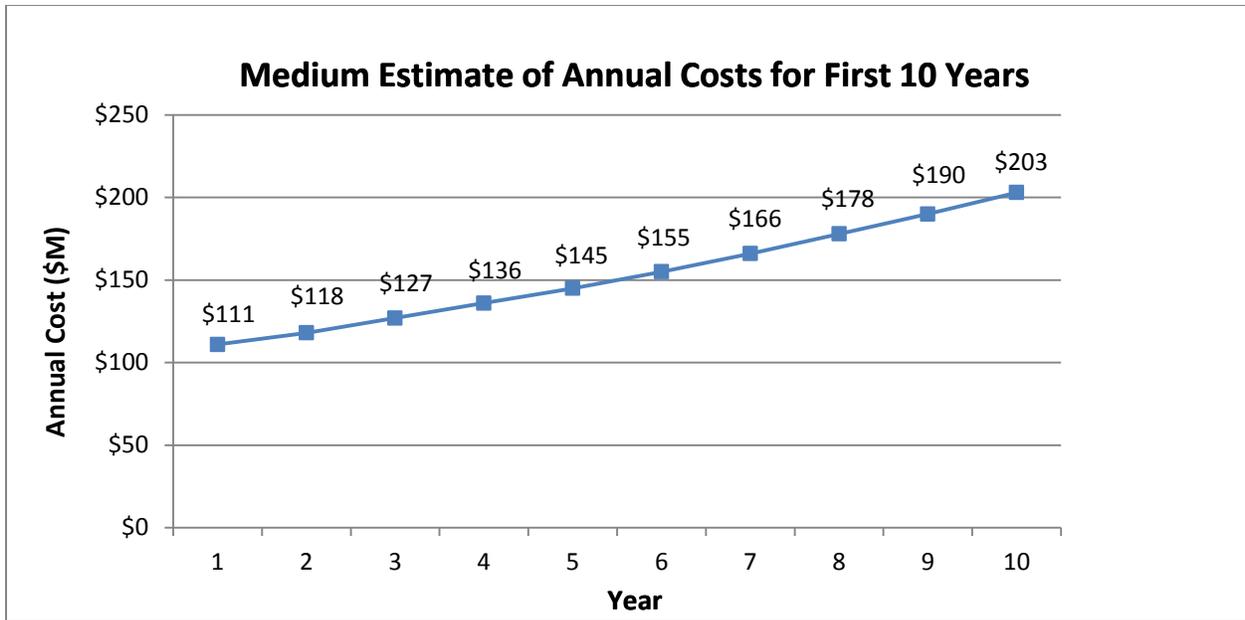
Cost of S 1313

The estimated cost of S 1313 for the first full year after passage is \$111 million.^{xxxvi} This cost represents our "medium" estimate of the change in prescription drug costs for commercial carriers and the New Jersey State health plans from the passage of S 1313. These costs are borne by the individuals, employers, and carriers participating in the commercial markets, and by the State and its employees and retirees participating in the SHBP and SEHBP. These extra costs arise because of the price difference between ADOs and non-ADOs and expected substitution of ADOs for non-ADOs prescriptions. In effect, the cost estimate anticipates manufacturers of ADOs to use passage of S 1313 as an opportunity to market and tout the advantages of ADOs being covered as a Tier 1 drug benefits that qualifies for the most favorable cost-sharing provisions.^{xxxvii}

The cost estimate of \$111 million was developed using health plan enrollment data and opioid drug price and claims data supplied by the New Jersey Department of Banking and Insurance, New Jersey Department of Treasury (Division of Pensions and Benefits), and commercial market insurance carriers. The cost estimate is based on the average prices of ADO and non-ADO scripts, calculated from a number of different opioid medications, and the number of opioid scripts consumed per person per year.^{xxxviii} These assumptions were derived from the data provided by the sources above.

S 1313 would increase insurance costs as a result of the price difference between non-ADO and ADO formulations. The price of a typical ADO script is many times higher than the price of a comparable non-ADO script. For example, a 30-day supply of Pfizer's abuse-deterrent Embeda, a combination drug containing morphine, costs \$268, while a 30-day supply of generic morphine costs roughly \$38.^{xxxix}

If passed, S 1313 will have an ongoing effect. The estimated costs for the first ten years after passage are shown on the chart below.



After the first year, the estimated cost increases from \$111 to \$118 million and steadily increases to \$203 million by the tenth year after passage. The present value (in current dollars) of these costs for the ten-year period is approximately \$1.3 billion.^{XL}

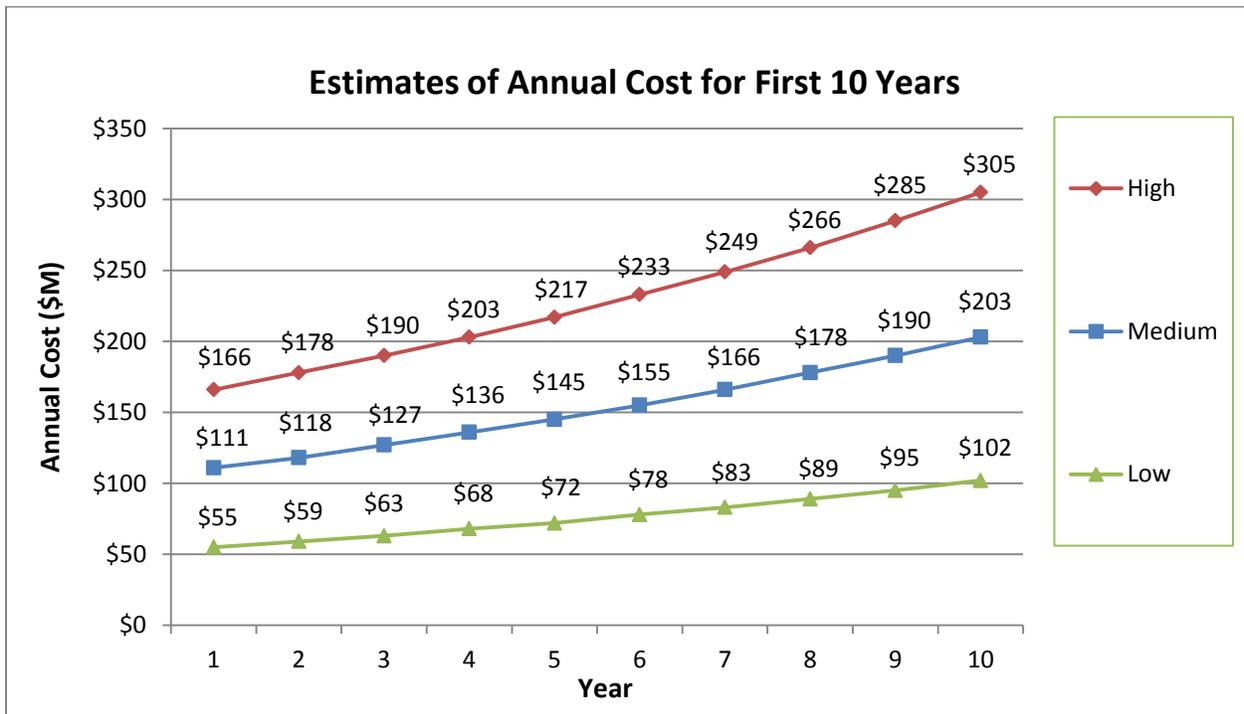
The yearly cost increases are not due to an increase in the number of individuals and employers purchasing health coverage in the commercial markets, nor an increase in the number of participants in the State health programs. The data indicate the growth in the number of purchasers in the commercial markets and participants in the State health plans has been relatively flat.^{XLI} Hence, it was assumed that the number of lives covered in the commercial markets and State health plans would remain constant.

Rather, the reason for the increase in estimated yearly costs for the ten-year period is the assumption that prescription opioid drug prices will increase 7% annually.^{XLII} This assumption is based on prescription drug cost increase projections found in carrier rate filings submitted to the New Jersey Department of Banking and Insurance and historical prescription drug claims data found in the State health plans annual rate renewal reports.^{XLIII}

A key assumption used in developing the cost estimates is the percentage of future opioid scripts that are ADO scripts (versus non-ADO scripts). The New Jersey data show that ADO scripts currently comprise approximately 1% of all opioid scripts. Upon passage of S 1313, this percentage is assumed to increase due to the requirement that ADOs be in health plans' formularies, increased awareness of potential opioid drug abuse, increased marketing efforts and the anticipated behavior of prescribing physicians.^{XLIV}

In developing the cost estimates, the medium estimate assumed that 40% of all future opioid scripts will be ADO scripts. At the time of this writing, there are no empirical data available to develop and assess this assumption, since states have only recently enacted laws to mandate the inclusion of ADOs in health plans, in particular at the lowest cost-sharing levels.

In order to provide the sensitivity of the cost estimates to this assumption, we provide cost estimates using alternative assumptions for the percentage of future opioid scripts that are ADO scripts. The chart below shows three sets of cost estimates denoted by low, medium and high. The medium cost estimates use the assumption that 40% of all future opioid scripts will be ADO scripts. The low and high cost estimates assume 20% and 60%, respectively.^{xlv}



The chart shows the first year low and high cost estimates to be \$55 and \$166 million, respectively. The costs increase steadily until the tenth year, when costs are \$102 (low) and \$305 (high) million. The present value (in current dollars) of these costs for the ten-year period for the low and high assumptions is \$0.7 and \$2.0 billion, respectively. The ultimate payers of these costs will be discussed in the next section.

Cost Allocation

In the previous section, we provide cost estimates from the passage of S 1313. In this section, we discuss how these costs will be allocated and paid among the individuals, employers, and carriers participating in the commercial markets, and among the State and its employees and retirees participating in the SHBP and SEHBP.

For this discussion, we assume a hypothetical individual is prescribed a non-ADO with a cost of \$125 per script. We further assume the passage of S 1313 results in the individual’s prescription being changed to an ADO with a cost of \$550 per script. These drug cost assumptions are developed from the claims data and are the same ones used in the development of the cost estimates presented in the previous section.

In the commercial markets, a typical health plan would have a coinsurance cost-sharing provision for prescription drugs. Based on the data provided by the carriers, the typical prescription drug coinsurance is 20%, meaning 20% of the drug’s cost is paid by the insured and the remaining 80% of the cost is paid by the carrier.

In the case of this hypothetical individual, her coinsurance increases \$85, from \$25 to \$110 (20% of \$550). The cost to the carrier increases by \$340 (from \$100 to \$440) and is ultimately passed on to purchasers of health coverage in the future in the form of higher premiums. The table below illustrates the changes in costs from S 1313 for this hypothetical individual.

	Before Senate Bill 1313	After Senate Bill 1313	Cost Increase
Cost of Opioid Script	\$125 (Non-ADO)	\$550 (ADO)	\$425
Cost Share Provision	20% Coinsurance	20% Coinsurance	NA
Paid by Patient	\$25	\$110	\$85
Paid by Carrier	\$100	\$440	\$340
Cost Covered by Premiums	\$100	\$440	\$340

In contrast to the commercial market health plans, the most frequently chosen State health plans have a copay cost-sharing provision for prescription drugs.^{XLVI} Under a copay arrangement, the person covered by the health plan pays a fixed dollar amount, no matter the cost of the prescription drug.

Under a State health plan with a \$7 prescription drug copay, for example, the hypothetical individual’s cost will not change if she is prescribed an ADO, rather than a non-ADO. She will pay the same \$7 copay for the ADO script. The increase in the cost of her prescription is \$425 (from \$118 to \$543, both after the \$7 copay) and is paid by the State Plans. The State may cover all of this cost or pass some along to members by increasing future health plan contributions from its employees and retirees. The table below illustrates the changes in costs from S 1313 for this hypothetical individual.

	Before Senate Bill 1313	After Senate Bill 1313	Cost Increase
Cost of Opioid Script	\$125 (Non-ADO)	\$550 (ADO)	\$425
Cost Share Provision	\$7 Copay	\$7 Copay ^{XLVII}	NA
Paid by Patient	\$7	\$7	\$0
Paid by State Plans	\$118	\$543	\$425

The difference between the State and the commercial market health plans, all things equal, is that the consumer of the ADO script pays more of its cost under a commercial market health plan.

Potential Unintended Consequences

In this section we discuss potential unintended consequences from the passage of S 1313. These consequences include the following:

- future changes in prescription drug cost sharing and/or formularies,
- future increases in the price of ADOs, and
- future increases in cost of health care waste.

As discussed in the previous section, how the cost is allocated among the carriers and purchasers of health insurance in the commercial markets and the State and its employees and retirees depends on the prescription drug plan cost sharing provisions. One way to change the allocation of these costs as a result of the passage of S 1313 is to change the prescription drug cost-sharing provisions.

If S 1313 passes, the State might move to minimize the cost that is passed on to non-consumers of ADOs. To do this, a coinsurance rather than a copay could be incorporated into the State health plan design. Or, if a copay design is preferred, the level of the copay could be increased, such that more of the cost is borne by the individual consuming the ADO. Although, the intent of such changes might be to pass on more of the cost to ADO consumers, changing prescription drug designs in the manner described above may result in increased copay and/or coinsurance for all State health plan users of prescription drugs.

Since S 1313 requires coverage of at least one prescribed ADO per opioid active ingredient on the formulary, a carrier may choose to limit the number of non-ADO formulations in the formulary in such a

manner as to manage the higher ADO costs. Thus, individuals who medically require certain opioids not included in the health plan formulary may find themselves paying a higher copay/coinsurance for a non-preferred prescription drug.

The cost estimates presented in the previous section assume baseline opioid drug prices remain the same before and after the passage of S 1313, aside from across-the-board price inflation after the first year. This may not prove to be the case. Price increases beyond assumed inflation might occur due to the loss of leverage of carriers and health plan sponsors in the negotiation of prescription drug prices, due to the bill's mandates.^{XLVIII} Carriers and health plan sponsors offer placement on preferred cost-sharing tiers as a tool to try to negotiate lower prices and larger rebates from pharmaceutical companies. When there is no longer an advantage to use one preferred drug over another, carriers and health plan sponsors will have a more challenging environment in which to negotiate discounts on behalf of their member. Price decreases are also possible as more ADO scripts come to market.

Finally, there is a necessary waste component to the replacement of non-ADO prescriptions with ADO prescriptions. Not all patients receiving ADO scripts are likely to need ADO formulations. For every ADO script written for such a patient, the cost of the drug represents a waste of resources. Furthermore, a percentage of opioid pills prescribed are never taken by the patient. The higher the proportion of ADO scripts written, the greater the waste of resources represented by the unused part of the more expensive prescription. The presence of unused ADOs in households can also lead to accidental ingestions by children or the diversion of the pills into illegal markets, additional forms of waste that are more severe than the waste of unused non-ADOs.

Conclusion: Balancing the Social, Economic, and Medical Considerations

The crisis of opioid addiction and overdose deaths in New Jersey is a serious social and public health concern and requires attention from policymakers, medical professionals and prescribers, first responders, law enforcement officials, and society at large. Existing New Jersey insurance regulations permit prescribers to write prescriptions for ADOs, as warranted, and forbid insurance carriers to close formularies to ADO formulations in the segments of the insurance market regulated by NJDOBI.

The empirical evidence on the impact of introducing ADOs into a market is inconclusive and sometimes contradictory. Some researchers have reported that the abuse-deterrent properties do, in fact, reduce overdose deaths associated with a particular opioid. Other researchers, however, point out that the abuse-deterrent properties in and of themselves do not prevent addiction, and that the higher cost and the more difficult abuse demands of the abuse-deterrent formulation drive users to cheaper and more lethal alternatives, such as heroin and fentanyl, the core cause of the epidemic in overdoses and overdose deaths in New Jersey and across the country. We noted as important that the latest CDC guidelines do not find current persuasive empirical evidence that ADOs are compelling alternatives to

non-ADO formulations and do not suggest that more widespread use of ADOs will have a significant impact in combatting the opioid epidemic.

It is clear that use of ADO formulations should be accompanied by a broad education outreach to prescribers. As noted above, one study found that nearly half of the physicians surveyed believed that ADOs were less addictive than non-ADO formulations. Such misconceptions about the relative “safety” of ADOs could lead to the unintended consequence of an even higher level of addiction, if ADOs are prescribed at a higher rate, as a result of their wrongly perceived lower association with addiction.

The expense of mandating the availability of ADOs at the lowest cost sharing levels appears likely to result in higher insurance costs to payors, including individuals, employers, and the State. The mandate could result in much higher rates of prescribing of ADOs, as abuse-deterrent formulations are added to formularies at favorable cost sharing levels, as ADOs are increasingly perceived as a response to the opioid epidemic, both among prescribers and the public, and as marketing efforts in favor of ADOs increase.

Mandating the availability of ADOs at the lowest cost-sharing levels is also likely to have unintended consequences. Among these are changes in broader prescription drug cost-sharing schemes and/or the design of plan formularies as a response to higher ADO costs, possible increases in ADO prices, and increasing costs of pharmaceutical waste. The possibility that ADO costs could decline as a result of an increase in the volume of ADO scripts as a proportion of all opioid scripts, and the possibility that future ADO costs could decline due to increased competition is acknowledged.

Thus, the single element of expanding the availability of ADOs appears unlikely to be a “silver bullet” or have a decisive impact on the opioid addiction and overdose epidemic in New Jersey. A policy that may have a more significant impact is a multi-faceted program addressing a number of aspects of the opioid crisis. Public health experts^{xxxiii},^{xxxiv} urge a broad-based approach to addressing the opioid epidemic.

Strategies identified by experts for addressing the opioid epidemic include, but are not limited to:

1. Increasing opioid education for prescribers,
2. Expanding community education concerning the dangers of opioid addiction,
3. Making non-opioid measures first line options for pain relief,
4. Prescribing ADOs where appropriate, recognizing their limitations,
5. Expanding and improving Prescription Monitoring Programs (PMPs) to include all prescribers,
6. Embracing harm reduction strategies,
7. Increasing the number of/access to substance abuse treatment programs,
8. Expanding support programs for families dealing with opioid abuse/overdose,
9. Improving community availability of Narcan,
10. Addressing the supply-side of opioid availability via drug enforcement, and
11. Increasing market availability of drug treatment/maintenance program substitutes, such as methadone and buprenorphine.

Endnotes/References

- ⁱ Senate Bill, No.1313, State of New Jersey, 217th Legislature. Introduced February 8, 2016, by Senator Joseph Vitale.
- ⁱⁱ Mandated Health Benefits Advisory Commission. New Jersey Department of Banking and Insurance. Accessed December 14, 2016 from http://www.state.nj.us/dobi/division_insurance/mhbac/index.htm
- ⁱⁱⁱ Sanders, W. (2017) Personal Communication. Social Impact of S 1313 on cost-sharing, consumer financial hardship and carrier's negotiating power. January 26, 2017.
- ^{iv} Wyman, O. (2016). Actuarial Impact of Capping Drug Cost-Sharing. Prepared on behalf of Pharmaceutical Care Management Association, December, 2016.
- ^v Center for Behavioral Health Statistics and Quality (2015). National Survey on Drug Use and Health: Detailed Tables. Substance Abuse and Mental Health Services Administration, Rockville, MD.
- ^{vi} New Jersey State Medical Examiner, reported in: Sterling, S. Overdose deaths skyrocket in NJ as opioid epidemic proves unassailable. NJ Advance Media for NJ.com, December 7, 2016. Accessed 12/12/16 from http://www.nj.com/news/index.ssf/2016/12/overdose_deaths_skyrocket_in_nj_as_opioid_epidemic_continues_it_s_boom.html
- ^{vii} New Jersey Department of Law and Public Safety, 2016.
- ^{viii} New Jersey Division of Mental Health and Addiction Services, November, 2016.
- ^{ix} Florence, Curtis S., Chao Zhou, Feijun Luo, and Likang Xu (2016). The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care*, 54(10): 901-906
- ^x Boscarino, J. 2010. Risk Factors for Drug Dependence among Out-patients on Opioid Therapy in a Large US Health-care System. *Addiction*, 105 (10): 1776-1782.
- ^{xi} Vosburg, S., *et al.* 2016. Prescription Opioid Abuse, Prescription Opioid Addiction, and Heroin Abuse among Adolescents in a Recovery High School: A Pilot Study. *Journal of Child & Adolescent Substance Abuse*, 25 (2): 105-112.
- ^{xii} Gaither, J., Leventhal, J., Ryan, S., *et al.* (2016). National Trends in Hospitalizations for Opioid Poisonings among Children and Adolescents, 1997-2012. *JAMA Pediatrics*, 170(12):1195-1201.
- ^{xiii} Lovegrove, M., Mathew, J., Hampp, C., Governale, L., Wysowski, D., & Budnitz, D. (2014). Emergency Hospitalizations for Unsupervised Prescription Ingestions by Young Children. *Pediatrics*, 134(4), October, 2014, e1009-e1016.
- ^{xiv} SAMSHA News Release (2017). U.S. Substance Abuse and Mental Health Services Administration, January 17, 2017.
- ^{xv} Vosburg, *op. cit.*
- ^{xvi} Scudder, L. & Throckmorton, D. (2016). Abuse Deterrent Opioids: What You Need to Know. *Medscape*, 8/25/16.
- ^{xvii} Hallcom, Donald, New Jersey Department of Human Services, Division of Mental Health and Addiction Services. Overdose Deaths in NJ, 2013 and 2014, compared. *NJ Medical Examiner*, 2015; by personal communication from Dr. Hallcom, October 31, 2016.

- ^{xviii}Paulozzi, L. & Kilbourne, E., *et al.* (2012). A History of Being Prescribed Controlled Substances and Risk of Drug Overdose Death. *Pain Medicine* 13, 87-95.
- ^{xix} FDA Facts: Abuse Deterrent Opioids. Downloaded December 14, 2016 from <http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm514939.htm>
- ^{xx}Coplan, P., Kale, H., Sandstrom, L., Landau, C., & Chilcoat, H. (2013). Changes in Oxycodone and Heroin Exposures in the National Poison Data System after Introduction of Extended-release Oxycodone with Abuse Deterrent Characteristics. *Pharmacoepidemiology and Drug Safety*, 22(12):1274-1282.
- ^{xxi}Compton, W., Jones, C., & Baldwin, G. (2016). Relationship between Non-medical Prescription-opioid Use and Heroin Use. *New England Journal of Medicine*, 374:154-163.
- ^{xxii}Dart, R., *et al.* (2015). Trends in Opioid Analgesic Abuse and Mortality in the United States. *New England Journal of Medicine*, 372:241-248.
- ^{xxiii}Cassidy, T., *et al.* (2014). Changes in Prevalence of Prescription Opioid Abuse after Introduction of an Abuse-deterrent Opioid Formulation. *Pain Medicine*. 15(3):440-451.
- ^{xxiv}Albert, A., Powell, D. and Pacula, R.L. (2017). NBER Working Paper 23031: Supply-Side Drug Policy In The Presence Of Substitutes: Evidence From The Introduction Of Abuse-Deterrent Opioids. National Bureau of Economic Research, January, 2017.
- ^{xxv} DEA Intelligence Report (2016). National Heroin Threat Assessment Summary-Updated. Unclassified. June, 2016. p. 8.
- ^{xxvi}Compton, W. *op. cit.*
- ^{xxvii}Albert, A. *op. cit.*
- ^{xxviii}Wrightman, R., Perrone, J., Portelli, I., & Nelson, L. (2012). Likeability and Abuse Likeability of Commonly Prescribed Opioids. *Journal of Medical Toxicology*, 8(4): 335-340.
- ^{xxix}Cicero, T. & Ellis, M. Abuse-deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned from Oxycotin. *JAMA Psychiatry*, 72(5):424-429.
- ^{xxx}Vosburg, S., *op. cit.*
- ^{xxxi}Hwang, C.S., Rutner, L.W., Kruszewski, S.P., Kolodny A., & Alexander, G.C. (2016). Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion. *Clinical Journal of Pain*, 32:(4): 279-84.
- ^{xxxii}Dowell, D., Haegerich, T.M., & Chou, R. (2016). CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. *Morbidity and Mortality Weekly Report, Recommendations and Reports* 2016; 65(No.RR-1):1-49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>.
- ^{xxxiii}Included is a cost sharing requirement where the insured or covered life is not to pay more for an ADO script than the cost sharing amount for a non-ADO script.
- ^{xxxiv}IHC and SEH enrollment information is available to the general public and is found at http://www.nj.gov/dobi/division_insurance/ihcseh/ihcsehenroll.html. IHC and SEH combined enrolled covered lives was 794,072 as of second quarter of 2016. Mid- to large-employer enrolled covered lives was 897,401 as of December 31, 2014.

^{xxxv} Per email dated January 24, 2017 from the New Jersey Division of Pension and Benefits, the number of members or covered lives in the State health prescription drug plans is 707,489 as of December 31, 2016. This number does not include enrollment from local government active employees and retirees on municipal prescription drug plans since that information was not available.

^{xxxvi} The estimated cost of \$111 million represents approximately 0.6% of total premiums in the combined commercial health insurance markets and New Jersey State health plans.

^{xxxvii} Arguably, even without Senate Bill 1313, the anticipated increase in acceptance of ADOs would increase prescription drug costs for commercial carriers and State health plans. We believe this is a fallacious argument. It assumes that commercial carriers and the New Jersey State health plans accept the medical benefit of ADOs over non-ADOs and allow ADOs into their formularies. Health plans generally pay a lower percentage of the cost of prescription drugs not in the formulary. In addition, without passage of S 1313, manufacturers of ADOs lose an opportunity to influence provider behaviors in favor of ADOs.

^{xxxviii} The cost estimates assume that the prices of ADO and non-ADO scripts are \$550 and \$125, respectively, and the number of opioid scripts consumed per 1,000 people per year is 275 scripts.

^{xxxix} Perrone, M., Mulvihill, G., and Whyte, L.E. (2016). Drugmakers Push Profitable, but Unproven, Opioid Solution on the States. The Center for Public Integrity, December 15, 2016.
<https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution>.

^{XL} Present value of the costs for the ten years assumes an interest rate of 3%.

^{XLI} This is based on comparison of year over year covered lives found in the enrollment data supplied by the New Jersey Department of Banking and Insurance and the State health plans rate renewal reports.

^{XLII} This assumption means both ADO and non-ADO prices increase at 7% per year. If the market for ADOs becomes significantly more competitive, as a result of new ADO manufacturers entering the market, or if Senate Bill 1313's mandates significantly affect the negotiating leverage of carriers and the State, the annual rate of increase in the prices of ADOs and non-ADOs may differ.

^{XLIII} 2017 rate renewal reports can be found at <http://www.state.nj.us/treasury/pensions/shbp-rate-renewal.shtml>.

^{XLIV} Manufacturers of ADOs may use Senate Bill 1313 as a marketing opportunity to further increase the future utilization of the relatively new ADOs.

^{XLV} The State of Massachusetts commissioned an actuarial study on the financial impact of Massachusetts Chapter 258 of the Act of 2014. This study assumes a "switch rate" of 30% for the low estimate and 70% for the high estimate. See Compass Health Analytics, "Actuarial Assessment of Chapter 258 of the Acts of 2014: 'An Act to Increase Opportunities for Long-term Substance Abuse Recovery' Abuse-Deterrent Opioids," page 11.

^{XLVI} The State health plan renewal reports include a description of the types of plans available to employees and retirees, as well as the past enrollment broken down by the type of health plan.

^{XLVII} The ADO script may have a different copay due to different classifications (or tiers) of prescription drugs. Based on review of the State health plan cost sharing provisions, the difference between copay of different tier prescription drugs is nominal.

^{XLVIII} Perrone, M., *op. cit.*

^{XLIX} Frieden, T.R. and Houry, D. Reducing the Risks of Relief--The CDC Opioid-Prescribing Guideline. (2016). *New England Journal of Medicine*, 347:1501-1504.

^L Kolodny, A., *et. al.* (2015). The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction. *Annual Review of Public Health*, 36: 559-574.

SENATE, No. 1313

STATE OF NEW JERSEY

217th LEGISLATURE

INTRODUCED FEBRUARY 8, 2016

Sponsored by:

Senator JOSEPH F. VITALE

District 19 (Middlesex)

SYNOPSIS

Mandates health benefits coverage for opioid analgesics with abuse-deterrent properties.

CURRENT VERSION OF TEXT

As introduced.



S1313 VITALE

2

1 AN ACT concerning health benefits coverage for opioid analgesics
2 with abuse-deterrent properties and supplementing various parts
3 of the statutory law.

4
5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:

7
8 1. a. A hospital service corporation contract that provides
9 hospital or medical expense benefits and is delivered, issued,
10 executed or renewed in this State, or approved for issuance or
11 renewal in this State by the Commissioner of Banking and
12 Insurance, on or after the effective date of this act, shall provide
13 coverage on its formulary, drug list, or other lists of similar
14 construct for at least one prescribed abuse-deterrent opioid
15 analgesic drug product per opioid analgesic active ingredient,
16 subject to the following requirements:

17 (1) Cost sharing for brand name abuse-deterrent opioid
18 analgesic drug products covered pursuant to this subsection shall
19 not exceed the lowest cost sharing level applied to brand name
20 non-abuse deterrent opioid drugs covered under the applicable
21 contract;

22 (2) Cost sharing for generic abuse deterrent opioid analgesic
23 drug products covered pursuant to this subsection shall not exceed
24 the lowest cost sharing level applied to generic non-abuse deterrent
25 opioid drugs covered under the applicable contract;

26 (3) An increase in patient cost sharing or disincentives for a
27 prescriber or dispenser shall not be allowed to achieve compliance
28 with this section; and

29 (4) Any prior authorization requirements or other utilization
30 review measures for opioid analgesic drugs, and any service denials
31 made pursuant thereto, shall not require first use of non-abuse-
32 deterrent opioid analgesic drugs in order to access opioid analgesic
33 drugs with abuse-deterrent properties. Nothing in this subsection
34 shall be construed to prevent the application of prior authorization
35 requirements to abuse-deterrent opioid analgesic drugs, provided
36 that those requirements are also applied to non-abuse-deterrent
37 versions of that opioid.

38 b. The provisions of this section shall apply to all hospital
39 service corporation contracts in which the hospital service
40 corporation has reserved the right to change the premium.

41 c. As used in this section:

42 “Abuse-deterrent opioid analgesic drug” means a brand or
43 generic opioid analgesic drug approved by the United States Food
44 and Drug Administration with abuse-deterrence labeling claims
45 indicating its abuse-deterrent properties are expected to deter or
46 reduce its abuse.

1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 2. a. A medical service corporation contract that provides
11 hospital or medical expense benefits and is delivered, issued,
12 executed or renewed in this State, or approved for issuance or
13 renewal in this State by the Commissioner of Banking and
14 Insurance, on or after the effective date of this act, shall provide
15 coverage on its formulary, drug list, or other lists of similar
16 construct for at least one prescribed abuse-deterrent opioid
17 analgesic drug product per opioid analgesic active ingredient,
18 subject to the following requirements:

19 (1) Cost sharing for brand name abuse-deterrent opioid
20 analgesic drug products covered pursuant to this subsection shall
21 not exceed the lowest cost sharing level applied to brand name non-
22 abuse deterrent opioid drugs covered under the applicable contract;

23 (2) Cost sharing for generic abuse deterrent opioid analgesic
24 drug products covered pursuant to this subsection shall not exceed
25 the lowest cost sharing level applied to generic non-abuse deterrent
26 opioid drugs covered under the applicable contract;

27 (3) An increase in patient cost sharing or disincentives for a
28 prescriber or dispenser shall not be allowed to achieve compliance
29 with this section; and

30 (4) Any prior authorization requirements or other utilization
31 review measures for opioid analgesic drugs, and any service denials
32 made pursuant thereto, shall not require first use of non-abuse-
33 deterrent opioid analgesic drugs in order to access opioid analgesic
34 drugs with abuse-deterrent properties. Nothing in this subsection
35 shall be construed to prevent the application of prior authorization
36 requirements to abuse-deterrent opioid analgesic drugs, provided
37 that those requirements are also applied to non-abuse-deterrent
38 versions of that opioid.

39 b. The provisions of this section shall apply to all medical
40 service corporation contracts in which the medical service
41 corporation has reserved the right to change the premium.

42 c. As used in this section:

43 “Abuse-deterrent opioid analgesic drug” means a brand or
44 generic opioid analgesic drug approved by the United States Food
45 and Drug Administration with abuse-deterrence labeling claims
46 indicating its abuse-deterrent properties are expected to deter or
47 reduce its abuse.

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1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 3. a. A health service corporation contract that provides
11 hospital or medical expense benefits and is delivered, issued,
12 executed or renewed in this State, or approved for issuance or
13 renewal in this State by the Commissioner of Banking and
14 Insurance, on or after the effective date of this act shall provide
15 coverage on its formulary, drug list, or other lists of similar
16 construct for at least one prescribed abuse-deterrent opioid
17 analgesic drug product per opioid analgesic active ingredient,
18 subject to the following requirements:

19 (1) Cost sharing for brand name abuse-deterrent opioid
20 analgesic drug products covered pursuant to this subsection shall
21 not exceed the lowest cost sharing level applied to brand name non-
22 abuse deterrent opioid drugs covered under the applicable contract;

23 (2) Cost sharing for generic abuse deterrent opioid analgesic
24 drug products covered pursuant to this subsection shall not exceed
25 the lowest cost sharing level applied to generic non-abuse deterrent
26 opioid drugs covered under the applicable contract;

27 (3) An increase in patient cost sharing or disincentives for a
28 prescriber or dispenser shall not be allowed to achieve compliance
29 with this section; and

30 (4) Any prior authorization requirements or other utilization
31 review measures for opioid analgesic drugs, and any service denials
32 made pursuant thereto, shall not require first use of non-abuse-
33 deterrent opioid analgesic drugs in order to access opioid analgesic
34 drugs with abuse-deterrent properties. Nothing in this subsection
35 shall be construed to prevent the application of prior authorization
36 requirements to abuse-deterrent opioid analgesic drugs, provided
37 that those requirements are also applied to non-abuse-deterrent
38 versions of that opioid.

39 b. The provisions of this section shall apply to all health
40 service corporation contracts in which the health service
41 corporation has reserved the right to change the premium.

42 c. As used in this section:

43 “Abuse-deterrent opioid analgesic drug” means a brand or
44 generic opioid analgesic drug approved by the United States Food
45 and Drug Administration with abuse-deterrence labeling claims
46 indicating its abuse-deterrent properties are expected to deter or
47 reduce its abuse.

1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 4. a. An individual health insurance policy that provides
11 hospital or medical expense benefits and is delivered, issued,
12 executed or renewed in this State, or approved for issuance or
13 renewal in this State by the Commissioner of Banking and
14 Insurance, on or after the effective date of this act, shall provide
15 coverage on its formulary, drug list, or other lists of similar
16 construct for at least one prescribed abuse-deterrent opioid
17 analgesic drug product per opioid analgesic active ingredient,
18 subject to the following requirements:

19 (1) Cost sharing for brand name abuse-deterrent opioid
20 analgesic drug products covered pursuant to this subsection shall
21 not exceed the lowest cost sharing level applied to brand name non-
22 abuse deterrent opioid drugs covered under the applicable contract;

23 (2) Cost sharing for generic abuse deterrent opioid analgesic
24 drug products covered pursuant to this subsection shall not exceed
25 the lowest cost sharing level applied to generic non-abuse deterrent
26 opioid drugs covered under the applicable contract;

27 (3) An increase in patient cost sharing or disincentives for a
28 prescriber or dispenser shall not be allowed to achieve compliance
29 with this section; and

30 (4) Any prior authorization requirements or other utilization
31 review measures for opioid analgesic drugs, and any service denials
32 made pursuant thereto, shall not require first use of non-abuse-
33 deterrent opioid analgesic drugs in order to access opioid analgesic
34 drugs with abuse-deterrent properties. Nothing in this subsection
35 shall be construed to prevent the application of prior authorization
36 requirements to abuse-deterrent opioid analgesic drugs, provided
37 that those requirements are also applied to non-abuse-deterrent
38 versions of that opioid.

39 b. The provisions of this section shall apply to those policies in
40 which the insurer has reserved the right to change the premium.

41 c. As used in this section:

42 “Abuse-deterrent opioid analgesic drug” means a brand or
43 generic opioid analgesic drug approved by the United States Food
44 and Drug Administration with abuse-deterrence labeling claims
45 indicating its abuse-deterrent properties are expected to deter or
46 reduce its abuse.

1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 5. a. A group health insurance policy that provides hospital or
11 medical expense benefits and is delivered, issued, executed or
12 renewed in this State, or approved for issuance or renewal in this
13 State by the Commissioner of Banking and Insurance, on or after
14 the effective date of this act, shall provide coverage on its
15 formulary, drug list, or other lists of similar construct for at least
16 one prescribed abuse-deterrent opioid analgesic drug product per
17 opioid analgesic active ingredient, subject to the following
18 requirements:

19 (1) Cost sharing for brand name abuse-deterrent opioid
20 analgesic drug products covered pursuant to this subsection shall
21 not exceed the lowest cost sharing level applied to brand name non-
22 abuse deterrent opioid drugs covered under the applicable contract;

23 (2) Cost sharing for generic abuse deterrent opioid analgesic
24 drug products covered pursuant to this subsection shall not exceed
25 the lowest cost sharing level applied to generic non-abuse deterrent
26 opioid drugs covered under the applicable contract;

27 (3) An increase in patient cost sharing or disincentives for a
28 prescriber or dispenser shall not be allowed to achieve compliance
29 with this section; and

30 (4) Any prior authorization requirements or other utilization
31 review measures for opioid analgesic drugs, and any service denials
32 made pursuant thereto, shall not require first use of non-abuse-
33 deterrent opioid analgesic drugs in order to access opioid analgesic
34 drugs with abuse-deterrent properties. Nothing in this subsection
35 shall be construed to prevent the application of prior authorization
36 requirements to abuse-deterrent opioid analgesic drugs, provided
37 that those requirements are also applied to non-abuse-deterrent
38 versions of that opioid.

39 b. The provisions of this section shall apply to those policies in
40 which the insurer has reserved the right to change the premium.

41 c. As used in this section:

42 “Abuse-deterrent opioid analgesic drug” means a brand or
43 generic opioid analgesic drug approved by the United States Food
44 and Drug Administration with abuse-deterrence labeling claims
45 indicating its abuse-deterrent properties are expected to deter or
46 reduce its abuse.

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1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 6. a. An individual health benefits plan that provides hospital
11 or medical expense benefits and is delivered, issued, executed or
12 renewed in this State, or approved for issuance or renewal in this
13 State by the Commissioner of Banking and Insurance, on or after
14 the effective date of this act, shall provide coverage on its
15 formulary, drug list, or other lists of similar construct for at least
16 one prescribed abuse-deterrent opioid analgesic drug product per
17 opioid analgesic active ingredient, subject to the following
18 requirements:

19 (1) Cost sharing for brand name abuse-deterrent opioid
20 analgesic drug products covered pursuant to this subsection shall
21 not exceed the lowest cost sharing level applied to brand name non-
22 abuse deterrent opioid drugs covered under the applicable contract;

23 (2) Cost sharing for generic abuse deterrent opioid analgesic
24 drug products covered pursuant to this subsection shall not exceed
25 the lowest cost sharing level applied to generic non-abuse deterrent
26 opioid drugs covered under the applicable contract;

27 (3) An increase in patient cost sharing or disincentives for a
28 prescriber or dispenser shall not be allowed to achieve compliance
29 with this section; and

30 (4) Any prior authorization requirements or other utilization
31 review measures for opioid analgesic drugs, and any service denials
32 made pursuant thereto, shall not require first use of non-abuse-
33 deterrent opioid analgesic drugs in order to access opioid analgesic
34 drugs with abuse-deterrent properties. Nothing in this subsection
35 shall be construed to prevent the application of prior authorization
36 requirements to abuse-deterrent opioid analgesic drugs, provided
37 that those requirements are also applied to non-abuse-deterrent
38 versions of that opioid.

39 b. The provisions of this section shall apply to all individual
40 health benefits plans in which the carrier has reserved the right to
41 change the premium.

42 c. As used in this section:

43 “Abuse-deterrent opioid analgesic drug” means a brand or
44 generic opioid analgesic drug approved by the United States Food
45 and Drug Administration with abuse-deterrence labeling claims
46 indicating its abuse-deterrent properties are expected to deter or
47 reduce its abuse.

1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 7. a. A small employer health benefits plan that provides
11 hospital or medical expense benefits and is delivered, issued,
12 executed or renewed in this State, or approved for issuance or
13 renewal in this State by the Commissioner of Banking and
14 Insurance, on or after the effective date of this act, shall provide
15 coverage on its formulary, drug list, or other lists of similar
16 construct for at least one prescribed abuse-deterrent opioid
17 analgesic drug product per opioid analgesic active ingredient,
18 subject to the following requirements:

19 (1) Cost sharing for brand name abuse-deterrent opioid
20 analgesic drug products covered pursuant to this subsection shall
21 not exceed the lowest cost sharing level applied to brand name non-
22 abuse deterrent opioid drugs covered under the applicable contract;

23 (2) Cost sharing for generic abuse deterrent opioid analgesic
24 drug products covered pursuant to this subsection shall not exceed
25 the lowest cost sharing level applied to generic non-abuse deterrent
26 opioid drugs covered under the applicable contract;

27 (3) An increase in patient cost sharing or disincentives for a
28 prescriber or dispenser shall not be allowed to achieve compliance
29 with this section; and

30 (4) Any prior authorization requirements or other utilization
31 review measures for opioid analgesic drugs, and any service denials
32 made pursuant thereto, shall not require first use of non-abuse-
33 deterrent opioid analgesic drugs in order to access opioid analgesic
34 drugs with abuse-deterrent properties. Nothing in this subsection
35 shall be construed to prevent the application of prior authorization
36 requirements to abuse-deterrent opioid analgesic drugs, provided
37 that those requirements are also applied to non-abuse-deterrent
38 versions of that opioid.

39 b. The provisions of this section shall apply to all small
40 employer health benefits plans in which the carrier has reserved the
41 right to change the premium.

42 c. As used in this section:

43 “Abuse-deterrent opioid analgesic drug” means a brand or
44 generic opioid analgesic drug approved by the United States Food
45 and Drug Administration with abuse-deterrence labeling claims
46 indicating its abuse-deterrent properties are expected to deter or
47 reduce its abuse.

1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 8. a. A health maintenance organization contract that provides
11 hospital or medical expense benefits and is delivered, issued,
12 executed or renewed in this State, or approved for issuance or
13 renewal in this State by the Commissioner of Banking and
14 Insurance, on or after the effective date of this act, shall provide
15 coverage on its formulary, drug list, or other lists of similar
16 construct for at least one prescribed abuse-deterrent opioid
17 analgesic drug product per opioid analgesic active ingredient,
18 subject to the following requirements:

19 (1) Cost sharing for brand name abuse-deterrent opioid
20 analgesic drug products covered pursuant to this subsection shall
21 not exceed the lowest cost sharing level applied to brand name non-
22 abuse deterrent opioid drugs covered under the applicable contract;

23 (2) Cost sharing for generic abuse deterrent opioid analgesic
24 drug products covered pursuant to this subsection shall not exceed
25 the lowest cost sharing level applied to generic non-abuse deterrent
26 opioid drugs covered under the applicable contract;

27 (3) An increase in patient cost sharing or disincentives for a
28 prescriber or dispenser shall not be allowed to achieve compliance
29 with this section; and

30 (4) Any prior authorization requirements or other utilization
31 review measures for opioid analgesic drugs, and any service denials
32 made pursuant thereto, shall not require first use of non-abuse-
33 deterrent opioid analgesic drugs in order to access opioid analgesic
34 drugs with abuse-deterrent properties. Nothing in this subsection
35 shall be construed to prevent the application of prior authorization
36 requirements to abuse-deterrent opioid analgesic drugs, provided
37 that those requirements are also applied to non-abuse-deterrent
38 versions of that opioid.

39 b. The provisions of this section shall apply to those contracts
40 by health maintenance organizations in which the health
41 maintenance organization has reserved the right to change the
42 premium.

43 c. As used in this section:

44 “Abuse-deterrent opioid analgesic drug” means a brand or
45 generic opioid analgesic drug approved by the United States Food
46 and Drug Administration with abuse-deterrence labeling claims
47 indicating its abuse-deterrent properties are expected to deter or
48 reduce its abuse.

1 “Cost sharing” means any coverage limit, copayment,
2 coinsurance, deductible, or other out-of-pocket expense
3 requirements.

4 “Opioid analgesic drug” means a drug in the opioid analgesic
5 drug class prescribed to treat moderate to severe pain or other
6 conditions, whether in immediate release or extended release form,
7 and whether or not combined with other drug substances to form a
8 single drug product or other dosage form.

9
10 9. a. The State Health Benefits Commission shall ensure that
11 every contract purchased by the commission on or after the
12 effective date of this act that provides hospital or medical expense
13 benefits shall provide coverage on its formulary, drug list, or other
14 lists of similar construct for at least one prescribed abuse-deterrent
15 opioid analgesic drug product per opioid analgesic active
16 ingredient, subject to the following requirements:

17 (1) Cost sharing for brand name abuse-deterrent opioid
18 analgesic drug products covered pursuant to this subsection shall
19 not exceed the lowest cost sharing level applied to brand name non-
20 abuse deterrent opioid drugs covered under the applicable contract;

21 (2) Cost sharing for generic abuse deterrent opioid analgesic
22 drug products covered pursuant to this subsection shall not exceed
23 the lowest cost sharing level applied to generic non-abuse deterrent
24 opioid drugs covered under the applicable contract;

25 (3) An increase in patient cost sharing or disincentives for a
26 prescriber or dispenser shall not be allowed to achieve compliance
27 with this section; and

28 (4) Any prior authorization requirements or other utilization
29 review measures for opioid analgesic drugs, and any service denials
30 made pursuant thereto, shall not require first use of non-abuse-
31 deterrent opioid analgesic drugs in order to access opioid analgesic
32 drugs with abuse-deterrent properties. Nothing in this subsection
33 shall be construed to prevent the application of prior authorization
34 requirements to abuse-deterrent opioid analgesic drugs, provided
35 that those requirements are also applied to non-abuse-deterrent
36 versions of that opioid.

37 b. As used in this section:

38 “Abuse-deterrent opioid analgesic drug” means a brand or
39 generic opioid analgesic drug approved by the United States Food
40 and Drug Administration with abuse-deterrence labeling claims
41 indicating its abuse-deterrent properties are expected to deter or
42 reduce its abuse.

43 “Cost sharing” means any coverage limit, copayment,
44 coinsurance, deductible, or other out-of-pocket expense
45 requirements.

46 “Opioid analgesic drug” means a drug in the opioid analgesic
47 drug class prescribed to treat moderate to severe pain or other
48 conditions, whether in immediate release or extended release form,

1 and whether or not combined with other drug substances to form a
2 single drug product or other dosage form.

3

4 10. a. The School Employees' Health Benefits Commission
5 shall ensure that every contract purchased by the commission on or
6 after the effective date of this act that provides hospital or medical
7 expense benefits shall provide coverage on its formulary, drug list,
8 or other lists of similar construct for at least one prescribed abuse-
9 deterrent opioid analgesic drug product per opioid analgesic active
10 ingredient, subject to the following requirements:

11 (1) Cost sharing for brand name abuse-deterrent opioid
12 analgesic drug products covered pursuant to this subsection shall
13 not exceed the lowest cost sharing level applied to brand name
14 non-abuse deterrent opioid drugs covered under the applicable
15 contract;

16 (2) Cost sharing for generic abuse deterrent opioid analgesic
17 drug products covered pursuant to this subsection shall not exceed
18 the lowest cost sharing level applied to generic non-abuse deterrent
19 opioid drugs covered under the applicable contract;

20 (3) An increase in patient cost sharing or disincentives for a
21 prescriber or dispenser shall not be allowed to achieve compliance
22 with this section; and

23 (4) Any prior authorization requirements or other utilization
24 review measures for opioid analgesic drugs, and any service denials
25 made pursuant thereto, shall not require first use of non-abuse-
26 deterrent opioid analgesic drugs in order to access opioid analgesic
27 drugs with abuse-deterrent properties. Nothing in this subsection
28 shall be construed to prevent the application of prior authorization
29 requirements to abuse-deterrent opioid analgesic drugs, provided
30 that those requirements are also applied to non-abuse-deterrent
31 versions of that opioid.

32 b. As used in this section:

33 "Abuse-deterrent opioid analgesic drug" means a brand or
34 generic opioid analgesic drug approved by the United States Food
35 and Drug Administration with abuse-deterrence labeling claims
36 indicating its abuse-deterrent properties are expected to deter or
37 reduce its abuse.

38 "Cost sharing" means any coverage limit, copayment,
39 coinsurance, deductible, or other out-of-pocket expense
40 requirements.

41 "Opioid analgesic drug" means a drug in the opioid analgesic
42 drug class prescribed to treat moderate to severe pain or other
43 conditions, whether in immediate release or extended release form,
44 and whether or not combined with other drug substances to form a
45 single drug product or other dosage form.

46

47 11. This act shall take effect on the 90th day after enactment.

STATEMENT

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This bill requires health insurers to provide health benefits coverage for prescribed abuse-deterrent opioid analgesic drugs. Opioid analgesic drugs are drugs prescribed to treat moderate to severe pain or other conditions. Abuse-deterrent opioid analgesic drugs are a brand or generic opioid analgesic drug approved by the United States Food and Drug Administration with abuse-deterrence labeling claims indicating its abuse-deterrent properties are expected to deter or reduce its abuse.

The bill requires health insurers to provide coverage on the insurer’s formulary, drug list, or other lists of similar construct, for at least one prescribed abuse-deterrent opioid analgesic drug product per opioid analgesic active ingredient, subject to the following:

(1) Cost sharing for brand name abuse-deterrent opioid analgesic drug products shall not exceed the lowest cost sharing level applied to brand name non-abuse deterrent opioid drugs covered under the applicable contract;

(2) Cost sharing for generic abuse deterrent opioid analgesic drug products shall not exceed the lowest cost sharing level applied to generic non-abuse deterrent opioid drugs covered under the applicable contract;

(3) An increase in patient cost sharing or disincentives for a prescriber or dispenser shall not be allowed to achieve compliance with the bill’s provisions; and

(4) Any prior authorization requirements or other utilization review measures for opioid analgesic drugs, and any service denials made pursuant thereto, shall not require first use of non-abuse-deterrent opioid analgesic drugs to access opioid analgesic drugs with abuse-deterrent properties.

The bill applies to health, hospital and medical service corporations; commercial individual and group health insurers; health maintenance organizations; health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs; the State Health Benefits Program; and the School Employees’ Health Benefits Program.

Appendix II

Overview of Current Cost-Sharing and Plan Design Features

Cost-sharing refers to how the costs of services covered under the plan are allocated between the carrier and the covered person. It does not refer to the costs of services NOT covered under the plan. Cost-sharing is usually divided into three categories: *deductibles*, *coinsurance*, and *copayments*. Standard plans can have one, two or all three types of cost-sharing. However, coinsurance and copayments cannot apply to the same services at the same time.

All standard plans have a maximum amount of cost-sharing required for the covered person – referred to as a maximum out-of-pocket (MOOP) – and when the MOOP is reached, the carrier pays all of the remaining costs for covered services for the rest of the plan year. Cost-sharing requirements begin again at the start of each plan year.

Deductibles – Deductibles are the amount of allowed charges for which the covered person is responsible **before** the carrier pays anything towards covered charges. For the standard individual plans, the per person deductible may not exceed \$3,000 for Bronze plans and \$2,500 for all other plans. The family deductible is double the per person deductible.

Coinsurance – “Coinsurance” is a term used to express the promise by the carrier to share, on a percentage basis, payment for allowed charges for covered health care services with the covered person. Most of the time, coinsurance applies after the deductible is satisfied. For example, a plan might have a \$1000 deductible, then 70% coinsurance, which means that the covered person must pay \$1,000 in covered charges before the carrier pays anything, then the carrier pays 70% of the covered charges and the covered person pays 30% of the covered charges (until the MOOP is met).

The standard plans may have coinsurance requirements that vary within a range of **50% to 100%**. If a carrier is offering a plan with tiers, different coinsurance could apply to each tier.

Copayments – Copayments are fixed dollar amounts that you pay per visit or service. So, for instance, the copayment for a visit to your PCP may be \$30, the copayment for filling a 30-day supply of a prescription using generic drugs might be \$10, and if you are admitted to a hospital, you might pay \$300 per day (for up to 5 days). Sometimes copayments are used in a plan instead of deductibles and coinsurance. Sometimes copayments apply after the deductible is satisfied.

Maximum Out-of-Pocket (MOOP) – The MOOP is the maximum amount of allowed charges for covered services that a covered person/family is obligated to pay before the carrier agrees to pay for **all** of the allowed charges for covered health care services. All charges the covered person pays towards the deductible, coinsurance and copayments help to satisfy the MOOP.

(some sections above excerpted from the IHC Buyers Guide- IHC and SEH Programs)...

Tiered Drug Benefits

Drug benefits often feature “tiers.” A tier is a level of coverage. New Jersey Department of Banking and Insurance Regulations only permit up to a three-tier coverage; four-tier drug plans are not permitted. If the benefits for drugs feature three tiers they generally are structured as: generic, formulary brand, and non-formulary brand drugs. The tiers generally have different cost-sharing, which might mean different levels of copayment, but could include a combination of deductible, copayments, and coinsurance.

Formularies

A formulary is a list of drugs developed by a carrier’s pharmacy and therapeutics committee, which by regulation must be composed of health care professionals with recognized knowledge and expertise in clinically appropriate prescribing, dispensing and monitoring of outpatient drugs. The committee is required to consist of at least two-thirds licensed and actively practicing physicians and pharmacists, and at least one pharmacist.

A formulary may be “open” or “closed”. A closed formulary covers only the drugs on the formulary list. An open formulary gives some coverage to drugs that are not listed, but generally requires the covered person to pay more in cost sharing. Since New Jersey Department of Banking and Regulations do not permit closed formularies in state-regulated coverage, a formulary is relevant only for the purposes of tiering drug benefits.

Benefit Designs in New Jersey State-regulated Coverage

Benefit designs vary among products and carriers. However, all variations are subject to the requirements of N.J.A.C. 11:22-5.9. Among other things, those regulations address maximum out of pocket exposure, the use of separate pharmacy deductibles, how the formulary is structured, the requirement to have more than one covered drug for each covered disease state in the most preferred tier, appeals rights for off-formulary drugs, and cost-sharing standards. Among its requirements, is a provision limiting coinsurance to no greater than 50%. In addition, N.J.A.C. 11:22-5.5 provides that copays for generic drugs may not exceed \$25 per 30-day supply, a preferred drug may not exceed a \$50 copay, and the non-preferred drugs may not exceed \$75. In no event may cost-sharing exceed the cost of the drug.

Carriers generally offer plan designs with four types of cost-sharing:

- **Coinsurance for all drugs:** The percentage may be up to 50%. Coinsurance makes consumers sensitive to the actual price of all drugs, because the out of pocket exposure is a percentage of the cost of the drug. Most plan designs in the individual market have drugs subject to coinsurance. Of note, S 1313 would not impact plans that have one coinsurance requirement for all drugs.
- **3-tiers with copayment:** This is a fairly common plan design, especially in the group markets. All plan designs offered in the SHBP and SEHBP have copayments with three tiers.
- **3-tiers with copayments and coinsurance:** Some plan designs have copayments in some tiers and coinsurance in others.
- **Qualified High Deductible Health Plans:** Federal rules govern cost sharing for qualified high deductible health plans. Such plans require consumers to meet a deductible for all non-preventive care services, which means the deductible applies to prescription drugs. Carriers may have a coinsurance requirement that applies after the deductible.

Bills like S 1313, which require that drugs be placed on a preferred tier, could provide an incentive for carriers to move from tiered products to the same coinsurance for all prescription drugs.

Negotiating Rates/Rebates with Pharmaceutical Companies

Carriers and pharmacy benefits managers (PBMs) negotiate with pharmaceutical companies for discounts or rebates. Competition among drugs depends, in part, on the number of alternative therapies available. In drug classes where several products are considered therapeutically equivalent, carriers and PBMs are able to negotiate with pharmaceutical companies for larger rebates. Part of the negotiation may be the promise to put a specific drug on a preferred tier and thus drive greater volume to the preferred drug compared to its competitor products. Mandates such as S 1313 remove this negotiation tool, which leads to smaller rebates and could result in higher premiums for consumers.

Appendix III



NEW JERSEY SENATE

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COMMITTEES
CHAIRMAN:
HEALTH, HUMAN SERVICES
& SENIOR CITIZENS
VICE CHAIRMAN:
LABOR

September 30, 2016

New Jersey Department of Banking and Insurance
Mandated Health Benefits Advisory Commission
PO Box 325
Trenton, NJ 08625

Members of the Mandated Health Benefits Advisory Commission,

I request that the Mandated Health Benefits Advisory Commission review the social and financial impact, and medical efficacy, of S1313. This bill, of which I am the sole sponsor, mandates health benefits coverage for opioid analgesics with abuse-deterrent properties.

I look forward to your review and the Commission's recommendation per this piece of legislation.

Best wishes,


Joseph F. Vitale
Senator, 19th District

JFV/sa