Report to the General Assembly on Insulin Pricing

Produced by:

Department of Insurance, Department of Healthcare and Family Services, Department of Human Services

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November 1, 2020

The Department of Insurance (DOI), the Department of Healthcare and Family Services (HFS), and the Department of Human Services (DHS) are pleased to submit the Insulin Pricing Report required by 215 ILCS5/356z.42.

Section 356z.42 of the Illinois Insurance Code (the Code) (215 ILCS 5/356z.42) (hereinafter "Section 356z.42") requires the Department of Insurance, in conjunction with the Department of Human Services and the Department of Healthcare and Family Services, to make available to the public a report that details the Department's findings on; (1) a summary of insulin pricing practices and variables that contribute to pricing of health coverage plans; (2) public policy recommendations to control and prevent overpricing of prescription insulin drugs made available to Illinois consumers; and (3) any other information the Department finds necessary.

Respectfully Submitted,

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Table of Contents

Statutory Language Mandating the Insulin Report

215 ILCS 5/356z.42

Sec. 356z.42 Insulin pricing report. By November 1, 2020, the Department of Insurance in conjunction with the Department of Human Services and the Department of Healthcare and Family Services shall make available to the public a report that details each Department's findings for the following:

(1) a summary of insulin pricing practices and variables that contribute to pricing of health coverage plans;
(2) public policy recommendations to control and prevent overpricing of prescription insulin drugs made available to Illinois consumers; and
(3) any other information the Department finds necessary. This section is repealed December 31, 2020.

Insulin Pricing Summary

The three agencies (DOI, HFS and DHS) requested that the University of Illinois College of Pharmacy (UIC) provide a general summary of insulin pricing practices and variables that contribute to the pricing of insulin in Illinois.

Background

There are almost 7.4 million Americans with diabetes who use insulin.[1,2] When evaluating the racial, ethnic and economic backgrounds of these individuals, approximately 20% of African Americans, 14% of Caucasians and 17% of Hispanics with diabetes use insulin.[1] Approximately 24% of adults with diabetes who use insulin are earning below the federal poverty level.[2]

There are only three insulin manufacturers in the United States.[3] These include Eli Lilly, Novo Nordisk, and Sanofi. Insulin was discovered almost 100 years ago. Since that time, many changes have been made such as moving from animal source insulin to genetic engineered formulations. The most popular rapid and long-acting human insulin analogues came onto the market in the 1990s and the patents for most of these products have expired.

After insulin became commercially available, there were a number of improvements in insulin formulation and devices to administer insulin (pens). With each change, new patents were approved by the Food and Drug Administration (FDA). Although some of these patents are for documented innovations, some are for very minor changes. This process of "evergreening" a drug allows manufacturers to use the patent process to their advantage by making minor modifications to their products and extending the patent life.

Dramatic increase in insulin pricing

There has been a dramatic increase in the average list price of insulin over the past 20 years. The list price of insulin has nearly tripled between 2002 and 2013. There are also regular price increases each year from insulin manufacturers.[4]

Another key driver in the cost of insulin is the prescribers' shift to the more expensive human insulin analogs. Although these newer forms of insulin offer some advantages, their benefit over less expensive forms of insulin is still somewhat unclear. The price of both human insulin and the newer human insulin analogues have increased. However, the price difference between the two classes is substantial. Human insulin cost to the consumer is between $25 and $100 per vial, while the human insulin analogues are $180 to $300 per vial. [5]

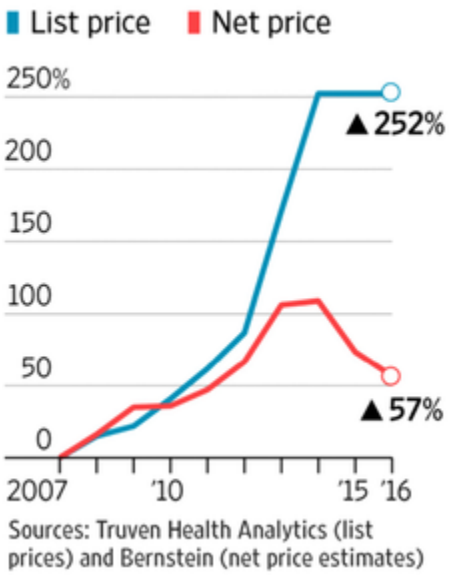
Net price versus List Price- Why is it important?

The list price of insulin is what a manufacturer sets as their price for the insulin product. However, there are a limited number of individuals who pay the full list price for any insulin

(mostly uninsured individuals, those in high-deductible plans and Medicare patients). Rather, most individuals pay a portion of the net price (list price minus any pharmacy discounts and any rebates paid to Pharmacy Benefit Managers (PBMs). An interesting development over the past few years is that there is a much slower increase in net price of insulin compared to list price. One report (shown below for an insulin analogue product) demonstrated a 252% increase in list price from 2007 to 2016 with only a 57% increase in net price.[6] The uninsured, Medicare and individuals in high-deductible plans are the ones shouldering this large increase in full price. They are the least likely to be able to afford the high cost.

Figure 1

Pricing shift in insulin analogue product [6]



The large gap between list price and net price is the negotiated discounts and rebates to PBMs and other stakeholders. A manufacturer will negotiate with a PBM to have their products listed on a lower-cost tier. Since PBMs are responsible for the formulary design of many plans, they determine what products are on the lowest-cost tier and thus more accessible for patients. In the United States, PBMs oversee the prescription coverage of over 260 million individuals.[7] Seventy percent of the claims are managed by just 3 PBMs (CVS Caremark, Express Scripts and Optum Rx). Because of their significant purchasing power, these PBMs have a strong negotiating power. Although PBMs pass their cost-savings to their customer (health-plans), they retain a percent of the rebate. There is conflicting information on what percent of the rebate is retained by the PBM; however, this information is confidential.

Impact of formulary changes

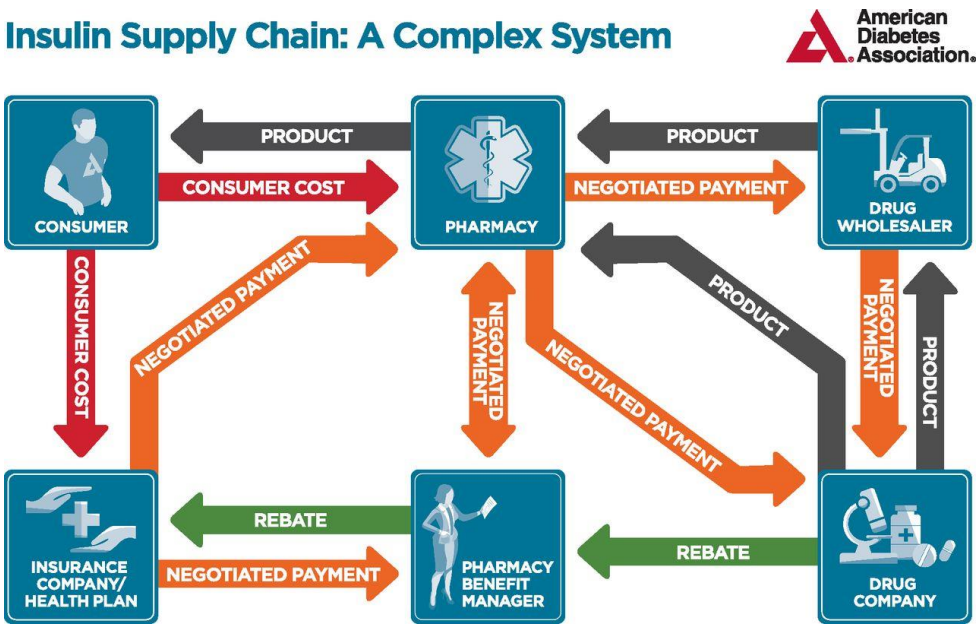
The American Diabetes Association Working Group reported that when PBMs make formulary changes based on rebate negotiations, there can be a financial as well as a clinical impact in

persons with diabetes.[7] PBMs frequently exclude more costly insulins from the formulary. That includes insulins made by manufacturers who offer the lowest rebate. These more "costly" products are often moved to higher tiers in a health-plan with a much higher patient co-pay. Formulary rule changes that are based on cost alone result in what is called "non-medical switching". These changes can occur year to year or sometimes more frequently. These actions result in patients having to switch to different insulins which may result in changes in dosing or frequency of administration. If a patient has a higher out-of-pocket expense for insulin, it has been reported that they may be less adherent or try to stretch their insulin by skipping doses. This has been reported in the survey done in Illinois of persons with diabetes.

The complex insulin supply chain

The supply chain for insulin is extremely complex and is not transparent.[7] The PBMs negotiate with manufacturers to receive the highest rebate. The PBMs negotiate with health plans and pharmacies to determine what they will pay the pharmacies for insulin and how the rebate will be shared with the health-plans. The problem with the current model is that most of these negotiations are confidential. The manufacturer does not know how the dollars flow from the PBMs to the health-plans and the health-plans do not know always how much the manufacturer rebate is with the PBMs. In the majority of cases, discounts and rebates negotiated between PBMs and manufacturers and between PBMs and pharmacies are confidential. Even PBM client health-plans are not privy to many of these negotiations, nor do they know the net price of insulin. There is a need for this contracting and rebate process to be more transparent to determine where there are opportunities to reduce the overall cost of insulin products to consumers.

Figure 2



Insulin biosimilars

The development of insulin biosimilars is a complicated process. A biosimilar drug is a biological product that is highly similar in structure and function to a product already approved by the FDA, known as the reference product. Producers of biosimilars use manufacturing techniques that are similar, but not identical to those used by the original patent holder. Thus, although a biosimilar and its reference insulin product will have the same amino acid sequence, they may differ slightly in their more subtle molecular characteristics and clinical profiles. The complex and expensive manufacturing process for insulin biosimilars, as well as the regulatory requirements, have slowed the development of these products.

In March 2020, the FDA made a change in the regulatory process and now permits insulin biosimilars to be approved through the more streamlined Biologics License Application (BLA) process. In June 2020, Semglee® was approved through the BLA. It is similar to Lantus; it has the same protein sequence and has a similar glucose-lowering effect. The next step of approval from the FDA is to go from a biologic classification to biosimilar. To be deemed a biosimilar, a drug must meet additional requirements to be deemed interchangeable.

It is expected that biosimilars will not have a major impact on insulin pricing until there are a number of products on the market resulting in more pressure on the brand manufacturers to lower price.

How are patients impacted by insulin pricing

A recent study from the Diabetes Daily included 1,700 people with diabetes.[8] The report included 57% of individuals with type 1 diabetes and 43% with type 2 diabetes. Over 44% of the people who responded to the survey struggled to afford insulin in 2019-2020. Approximately 25% of those who struggled make between $25,000 and $50,000 per year. Over 60% of survey respondents paid less than $300 per month for insulin and 80% paid less than $500 per month.

One barrier to care is that many individuals have no idea how much their insulin will cost when they arrive at the pharmacy.[8] In this survey, 79.2% of people indicated they did not know the cost for their insulin when they arrived at the pharmacy. In addition, 70% of these individuals were not able to fill the prescription due to high cost. This survey reported 68% of respondents altered the way they used insulin to save money. Individuals increased exercise to reduce insulin need, reduced their insulin dose or skipped doses.

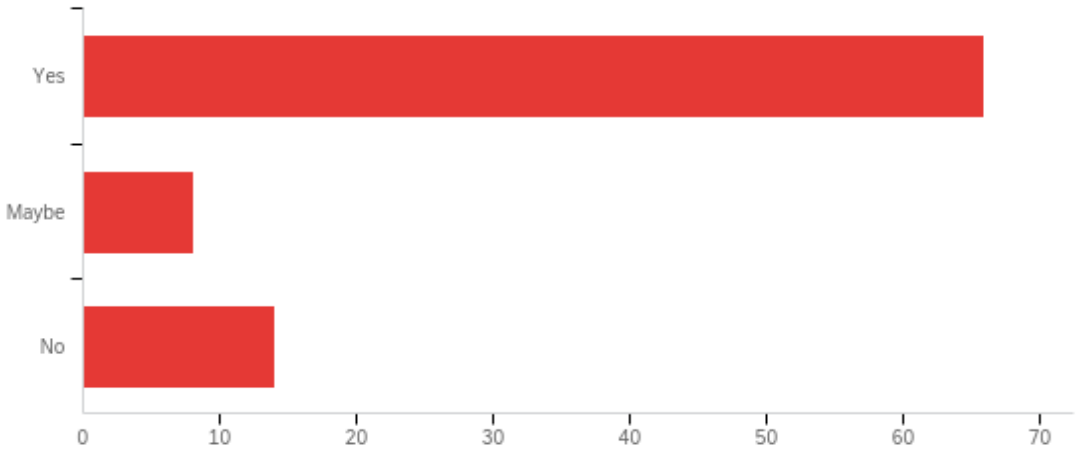
Bringing the insulin pricing problem to Illinois

To determine what the impact of insulin pricing is on persons with diabetes in Illinois, two surveys were conducted as part of this report. One survey targeted pharmacists and diabetes educators while a second survey focused on concerns of individuals with diabetes or their caregivers. These surveys were distributed through the Illinois Pharmacist Association and Illinois Council of Health-System Pharmacists, as well as the American Diabetes Association.

Pharmacists and Diabetes Educators

The results of these surveys indicate that pharmacists primarily (71%) dispense the more expensive human insulin analogues to their patients receiving insulin. It was not surprising to see that pharmacists and diabetes educators indicated that 96% of their patients experienced a non-medical switch of insulin. When patients were switched, pharmacists and diabetes educators reported that 86% had or may have had a need to change insulin doses. Ninety five percent of respondents indicated that they have had prescribers change insulin products due to cost. When asked about patients stretching their insulin doses, 75% stated that they had patients who did that. (see chart below)

Have you had patients take less than the prescribed dose of insulin so their insulin supply would last longer?



Persons with diabetes or caregivers

When evaluating the responses from individuals with diabetes, some interesting patterns emerged. When asked if ever had to choose between insulin and other basic needs, like groceries or rent, 26% (23) responded yes while 20% indicated they had to choose between insulin and utilities (heat, air-conditioning). Approximately 25% (22) indicated that they had rationed insulin in order to save money.

Conclusion

The current insulin supply chain process is complex and involves many stakeholders. The negotiations of these stakeholders are not transparent. The PBMs have an extremely strong negotiating power due to confidentiality. The rebate and pricing structure of insulin encourages continued high list prices for insulin. People with diabetes are harmed from the high list price of insulin and often have high out-of-pocket expense. People with diabetes have reported skipping doses or using lower doses to stretch their insulin supply.

Illinois Department of Insurance

Impact of Co-pay cap on rates

A review of 17 ACA compliant rate submissions for calendar year 2021 was conducted. Based on the review, the impact of the Section 356z.41 of the Code (215 ILCS 5/356z.41) (hereinafter "Section 356z.41")has been projected by Issuers to fall into one of two categories: (1) No Impact/Negligible Impact or (2) Measured Impact

A. No Impact/Negligible Impact

A designation of no/negligible impact to premium is projected by 13 of the 17 Issuers. Support provided for this level of impact are (1) internal cost model/pricing limitations, (2) majority, if not all, plan benefit designs already accommodate the new legislation, and (3) decision to first monitor impact prior to making pricing adjustments.

B. Measured Impact

The effect was determined to have a measured Per Member Per Month (PMPM) cost or percent of premium impact for 4 of the 17 Issuers, two of which have a large market share. PMPM cost is defined as the annual cost for the services divided by the number of people on a monthly basis.

Issuer	Impact
Issuer 1	$0.25 PMPM
Issuer 2	0.20% of premium
Issuer 3	$0.39 PMPM
Issuer 4	0.0-0.17% of premium

It is important to note that while some issuers measured the impact of the new bill, the impact was still determined to be immaterial and may not have been accounted for in the 2021 rate development.

C. Co-Pay Plan Benefit Designs

An additional analysis was performed to estimate the percent of members that have a co-pay plan that already complies with Section 356z.41requirements – and more importantly, to estimate the percent of members that would benefit from Section 356z.41. While we do not have full visibility into all of the plans and carriers, based on the information we did receive we estimate that approximately 96% of members who are in a co-pay plan already have a co-pay below $100. See the table below for a distribution of the members that have co-pays at or below the various co-pay amounts:

Pricing Practices of Plans

There is no prescribed method or standard for how issuers price their plans, so long as they are abiding by their respective regulations and follow sound actuarial approaches. There are,

however, similarities in how many of the issuers price their plans. In terms of pricing the impact of the co-pay limit on insulin drugs, many issuers will rely on their internal pricing models.

A. Internal Pricing Models

These internal pricing models are models that most issuers (or their consultants) will have to estimate the total cost of care, the percent of the claims that will be paid for by the member and the percent of the claims that will be paid for by the issuer. These pricing models are dynamic and will account for variations in member cost sharing, such as co-pays – i.e. the higher the co-pay a member pays, the less the issuer will pay. As we saw from the 'Impact of co-pay cap on rates' section above, the majority of members are not affected by this change. Issuers' pricing models may not be sensitive enough to accurately detect the impact of the changes or many of members already have cost sharing below the limit included in the regulation.

B. Other variables to consider in the cost of the health plan from insulin claims

Other variables to consider in the cost of insulin drugs include:

- The cost of the drug – usually negotiated by the pharmacy benefits managers (PBMs)
- Rebates for the drugs to the health plan – also typically negotiated by the pharmacy benefit managers
- The tier placement of insulin drugs – the higher the tier the insulin drug is placed in, the higher the member's co-pay
- Formulary placement – health plans and/or PBMs decide the list of drugs that will be covered without needed exemptions.

The above-mentioned variables to consider are further discussed in the 'Recommendation' section below.

Public Policy Recommendations for the Insulin Report

Work with Federal Officials on Addressing Self-Insured Plans

It is critical when constructing public policy recommendations to consider which regulatory bodies oversee specific plans that are available to consumers in Illinois. By understanding proper regulatory authorities, and in some cases the State's lack of regulatory authority, advocates and officials can focus on specific areas of regulation that need to be addressed. For example, many state insurance laws and regulations do not apply to Illinoisans with employer self-funded health insurance, commonly known as self-insured healthcare plans. Self-insured plans are plans where the business pays out the benefits covered by the plan directly, often with the assistance of a third party administrator, and any leftover premiums paid by employees are

returned to the business instead of the insurance carrier.[1] Self-insured plans give a business more autonomy over plan networks and included services.[2] Self-insured plans also fall under the authority of the federal government and are regulated under the Employee Retirement Income Security Act of 1974 (ERISA), which is a federal law that sets standards and procedures for employee benefit plans.[3] The Illinois Department of Insurance (IDOI) is prohibited from regulating self-insured plans, meaning self-insured plans are not subject to state premium taxes or state mandated benefits.[4]

Due to the State's lack of regulatory authority over self-insured plans, Section 356z.41, the mandate requiring an insurer to limit the total amount that an insured is required to pay for a 30-day supply of covered prescription insulin drugs not to exceed $100.00 per prescription, does not apply to these plans. Many businesses are currently favoring self-insured plans because of the potential profits, the ability to save money, and greater autonomy to the business.[5]

Because around 50-60% of Illinoisans have coverage that is regulated by the federal government, the IDOI recommends state officials and advocacy groups work with federal officials to study the effects on insulin pricing practices for plans that the State is unable to regulate. This study would help the State better understand the pricing structures around these plans and could further policy construction and recommendations to lower the cost of insulin drugs in collaboration with federal officials.

There are additional benefits to exploring plans that fall outside of the mandate's current authority. Other plans not required to comply with Section 356z.41 are high-deductible health plans (HDHPs) and coinsurance-based plans.

- HDHPs are plans with higher deductibles and lower monthly premiums.[6] A HDHP can include a health savings account (HSA), which allows consumers flexibility and discretion on how they wish to pay for certain medical expenses on a tax-advantaged basis.[7] In 2019, the federal government released new guidance that will allow some HDHPs to cover preventative services and medications for those with chronic conditions, including insulin.[8] However, this federal guidance applies only to HDHPs with HSAs. This means that when HDHPs without HSAs renew each plan year, consumers must

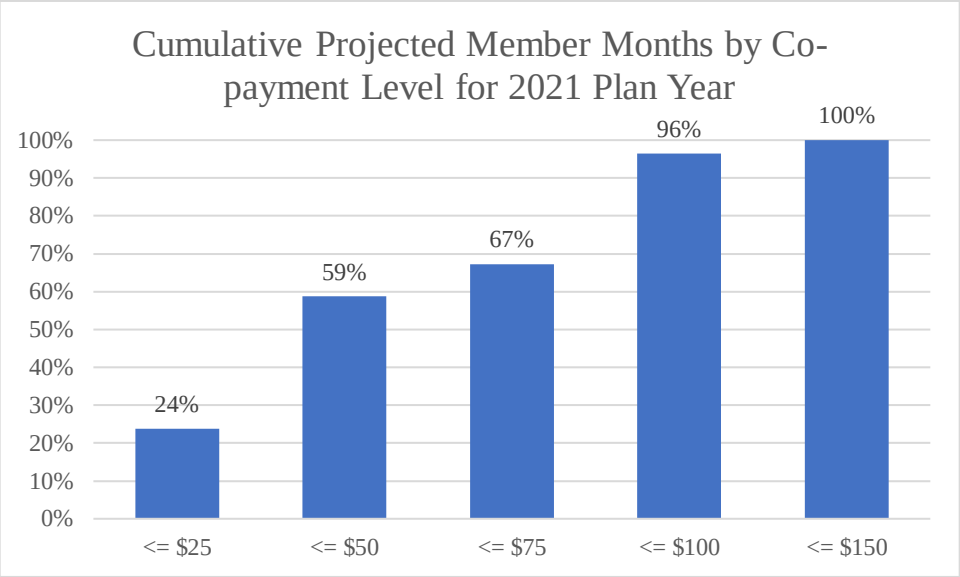
[1] *Fully Insured vs. Self-Funded Health Insurance Plans*; Elements; https://www.pbahealth.com/fully-insured-vs-self-funded-health-insurance-plans/ ; (Aug. 27, 2012).
[2] *Id*.
[3] *ERISA*, U.S. Department of Labor; https://www.dol.gov/general/topic/health-plans/erisa; Aug. 24. 2020.
[4] *Self-Insured Health Plans vs. Fully Insured Health Plans for your business*; O'Neill Insurance, https://oneillinsurance.com/blog/self-insured-health-plans-vs-fully-insured-health-plans-for-your-business-3/; Apr.1, 2019.
[5] *Id*.
[6] *High Deductible Health Plan (HDHP),* Heathcare.gov; https://www.healthcare.gov/glossary/high-deductible-health-plan/ (Sept. 4, 2020).
[7] *Id*.
[8] *Some Health Plans with High Deductible Health Plans will not Cover Insulin before Deductible is met*, GLU; , (Published Aug. 19, 2019).

purchase insulin at full cost until their deductible is met. Researching the consumer impact of the incurred costs of insulin under these non-HSA plans would be beneficial in shaping public policy recommendations for plans that require consumers to pay the full cost of insulin until their deductible is met.

- Coinsurance-based plans are plans that require the members to pay a percent of the cost of the drug instead of a fixed-dollar co-pay. The percentage that a member would be required to pay would depend not only on the cost of the drug, but the robustness or richness of plan benefits of the plan. As with the HDHP plans, researching the costs of insulin drugs and the amounts that members under these coinsurance-based plans pay would be beneficial in shaping public policy recommendations.

Conduct a Data Call on ACA Plans to Obtain Data.

Many Affordable Care Act (ACA) plans subject to the new mandate have reported that the plan's insulin co-pay cap is already much lower than what is mandated in Section 356z.41. While we do not have full visibility into all of the plans and carriers, based on the information we did receive we can see that 96% of members who are in a co-pay plan would already have a co-pay below $100.



Section 356z.41 set statutory co-pay caps for insulin that are, in practice, much higher than most current co-pays for plans that must follow the mandate.

Competition varies significantly by geography. The available benefit designs and cost sharing required by members can be very different by geography, with urban areas in the state having many more alternatives. As such, there is the potential that residents in urban areas will have lower copays. Illinois is split up into 13 different geographical rating areas that are defined based on counties to access individual and small group markets in Illinois.[9] They are as follows:

Rating Area 1	Cook
Rating Area 2	Lake, McHenry
Rating Area 3	DuPage, Kane
Rating Area 4	Grundy, Kankakee, Kendall, Will
Rating Area 5	Boone, Carroll, DeKalb, Lee, Ogle, Stephenson, Winnebago
Rating Area 6	Bureau, Hancock, Henderson, Henry, Mercer, Rock Island, Warren, Whiteside
Rating Area 7	Knox, LaSalle, Marshall, McDonough, Peoria, Putnam, Stark, Tazewell, Woodford, Fulton
Rating Area 8	McLean, Livingston, DeWitt
Rating Area 9	Champaign, Coles, Douglas, Edgar, Piatt, Ford, Iroquois, Vermillion, Clark, Cumberland
Rating Area 10	Adams, Brown, Christian, Logan, Macon, Mason, Menard, Morgan, Moultrie, Pike, Sangamon, Schuyler, Scott, Shelby
Rating Area 11	Bond, Calhoun, Clinton, Greene, Jersey, Macoupin, Montgomery, Randolph, Washington
Rating Area 12	Madison, Monroe, St. Clair
Rating Area 13	Alexander, Clay, Crawford, Edwards, Effingham, Fayette, Franklin, Gallatin, Hamilton, Hardin, Jackson, Jasper, Jefferson, Johnson, Lawrence, Marion, Massac, Perry, Pope, Pulaski, Richland, Saline, Union, Wabash, Wayne, White, Williamson

Data suggests that there is greater competition in the urban areas of the state, allowing for multiple carriers to offer plans, whereas southern and central portions of the state have much less carrier competition, often resulting in only 1 to 2 carriers per rating area.[10] In urban areas where there is more competition, it is likely that carriers will keep co-pay costs lower than the monthly limit of $100. Conversely, in rural areas of the State with little to no competition, the carrier may be less incentivized to keep co-pay caps lower than what is statutorily required by Section

[9] *Illinois Geographic Rating Areas: Including State Specific Geographic Divisions*, CCIO; https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/il-gra (Aug. 24, 2020).
[10] *Id.*

356z.41, creating concern that consumers in these rural rating areas are disproportionately affected by higher insulin co-pays.

To compound this issue, Illinois' rate of poverty tends to increase in counties within rural rating areas with the little to no carrier competition.[11] The concern is that this could result in increased insulin co-pays closer to the $100 threshold for counties having a higher likelihood of poverty, potentially resulting in fewer consumers purchasing plans subjected to the mandate in Section 356z.41. The potential issues in rural areas are important because the American Diabetes Association has shown that the greatest rates of poverty have greater numbers of individuals with diabetes.[12]

Because of these considerations, a more holistic approach is critical in assessing plans by geographical rating areas to understand what the cost to consumers are and the variation that exists. The Department recommends a data call to insurance carriers who offer plans that are subject to Section 356z.41 in order to receive carrier information on: (1) the plan's current insulin costs and coverage by tier; (2) the distribution of covered insulin drugs by tier (3) whether the co-pay cap or member cost sharing has increased or decreased since the law went into effect; (4) geographical service area of the plans in question. Data acquired from the data call will allow the Department to recommend a comprehensive approach that effectively lowers costs for consumers with plans that are subject to the mandate in Section 356z.41. The Department recommends an appropriation in order to conduct this study to ensure the Department has the financial means to thoroughly complete the data collection and analysis.

Conduct Various Studies and regulatory Measures on Entities that Contribute to the Drug Pricing Chain.

There are many entities that are involved in determining drug prices.[13] While these entities continue to operate, there is little transparency or understanding in the process of how pricing is established, often leaving patients with little to no knowledge on pricing of the medications they must take in order to remain healthy.[14] Establishing transparency within organizations that contribute to drug pricing practices within the State will allow policy makers the tools to establish a holistic solution to lower insulin pricing practices.

[11] *Illinois Poverty Rate by County*, IndexMundi; https://www.indexmundi.com/facts/united-states/quick-facts/illinois/percent-of-people-of-all-ages-in-poverty#map (Aug. 24, 2020).
[12] *Diabetes and Poverty*, OnTrack Diabetes; https://www.ontrackdiabetes.com/everyday-life/diabetes-poverty
[13] *How are Prescription Drug Prices Determined?,* AMA; https://www.ama-assn.org/delivering-care/public-health/how-are-prescription-drug-prices-determined (Aug. 25, 2020).
[14] *Id*.

Pharmacy Benefit Managers (PBMs)

A PBM is an entity that functions as an intermediary between insurance carriers and drug manufactures.[15] PBMs are typically responsible for developing and maintaining an insurance carrier's drug formulary, contracting with pharmacies, negotiating discounts with drug manufacturers, and processing and paying prescription drug claims.[16] A PBM is a company that handles an insurance carrier's prescription drug program.[17] These entities can purchase medications directly from drug companies.[18]

In 2019, HB 465 passed both chambers in the Illinois General Assembly, mandating that all PBMs that wish to operate in Illinois, register with the Department of Insurance. HB 465, codified as Section 513b1 of the Code (215 ILCS 5/513b1) (hereinafter "Section 513b1"), gave the Department of Insurance examination authority over PBMs, along with regulations/requirements that PBMs shall follow if the entities wish to operate within the State.[19] Specifically, the Department may request access to all books, records, documents and other papers relating to the PBM's business affairs.[20]

Since PBMs are one of the main entities impacting the price of a drug product consumer realize, The Department recommends conducting an exploratory examination of all recently registered PBMs that operate within the State. The examination's objective would be to gain knowledge of the pricing practices within the State, along with any specific information PBMs have for insulin pricing. Specific inquiries made to PBMs could include, but are not limited to: (1) PBM pricing practices of insulin drugs before and after the enactment of Section 513b1; (2) What insulin tier changes did the PBM make in response to the enactment of Section 513b1; and (3) Rebate amounts, both historical and projected, for insulin drugs as the negotiated rebates are amongst the more impactful values offered by PBMs. This study will allow the Department of Insurance to share detailed knowledge of other entities involved in insulin pricing within the State. The Department recommends a legislative appropriation in order to conduct this study to ensure the Department has the financial means to thoroughly complete the data collection and analysis.

Pharmacy Services Administration Organizations (PSAOs)

Pharmacy Services Administration Organizations (PSAOs) are organizations that assist independent pharmacies with various administrative tasks, such as assisting with third party payers or their PBMs, as well as provide independent pharmacies with administrative

[15] *Pharmacy Benefit Managers*, National Association of Insurance Commissioners; https://content.naic.org/cipr_topics/topic_pharmacy_benefit_managers.htm (last updated Jan. 1, 2020).
[16] *Id*.
[17] *Pharmacy Benefit Manager*, Verywell Health; https://www.verywellhealth.com/pharmacy-benefit-manager-1124201 (June 2, 2020).
[18] *Id*.
[19] 215 ILCS 5/513b1.
[20] *Id.*

assistance.[21] Independent pharmacies are retail pharmacies that are not directly affiliated with franchised chain pharmacies.[22] Unlike franchised pharmacies, most independent pharmacies have limited time and resources to complete administrative tasks.[23] PSAOs provide assistance in completing these tasks, which include but are not limited to, negotiating reimbursement rates, payment terms, and pricing updates, filing reimbursement challenges and appeals, audit assistance, payment reconciliation, and provide other business support functions.[24] The goal of a PSAO is to achieve administrative efficiencies for independent pharmacies.[25]

PSAOs are utilized by many of the independent pharmacies operating in the United States.[26] PSAOs develop networks of independent pharmacies through contractual agreements.[27] Many PSAOs are owned by drug wholesalers as well as independent pharmacy cooperatives.[28] The three largest PSAOs are owned by drug wholesalers, McKesson, Cardinal, and Amerisource Bergen.[29] All of these drug wholesalers are operational and have operational PSAOs in Illinois. In a study conducted by the Governmental Accountability Office in 2013, PSAOs owned by wholesalers represented 9,575 to 12,080.[30] Wholesaler PSAOs might have extra services that can be provided to independent pharmacies, such as a central payment service. PSAOs owned by wholesalers are likely able to provide extra services because of their strong financial backing.[31]

There are various reasons why PSAO owners operate PSAOs. These reasons can span from benefiting independent pharmacies to the PSAO owner benefiting in another line of business while owning the PSAO.[32] Wholesalers benefit by owning PSAOs because of their interest in developing relationships with independent pharmacies, which increase a potential customer base for the distribution line of the wholesaler.[33] Wholesalers may also benefit by having their PSAOs assist independent pharmacies by entering into multiple PBM contracts, increasing the drug volume needed by independent pharmacies.[34]

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[21] *Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, U.S. Government Accountability Office; https://www.gao.gov/products/gao-13-176 (Published Jan. 29, 2013).
[22] Independent Pharmacy, Wikipedia the Free Encyclopedia; https://en.wikipedia.org/wiki/Independent_pharmacy#:~:text=Independent%20pharmacy.%20An%20independent%20pharmacy%20is%20a%20retail,-owned%2C%20privately%20held%20businesses%20in%20varying%20practice%20settings. ; (last edited Apr. 10, 2020).
[23] *Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, U.S. Government Accountability Office; https://www.gao.gov/products/gao-13-176 (Published Jan. 29, 2013).
[24] *Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, U.S. Government Accountability Office; https://www.gao.gov/products/gao-13-176 (Published Jan. 29, 2013).
[25] *Id*. at 1.
[26] *Id*. at 3.
[27] *Id*. at 2.
[28] *Id*. at 4.
[29] *Id*. at 25.
[30] *Id*. at 25.
[31] *Id*. at 29.
[32] *Id*. at 29.
[33] *Id*. at 27.
[34] *Id*. at 27.

PSAOs are not known to be lucrative to wholesalers that own them.[35] However, the wholesaler's subsidiary PSAO might benefit another line of business under the wholesaler's ownership, which would render the PSAO beneficial regardless of its profitability.[36]

To further transparency in the drug pricing chain, PSAOs should be subject to transparency requirements, whether that be through licensing or registration. Illinois recently required the registration of PBMs effective July 1, 2020.[37] Because PSAOs also act in a way that is critical to understanding drug costs and supply chain, the Department recommends that PSAOs be registered with a State agency, similar to PBMs.

The Department recommends legislation that mandates the registration of PSAOs, similarly to the recently enacted PBM registration, which mandated PBMs to register with the Department of Insurance.[38] Specifically, during a registration process PSAOs should be required to disclose whether the organization is owned by a drug wholesaler. The Department suggests working collaboratively with other state agencies and stakeholders to complete this registration process. Multi-agency work is required because unlike PBMs, who operate on behalf of health plans, PSAOs cannot be considered risk bearing entities. Therefore, the regulatory process of registering PSAOs would not be appropriate if located within the Illinois Insurance Code and under the authority of DOI.

[35] *Id* at 29.
[36] *Id*. at 29.
[37] 215 ILCS 5/513b1.
[38] *Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, U.S. Government Accountability Office; https://www.gao.gov/products/gao-13-176 (Published Jan. 29, 2013).

Illinois Department of Healthcare and Family Services

Background

The Department of Healthcare and Family Services administers and, in conjunction with the federal government, funds health care / medical services for about 25 percent of the state's population.

Illinois' medical assistance programs, consisting of Medicaid and related medical programs, provide comprehensive health-care coverage to about 3.2 million Illinoisans. The programs cover children, parents or relatives caring for children, pregnant women, veterans, seniors, eligible individuals, and persons who are blind and persons with disabilities.

The medical assistance programs are administered under provisions of the Illinois Public Aid Code; Illinois Children's Health Insurance Program Act; Covering All Kids Health Insurance Act; and Titles XIX and XXI of the federal Social Security Act. The department's mission centers around helping Illinoisans access high quality health care and fulfill child support obligations to advance their physical, mental, and financial well-being.

Although not required by the federal government, the Illinois Medicaid program provides an expansive pharmacy benefit to Medicaid customers. This program is managed by the Bureau of Professional and Ancillary Services (BPAS) in the Division of Medical Programs. BPAS is responsible for negotiating supplemental rebate contracts with pharmaceutical manufacturers for Medicaid customers receiving prescription drugs in the outpatient setting. BPAS coordinates the Drug and Therapeutics Advisory Board, which is the vehicle for establishing acceptable new drugs and medications for the Medicaid Preferred Drug List.

The Medicaid Drug Rebate Program (MDRP) is a federal-state-drug manufacturer program that provides significant rebates to Medicaid programs that offset the costs of prescription drugs while ensuring patients can access needed medicines. The Department of Healthcare and Family Services also negotiates supplemental rebates with drug manufacturers, further reducing spending. Last year, HFS approximately $1 Billion in rebates back to Illinois, which reduces the overall cost to the State by about one-third.

I. Overview of Types of Insurance Plans HFS has Authority Over

HFS has authority over a variety of insurance plans including traditional Medicaid, All Kids, Affordable Care Act Adults and Dual-eligible beneficiaries (enrolled in Medicare Part A and/or Part B, and in Medicaid).

II. Pricing Practices of HFS Plans

Effective January 1, 2020, HFS established a Universal preferred drug list (PDL). All Managed Care Organizations (MCO) providing service to HFS clients must comply with the Universal PDL. As a result of this change, MCOs providing service to Medicaid clients are no longer able to negotiate separate supplemental rebate agreements with manufacturers. All supplemental rebates are collected directly by HFS. States and the federal government share

in the statutory rebate amount based on the federal medical assistance percentages (FMAP), which is the share of Medicaid spending in each state paid for by the federal government. Manufacturers submit rebates directly to states. The ACA increased rebate amounts from 18.1% to 23.1% for brand drugs and from 11% to 13% for generics, but the state share is only calculated off the pre-ACA rebate amount, which means the federal government now gets a bigger share of the rebates.[10]

Although the cost of insulin to the State can have a significant impact on the HFS drug budget, these changes are not passed on to the client. Both human insulin analogues (Lantus, Levemir) are preferred on the universal PDL. By having both agents available without prior approval, all Medicaid clients (Fee for Service and Managed Care) have access to either product, depending on the specific needs of the client.

III. Impact of co-pay cap on rates

Illinois Medicaid customers are not subject to co-pays for insulin products.

IV. Public Policy Recommendations (continued)

These recommendations are intended to supplement the recommendations listed in the DoI section and are not limited to the HFS population.

1. Recommend solutions that provide access to affordable and safe insulin in emergency circumstances, particularly for patients with type 1 diabetes who may be uninsured or unable to afford insulin.
2. Recommend that all brand human insulin analogues are available in the lowest cost-sharing tier on all formularies including commercial and government to reduce non-medical switching.
3. Continue to streamline the burdensome requirements for FDA approval of biosimilar insulin products. Until multiple biosimilars are available, lower prices of insulin will not be realized.

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Illinois Department of Human Services

Overview of BPCSS (Bureau of Pharmacy and Clinical Support Services) pharmacy responsibilities:

- Administers drug procurement activities, including purchasing, storing, repackaging, and distributing medication for residents of State-operated mental health and developmental disabilities facilities.
- Coordinates, provides clinical direction for, and monitors activities of pharmacy staff in State- operated facilities.
- Chairs the IDHS Mental Health and Developmental Disabilities Pharmacy & Therapeutics Committee, which is the vehicle for establishing acceptable medications for use in the Department's inpatient facilities.
- Provides consultation to the Program Offices of MH and DD relative to staffing, ethical, legal, licensing, and other operational issues concerning the practice of pharmacy within the IDHS in-patient facilities.
- Serves as User Project Manager for the IDHS Clinical Information System.

Background

Like most bills, SB 667 went through many iterations before being signed by the Governor. Senate Amendment 4 created the Insulin Assistance Program which, as drafted, would have been housed at IDHS. The intent of the program was to provide insulin products and related supplies to families with a Federal Poverty Level of 600% or less. On January 24, 2020, P.A. 100-625 was signed into law. The final bill did not include the Insulin Assistance Program but instead mandated a report. The report will detail the Department of Insurance, Department of Human Services, and Department of Healthcare and Family Services findings regarding insulin pricing practices and variables that contribute to the pricing of health coverage plans, and public policy recommendations to control and prevent overpricing of prescription insulin drugs. The report shall be made available to the public

Prescribed drug expenditures incurred by Medicare D only or dual eligible residents of IDHS MH and DD care facilities are reimbursed through the Medicare Part D program or are covered by IDHS's budget for Medicaid-related expenditures. The Medicare Part D program is primarily designed for retail pharmacies dispensing and acquiring the copay from the beneficiary at the point of sale. As State-operated facilities do not collect a copay from the beneficiary there is no point of sale.

Insulin pricing practices and IDHS:

IDHS has no control or authority over pricing practices. IDHS is a consumer of insulin. Based on our majority population covered by Medicare Part D, dual eligible, and Medicaid, IDHS covers the related expenditure on insulin no matter how Medicare Part D plans reimburse or how copays are applied. The State of Illinois has both State Operated Psychiatric Hospitals and State

Operated Developmental Centers throughout the state. Current average population of residents is 3,700 in 13 facilities, approximately 4.1% receive insulin products and 2% are reimbursed via Medicare Part D.

Variables that contribute to pricing of health coverage plans:

Preferred insulin products are directed by Medicare Part D formulary status (what the coverage is and what the copay of the insulin is) and the rebate agreement with the preferred manufacturer, requiring brand name, now that there are some generics on market.