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SB 144 (Pharmacy Vaccines)
Testimony of Bill Cotton, MD, FAAP
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Chairman Cutrona, Vice Chair Gross, Ranking Member Somani, and members of the House Health Provider Services Committee, thank you for the opportunity to provide testimony on Senate Bill 144. As you know, this legislation expands the scope of practice for pharmacy-based providers as it relates to childhood vaccinations. Our concerns with this bill do not stem from any belief that pharmacists, pharmacy interns, and pharmacy technicians are not dedicated healthcare providers. Further, for many families, pharmacies are the most accessible site of care. This issue is complex and requires us to look at where we have been over the past decade. We are concerned that SB 144 will harm our well-child rates and result in poor data collection related to vaccination status for kids. Simply put, we do not feel SB 144 will positively impact immunization rates for children in Ohio.

We know from the COVID-19 pandemic that pharmacies are critical frontline healthcare providers and sites of care. And while we want pharmacists involved in vaccine administration, it is important to provide some historical perspective. Prior to 2015, pharmacies could only administer influenza vaccines to children ages 14-17. For all other ACIP-recommended vaccines, pharmacies could not offer them to minors. Just to be clear, pharmacies have only been able to offer vaccines to children (with the exception of influenza) for less than a decade in Ohio. The scope of practice was modified in House Bill 394 (130th), which was introduced by then-State Representatives Ryan Smith and Nickie Antonio. Under this bill, which took effect in early 2015, pharmacists were granted the ability to provide ACIP-recommended vaccines to children as young 13; further, the ability to administer the influenza vaccine was lowered to age 7. For kids ages 7-12, pharmacies could offer other vaccines besides seasonal flu, but they were required to have an order or prescription from a physician.

SB 144 would modify this framework by removing the requirement that pharmacists have a prescription for vaccine administration (besides seasonal flu) to children ages 7-12. The bill further lowers the minimum age for any vaccine administration to age 5. As a result, pharmacists, pharmacy techs, and pharmacy interns would be able to administer all ACIP-recommended vaccines to children as young as 5. This is meant to codify temporary federal rules that allowed pharmacies to administer vaccines to children as young as 3, preempting state law.

As you heard during sponsor and proponent testimony, the Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the U.S. Department of Health and Human Services to adopt policies during a public health emergency to combat the spread of infectious diseases or illnesses. In February 2020, at the onset of the COVID-19 pandemic, the Secretary issued a declaration invoking the PREP Act to adopt a series of emergency countermeasures. The third amendment, issued on August 19th, 2020, permitted pharmacists to offer all ACIP-recommended vaccines to children ages 3-17, notwithstanding any state laws to the contrary. The eighth amendment, issued on August 4th, 2021, expands this authority to pharmacy technicians and pharmacy interns.

In April 2023, the Federal Public Health Emergency (PHE) was terminated by the HHS Secretary. Many of us have discussed this as it signaled the restart of Ohio Medicaid's eligibility redetermination process. However, the expiration of the PHE also had an impact on the scope of practice for pharmacists, pharmacy techs, and pharmacy interns in Ohio. The eleventh amendment to the declaration, which was announced on April 14th, 2023, extended the ability of pharmacy providers to administer COVID-19 and seasonal flu vaccines to any children ages 3 and older through December 31st, 2024. However, the amendment also removed the ability of these providers to administer ACIP-recommended vaccines to children and returned control to state laws. According to the Ohio Board of Pharmacy, as of May 12th, 2023, pharmacists, pharmacy interns, and pharmacy technicians can no longer administer routine childhood vaccines to children under the PREP Act. This means that, for the past year, parents have not had expanded options for childhood vaccines beyond those afforded in state law under the 2014 compromise.

Unfortunately, the overlapping federal and state law and rule changes, along with expiring COVID-19 era federal orders, have created a lot of confusion for parents. Under current state and federal law, which will be in effect until December 31st, if you want to have your child immunized against COVID-19 or influenza, you can take your child to a pharmacy provided they are at least 3 years of age. For all other childhood vaccines (see chart below), you can take your child to a pharmacy so long as they are 13 years of age and older. For children ages 3-12, you would need a prescription or order from your physician to receive childhood vaccines (besides COVID-19 and influenza) from a pharmacy.

Obviously, we want as many children as possible immunized against vaccine-preventable diseases. However, we do not want to sacrifice comprehensive primary care for children just to chase higher rates. When children come in for annual visits, sports physicals, or even to flu vaccine clinics, pediatricians are able to perform screenings for developmental and behavioral health issues, answer questions from parents and kids on various topics, and provide guidance to parents on potential risks and key developmental milestones. For example, at the 11/12-year-old well child visit, children receive the meningitis and Tdap vaccines. They also receive screenings for behavioral health concerns and suicidality; further, this is an ideal time for pediatricians to discuss certain risks with parents and patients such as drug and alcohol abuse or sexual activity. If parents opt to take their children to a pharmacy instead of a primary care provider, these assessments and discussions are lost.

Given that pharmacies often do not participate in the Vaccines for Children (VFC) program, kids on Medicaid would not be able to receive vaccines from pharmacists, pharmacy techs or pharmacy interns. This means that half of Ohio children would not benefit from any expanded access in SB 144. VFC is a federal program that provides free vaccines to providers while the Ohio Department of Medicaid (ODM) pays a fee to cover the cost of storage and administration. All Medicaid-eligible kids are also VFC eligible, and the only cost to the state is the administration fee.

During the COVID-19 pandemic, Ohio Medicaid did change their reimbursement to allow pharmacies to administer all ACIP-recommended vaccines to covered children without participating in VFC. To accomplish this, ODM reimbursed providers the administration fee plus compensation for the cost of vaccines. While this was done as an emergency measure to boost Ohio's vaccine rates, this policy has since expired and making it permanent would generate significant cost to taxpayers as Medicaid would be covering vaccine acquisition costs. Under VFC, there is no cost to purchase vaccines. Any discussion around improving vaccine access must include VFC as a necessary component.

Another factor in all of this is the role of ImpactSIIS, the state vaccine registry. The Ohio Department of Health (ODH) maintains the database, which is an invaluable tool in collecting and analyzing vaccination status. In the case of an outbreak, ImpactSIIS data can be used to quickly identify children who may be at increased risk due to lack of vaccination. Health departments report all vaccine administration to ImpactSIIS, as do children's hospitals, primary care providers, and other sites of care. Additionally, most EMR's will push info to the registry, providing the best data currently available. Current rules promulgated by the Ohio Board of Pharmacy, as well as PREP Act requirements in place until December 31st, require pharmacists to report vaccine administration to either the patients primary care provider, a local health department, or into OARRS or an EMR system. Pharmacies can also report directly to ImpactSIIS, but this is not widely done.

As you can tell, there are a lot of components to this discussion and Ohio's vaccine administration policies were on a roller coaster ride during the COVID-19 pandemic. Before I talk about potential changes to SB 144, I want to hone in on what we feel is the biggest issue with childhood vaccination rates. During the COVID-19 pandemic, the pool of eligible providers for childhood vaccines grew significantly as a result of federal declarations. However, Ohio's vaccine rates did not see an increase; additionally, our well-child visit rates plummeted. Some of this is attributable to the idling of non-essential healthcare services in 2020 as well as lingering hesitancy among some parents to visit healthcare sites during the COVID-19 pandemic. It is apparent that some parents did opt to seek vaccines at a pharmacy, and we are hoping to have more data from ODM to illustrate this. However, these were missed opportunities for children to receive the full spectrum of services and guidance that comes from routine physician office visits.

If you are sincere about wanting to boost Ohio's childhood vaccine rates, then the most impactful policy would be to restrict or change the process for opt outs. Ohio has one of the most lenient processes for declining vaccines and since the introduction of the 'philosophical' exemption in 2005, we have dealt with poor rates and outbreaks. Anti-vaccine sentiment during the COVID-19 pandemic did not help, and we are still recovering from its effects. We do not feel that SB 144 will have a demonstrable impact on Ohio's childhood vaccine rates simply because we do not believe access is the biggest hurdle. And while there are many constructive ways to reduce opt outs while protecting parental rates, we understand that the focus of SB 144 is pharmacy vaccination.

As previously noted, pharmacies can provide seasonal flu and COVID-19 vaccines to children as young as 3 under current federal rules that expire on December 31st. We have no objection to making this permanent in state law. Unlike routine childhood vaccines, which are clustered at various key developmental milestones, COVID-19 and influenza are annual vaccines that are best given at a specified time (such as the start of flu season or whenever a patient is eligible for a COVID booster). These often do not align with well-child visits and therefore parents would benefit from additional options to fit their busy schedules. Further, for routine childhood vaccines, we would support lowering the age so that pharmacists can administer these vaccines with a physician order or prescription to children as young as 3. We would also be happy to explore additional language to create more flexibility for pharmacies and primary care providers to partner to boost childhood vaccination in their communities. If pharmacies want to provide vaccines to children ages 3-12 (besides COVID-19 and influenza), then participation in VFC must be mandatory to ensure all children have access, not just those on private insurance.

Again, we feel it is best that children receive vaccines in a primary care setting where they can also receive important screenings and guidance. We recognize that this isn't always feasible or convenient for parents, however there are better options to obtain vaccines than at a pharmacy. Families can receive vaccines and other services at their local health department at no cost. And many communities are partnering with children's hospitals and other providers to expand school-based health care. These are better options for busy parents as they have stronger linkages with primary care and vaccines are more likely to be reported to the state vaccine registry. Having accurate data on vaccination status is critical to responding to local outbreaks of vaccine-preventable diseases in schools and other communal settings.

In closing, we are committed to working with interested parties to find a way for pharmacy-based providers to play a greater role in childhood vaccination that will have the effect of boosting our vaccine rates without sacrificing comprehensive primary care for these children. SB 144 is well intentioned, and we are all committed to keeping our kids healthy. Vaccination administration policy has changed and changed back in Ohio in recent years. However, I hope we can all agree that the best option for kids and their parents is to receive care from a trusted primary care provider. Thank you for your time and I would be happy to answer any questions.

Source Material—

The PREP Act and COVID-19, Part 2: The PREP Act Declaration for COVID-19 Countermeasures
Congressional Research Services – July 21, 2023

Immunizations by Pharmacists and Pharmacy Interns
Ohio Board of Pharmacy – June 16, 2023

Administration of COVID-19 Vaccines during the COVID-19 Pandemic
Ohio Board of Pharmacy – May 11, 2023

Fact Sheet: HHS Announces Intent to Amend the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19
U.S. Department of Health and Human Services – April 14, 2023