Agenda

No.	Agenda Items	Time	Lead
1.	Welcome and Opening Business	10	Mary Fliss – Deputy, Clinical Strategy and Operations, HCA
2.	Patient Perspectives Presentation on Emergency Supply	60	Donna Sullivan – Chief Pharmacy Officer, HCA Kevin Wren – Washington Insulin for All
3.	Short-Term Emergency Supply Comparison Grid	30	Hayley De Carolis - Center for Evidence-based Policy
4.	*Break*	*10*	
5.	Overview and Discussion of Workgroup Survey #3 Results	60	Mike Bonetto – Center for Evidence-based Policy
6.	Next Steps	10	Mary Fliss – Deputy, Clinical Strategy and Operations, HCA

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1. Welcome and Opening Business

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2. Patient Perspectives on Emergency Supply

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Questions?

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3. Summary of Emergency Supply Insulin Legislation

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Emergency Supply Programs

- Maine Insulin Safety Net Program
- Minnesota Insulin Safety Net Program
- Utah Pharmacy Practice Amendments Bill 207
- Ohio House Bill 37

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Emergency Supply Programs

- Maine Insulin Safety Net Program
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Maine Insulin Safety Net Program

- S.P. 260 signed into law June 21, 2021
- Implemented March 1, 2022
- Legislation for insulin safety net program includes:
  - **Urgent need safety net program**
  - Manufacturer's patient assistance program
  - Insulin product registration fee
  - Annual reports
- Urgent need program provides 30-days supply to eligible individuals

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Key Definitions

- "Insulin": includes various types of insulin analogs and insulin-like medications, regardless of activation period or whether the solution is mixed before or after dispensation
- "Manufacturer": any manufacturer engaged in manufacturing insulin that is self-administered or an outpatient basis, except for a manufacturer with an annual gross revenue of $2,000,000 or less from insulin sales in the State
- "Urgent need of insulin": having less than 7 days of insulin available and in need of insulin in order to avoid the likelihood of suffering significant health consequences

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Patient Eligibility

- Resident of Maine
- Not enrolled in MaineCare
- Not enrolled in health plan that limits cost-sharing to $75 or less for 30-days supply
- Household income < 400% FPL
- Not eligible for federal health care coverage
- If on Medicare Part D – must also spend at least $1,000 on prescription drugs in calendar year

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Application

- Application for urgent-need program must be available online (via Board of Pharmacy) and at health care settings (e.g., health care providers, hospital emergency departments, urgent care clinics, community health clinics)
- Must demonstrate all eligibility criteria on application form
- Pharmacy is responsible for reviewing application when patient request emergency supply
  - Unlike ongoing assistance program where manufacturer is responsible for reviewing application and determining eligibility
- Pharmacy must supply patient with information sheet about health insurance consumer assistance program

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Patient Access

- Patient must present signed and dated application, valid prescription, and Maine identification (e.g., driver's license, ID card) at pharmacy
- If patient does not have valid prescription, pharmacy can still dispense insulin

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Program Monitoring

- Requires annual reporting from manufacturers
  - How many people accessed urgent insulin
  - How many residents are participating in the patient assistance program
  - Value of the insulin dispensed
- State Pharmacy board will aggregate data and submit annual report to state legislature
- Pharmacy must retain copy of application form submitted
- Pharmacy must notify prescriber of dispensed insulin no later than 72 hours after

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Pharmacy Reimbursement

- Pharmacies may charge up to $35 copay for 30-days supply of insulin dispensed to cover the pharmacy's costs of processing and dispensing the insulin
- Manufacturer reimburses pharmacy for dispensed insulin either with replaced supply or in an amount that covers the pharmacy's acquisition cost

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Funding/Financing

- Manufacturers with an annual gross revenue of $2,000,000 or more from insulin sales in the State must:
  - Pay $75,000 fee annually
  - Pay pharmacy for dispensed insulin or supply insulin to backfill dispensed amount
    - No specified timeline for reimbursement
  - Establish patient assistance program
  - Approve or deny applications for patient assistance program
  - Submit data for annual report

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Emergency Supply Programs

- Maine Insulin Safety Net Program
- Minnesota Insulin Safety Net Program
- Utah Pharmacy Practice Amendments
- Ohio House Bill 37

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Minnesota Insulin Safety Net Program

- HF 3100 “Alec Smith Insulin Affordability Act” signed into law April 15, 2020 and implemented July 1, 2020
- Legislation for insulin safety net program includes:
  - **Urgent-need insulin program**
  - Continuing safety net program
  - Legislative reports
  - Legislative auditor
  - Program satisfaction surveys
- Urgent need program provides 30-days supply to eligible individuals

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Patient Eligibility

- Resident of Minnesota
- Not enrolled in medical assistance or MinnesotaCare
- Not enrolled in health plan that limits cost-sharing to $75 or less for 30-days supply
- Have not received urgent-need supply of insulin through program within previous 12-months
- Has urgent need for insulin

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Application

- Developed by MNsure (Minnesota's health insurance marketplace)
- Must be available online, pharmacies, and other health care settings
- Pharmacy is responsible for reviewing application when patient request emergency supply
  - Unlike ongoing assistance program where manufacturer is responsible for reviewing application and determining eligibility within 10 business days
- Pharmacy must also provide patient with information sheet and a list of trained navigators to contact to assist in accessing ongoing insulin options such manufacturer's patient assistance program

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Patient Access

- Patient must present signed and dated application, valid prescription, and Minnesota identification (e.g., driver's license, ID card) at pharmacy
- Unlike Maine's law, patient is required to have valid insulin prescription

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Program Monitoring

- Pharmacy must notify prescriber no later than 72 hours after insulin is dispensed
- Pharmacy must retain copy of patient's completed application
- Manufacturers must report how many residents received emergency insulin, number of residents participating in patient assistance program, and the value of insulin provided
- Aggregated report due annually from board
- The commissioner of health, in consultation with others, must develop and conduct a program satisfaction survey of patients
  - Report was submitted to legislature January 15, 2022

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Emergency Supply Programs

- Maine Insulin Safety Net Program
- Minnesota Insulin Safety Net Program
- Utah Pharmacy Practice Amendments
- Ohio House Bill 37

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Utah Pharmacy Practice Amendments

- Effective 5/4/2022
- Built on Utah Insulin Access Amendments (2020) which included:
  - Incentive for health benefit plans to reduce require copayments for insulin
    - Capped at $30 per prescription of a 30-days supply (with exceptions)
  - Study on insulin pricing
  - Public Employees' Benefit and Insurance "Insulin Discount Program" that allows Utahns to purchase insulin at discounted, post-rebate rate
  - Increase to number of days for which an insulin prescription can be refilled
  - **Authorizes a pharmacist to refill an expired insulin prescription**

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Eligibility

- Eligibility criteria is prescription-specific, not patient
- "Exhausted prescription": a prescription for an insulin that the patient is currently using that:
  - Expired no earlier than 6 months before request
  - Is not expired and has no refills remaining
- A pharmacist may dispense emergency supply no more than one time per exhausted prescription

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Patient Access

- Pharmacist may dispense emergency refill for exhausted prescription based on prescriber's instructions in an amount up to 60-days
- Before dispensing insulin, pharmacist must:
  - Attempt to contact prescriber
  - Notifying patient of outcome of attempt to contact prescriber
  - Inform prescriber of dispensed insulin information within 30 days
- Pharmacist may dispense the therapeutic equivalent when filling a prescription for:
  - A glucometer
  - Diabetes test strips
  - Lancets
  - Syringes
  - Needs
  - Other supplies for treating diabetes designated by rule

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Pharmacy Reimbursement

- Unlike other legislation, cost of emergency supply is not required to be reimbursed by manufacturers
- No language in statute related to reimbursement, copays, or insurance coverage

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Emergency Supply Programs

- Maine Insulin Safety Net Program
- Minnesota Insulin Safety Net Program
- Utah Pharmacy Practice Amendments
- Ohio House Bill 37

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Ohio 2021 HB 37

- Effective June 1, 2022
- Expands emergency dispensing authorization of up to 30-days supply for all noncontrolled medications
- Allows pharmacist to dispense drug without prescription:
  - If the pharmacy has record of prescription
  - Pharmacist is unable to obtain authorization for refill from provider
  - If pharmacist determines drug is essential to sustain life and failure to dispense drug could result in harm to patient

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Patient Eligibility

- All insured patients
- Drug may be dispensed no more than 3 times in a 12-months period – and cannot be dispensed consecutively
- The first time drug is dispensed, patient can get 30-days supply. For subsequent time, patient can only receive 7-days supply.

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Patient Access

- Pharmacist must be unable to obtain authorization from prescriber
- Pharmacist must determine:
  - Drug is essential to sustain life or continue therapy for chronic condition of patient
  - Failure to dispense drug could result in harm to health of patient
- Coverage and copays for emergency supply are same as when insulin is dispensed in non-emergency situations

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Program Monitoring

- Pharmacy must keep record drug dispensed, amount, original prescription, and patient information for one year after the day of dispensing
- Pharmacist must notify prescriber no later than 72 hours after drug is dispensed

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Discussion

Name	Summary
Maine Insulin Safety Net Program	• Patient must bring completed application (reviewed by pharmacist), valid prescription (with exceptions), Maine ID • Can only access 30-days emergency supply once in 12-months period • Pharmacy may charge up to $35 copay to cover dispensing costs • Manufacturer must reimburse pharmacy in amount that covers acquisition cost or with replaced supply • State levies $75,000 annual license fee on manufacturers with annual gross revenue of $2,000,000 or more in state
Minnesota Insulin Safety Net Program	• Same elements as Maine except no licensing fee levied on manufacturers • Also includes program satisfaction survey and patient resources on accessing navigators
Utah Pharmacy Practice Amendments (2022)	• Includes authorization for pharmacist to refill an exhausted but not expired insulin prescription • No mention of patient insurance coverage or copays/reimbursement
Ohio House Bill 207	• Expands emergency dispensing authorization of up to 30-days supply for all noncontrolled medications • Pharmacy must have record of prescription and must be unable to obtain authorization for refill from prescriber • Drug may be dispensed no more than 3 times in a 12-months period – and cannot be dispensed consecutively • Coverage and copays for emergency supply are same as when insulin is dispensed in non-emergency situations

Questions?

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4. Break (10 minutes)

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5. Workgroup Survey #3 Responses

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Survey Respondents
(8 respondents)

Respondents	Survey 1	Survey 2	Survey 3
Benefits Managers	2	1	0
Distributor/Wholesaler	1	1	1
Pharmacies	1	0	1
Purchaser	1	0	0
Health Carriers	0	1	1
Patient/Representative	3	4	2
Regulator	2	2	2
State Agency	3	3	1
Not Specified	0	1	0
Total	**13**	**13**	**8**

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Both programs allow pharmacies to collect a copayment up to $35 from the patient to cover pharmacy's cost of processing and dispensing emergency supply of insulin. What, if any, aspects of how pharmacies are paid for their services would you recommend including as part of the workgroup's report to the legislature?
To facilitate access, **the copayment should be de minimis**, if any (more on the lower than upper side of $35). We could discuss how dispensing and processing fees for emergency insulin could be covered outside of copayment.
Why is the limit set to $35? That number seems arbitrary, and we should seek to lower the burden facing patients while also looking to compensate pharmacists. When you're rationing insulin, any dollar that can be spared could mean the difference between eating and paying rent. We need to account for pharmacists' time as well as the supplies, but cost is the greatest barrier farming patients, and we should lower it if we have a chance.
As long as the **pharmacy is made whole including a dispensing fee**, I am not sure what to include in the report.
Is it expected that this amount would cover the dispensing fee to the pharmacy? Is this aligned to the market?

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We have discussed in the workgroup the importance in **supporting more than just dispensing a generic insulin allotment. Ensure that supplies and time released insu**lin are available under the copayment limit and for the emergency dispensing.
I think the **copay for emergency should be 0.** $35 is a lot for someone struggling. This is emergency access to a lifesaving medicine, not a luxury item that one can go without or save up for. Pharma and PBMs can afford to pay for it. Preventing hospitalizations and complications by increasing access will offset the cost.
Any **PBM and Manufacture rebates**.
The **notification to prescribers is an additional burden** for the pharmacy filling the prescription and I would not recommend notification back to the prescriber. The **pharmacies need to be supported by the manufacture through replacement stock or reimbursement** from the manufacture or through state funding. Community pharmacies cannot be required to absorb the cost of providing these services.

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Both bills allow patient access to the emergency 30-day supply of insulin to once in a 12-month period based on a completed application. What, if any, aspects about this verification process would you recommend including as part of the workgroup's report to the legislature?
To be discussed: **avenue to submit application**? Could this be done in the pharmacy, at some type of portal, as a last resort?
I **don't think it should be limited to state residents with ID**. Undocumented, homeless, tourists, there are so many who need insulin who do not satisfy these criteria but who would need insulin given any number of life events or emergencies. Dropping a vial while on vacation or living on the streets, means you might die. The most vulnerable of us need the barrriers to access removed as much as possible. Why do we need to limit access to once per year? It only takes an instant to lose your insulin or access to health care, so we should expand the number of times one can access this program, not just the eligibility criteria.
I would like to make sure that this is **available for undocumented immigrants that do not have insurance**. The individual should not have to prove citizenship or immigration status.
I would recommend **using ArrayRX to the extent possible** given their experience with Washington's Prescription Drug Card.

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Diabetes is a chronic condition that is not going to be treated with a one-time 30-day supply. I recommend we review this and think about how we can **ensure patients get ongoing insulin supplies from manufactures** or other sources until such time as the patient has other ways to receive insulin through insurance or other means.
Including the discussion of **provisions to update a practitioner, or wrap around services** from a patient navigator would be of interest to the legislature and a point of discussion regarding the pros and cons
There should be a **minimal verification process** to not burden disabled people or staff.
That for those who need a 30-day supply are **notified of other health insurance options or state programs** so they can gain access to affordable insulin moving forward.

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Maine's insulin safety net program requires manufacturers who sell or distribute 500,000 or more units of insulin per year to pay a $75,000 annual registration fee to the Maine Board of Pharmacy which funds one full-time equivalent (FTE) position to manage Insulin Safety Net Program. What, if any, aspects of this funding would you recommend including as part of the workgroup's report to the legislature?
The annual registration fees might be beneficial but **might result in some post-enactment challenges**.
$75,000 is nothing compared to the billions manufacturers make every year from the sale of insulin in the US. They've price gouged for decades. This fee should be in the $ millions if we want to change their behavior.
When our funding it based on a **fee to manufacturers that can have a negative connotation** as well. This was one of the reasons why a tax was not included in the Drug Price Transparency Program or the Prescription Drug Affordability Board legislation.
Requiring manufacturers to pay for program administration is better than using state funds. Without knowing the number of manufacturers it's difficult to say if the amount is reasonable. I would also hope that it wouldn't discourage low-cost insulin producers new to the market.

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I support the concept of manufacturers being required to provide funding for management of the program.
I would include feedback on how such a fee was implemented and was it actually assessed and paid.
If we need to have a staff oversee the program, then Pharma and PBMs should play for it. The staff member deserves a higher wage than $75,000 for the important work they are doing.
The number of people who use the safety net.

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Both bills require manufacturers to reimburse pharmacies with backfilled supply of the emergency insulin dispensed or reimburse monetarily for the dispensed insulin equal to the pharmacy's acquisition cost. What, if any, aspects of this reimbursement or replenishment model would you recommended including as part of the workgroup's report to the legislature?
Reimburse pharmacies with backfilled supply of the emergency insulin.
There should be an **accounting of the supplies and effort**, so this should included.
I would **leave this up to the pharmacies** to provide us with their preference.
The **manufacturer paying pharmacies' acquisition costs or to replace the supply is a good option.**
I would **support a monetary reimbursement model so long as it is timely.** This model would also ensure the pharmacy can use existing wholesaler channels for ordering medications rather than having to work a different process to get replacement insulins.

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It is important that **remuneration is included for the pharmacy and a dispensing fee**, so the program is not a burden on a pharmacy and there is the willingness to participate. These provisions should be included in the report.
Pharma should be paying the copay fee too. They could choose to sell their drug at a reasonable price, but they choose to exploit disabled people. Let's not reward them and punish disabled Americans instead.
Transparency and what the costs are for the pharmacies.

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What, if any, aspects of the Maine or Minnesota legislation or any other legislation related to insulin would you recommend for including as part of the workgroup's report to the legislature?
I thought that the eligibility requirements were reasonable.
We need a state patient benefit program that ensures everyone that doesn't get access with ill the other programs/emergency access hoops they may need to jump through. We need to seal up all of the cracks that Washingtonians could fall through to so right by diabetics in Washington.
Look at a **purchasing program like Utah that allows uninsured to access insulin all year.**

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What, if any, aspects of the Maine or Minnesota legislation or any other legislation related to insulin would you recommend against including as part of the workgroup's report to the legislature?
n/a
I am all for emergency access but **think it needs to be a 90-day supply**, be as little cost to patients as possible, can be **accessed more than once per year**, and not require ID or state residency
Pharmacy should not have to notify the prescriber, that is just admin burden that is not necessary.
A 90-day supply will better ensure a person is able to get through their transition/hard time and ensure people arent rationing. I do not think pharmacists dhould have to report to providers when they gove out emergency insulin. This is an unnecessary burden.
None

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Greater flexibility in providing emergency insulin supply than once per 12-month period as listed in both state rules.

G**reater flexibility for patients under 18 years old who may not have a parent or guardian** who can provide proof of residency.

Repayments to pharmacies by manufactures for insulin doses dispensed be mandated to **occur within 10 business days**.

I would **not include rules requiring pharmacies to retain copies of patient applications**. This creates an additional regulatory requirement that seems unnecessary.

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Wrap-Up Any additional feedback you wish to provide?
Thank you!
Disabilities such as diabetes have been used to justify inequality in Americas history. Injustice continues today. We are human and diabetes is not our fault. We deserve the right to live.
30-day supplies for an emergency are great and the **process should be easy for consumers** to access.

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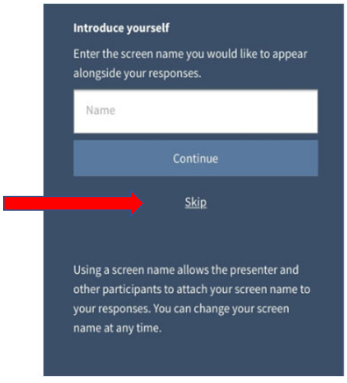
Poll Everywhere Participation

- Navigate to the link **PollEv.com/cebpohsu300** and wait for the question prompts on your screen
- You should be able to click on link in the chat feature
- If you wish to be anonymous, select the skip option if/when prompted to enter your name
- Your device will automatically advance you to the active poll
- Results will appear on the screen after you answer; you can change your response if you wish



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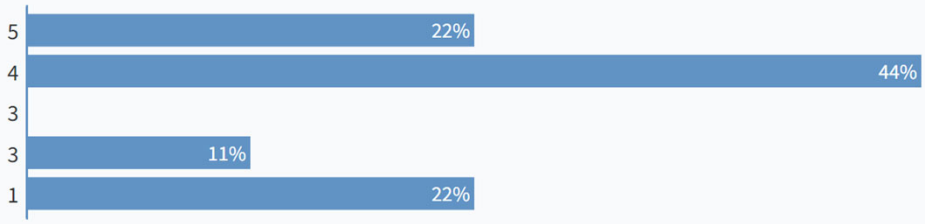
When poll is active, respond at **pollev.com/cebpohsu300**
Text **CEBPOHSU300** to **22333** once to join

On a scale of 1-5 (with 5 being Strongly Support), how strongly would you support a co-payment not to exceed $35 for an emergency supply of insulin?

When poll is active, respond at **PollEv.com/cebpohsu300**
Text **CEBPOHSU300** to **22333** once to join

On a scale of 1-5 (with 5 being Strongly Support), how strongly would you support eligibility criteria that includes being a Washington resident to access an emergency supply of insulin?



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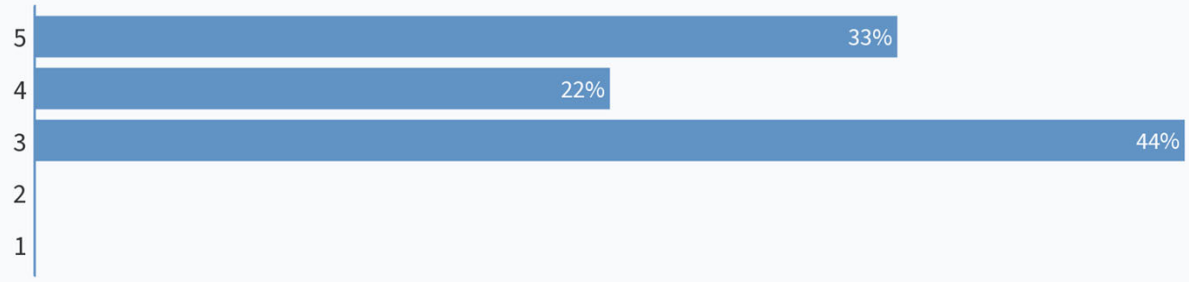
When poll is active, respond at **pollev.com/cebpohsu300**

Text **CEBPOHSU300** to **22333** once to join

On a scale of 1-5 (with 5 being Strongly Support), how strongly would you support requiring manufacturers to pay an annual registration fee if they sell or distribute a certain volume of insulin in Washington?



What other key takeaways do you have from the reviewed state legislation that the work group should consider?

- There should be a standard, easy to use registration system if it is selected to be used as part of this program.
- We will have to create a marketing/educational campaign for health care providers and patients alike.
- We started looking at long term solutions not just these short term ones like copay caps and emergency suppply
- It is really important the process is easy to use for everyone. The consumer, the pharmacy, the state and insurance.
- We should focus our future work on the two "buckets" that Mike laid out.
- I want to support additional manufacturers as they come on board
- The requirement of manufacturer reporting.

Start the presentation to see live content. For screen share software, share the entire screen. Get help at **pollev.com/app**

6. Next Steps

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Timeline

Task/Deliverable	Date
Total Cost of Insulin Workgroup #1	*July 8, 2022*
Preliminary report due	*August 12, 2022*
Total Cost of Insulin Workgroup #2	*August 25, 2022*
Total Cost of Insulin Workgroup #3	October 27, 2022
Total Cost of Insulin Workgroup #4	December 6, 2022
Draft of final legislative report due	February 13, 2023
Total Cost of Insulin Workgroup #5	March 16, 2023
Final legislative report due	March 31, 2023

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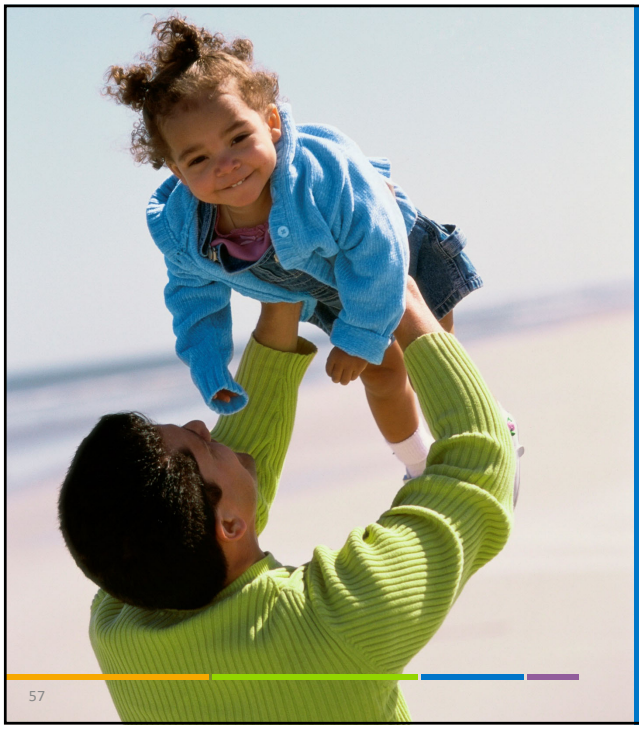

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Questions?

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