

December 17, 2020

Secretary Alex M. Azar II
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

Our organizations, committed to improving the health and well-being of children and adolescents, write to express our concern about the administration's action under the Public Readiness and Emergency Preparedness Act (PREP Act) related to routine childhood vaccinations. While we share your concern about the decrease in childhood vaccination rates since the start of the COVID-19 outbreak, we believe the administration's approach to the issue will not achieve the desired outcome and may have serious unintended consequences.

The administration's COVID-19 declaration under the PREP Act was amended in August, expanding its reach to include childhood vaccines that protect against a number of pathogens other than SARS-CoV-2. The amendment preempts state laws and regulations relating to the administration of vaccinations by pharmacists, authorizing pharmacists and pharmacy interns to order and administer all routine childhood vaccines to children and adolescents age 3 and above.

States have a variety of laws and regulations in place to govern the administration of vaccines. Each state has carefully considered these policies and many have put safeguards in place to ensure continuity of care for children. For instance, some states that allow pharmacists to administer vaccines require a prescription from a physician. Preempting such regulations may deprive children of the optimal medical care they receive from their primary care physician that knows each child's medical history.

Many primary care physicians are also equipped to administer, document, and report vaccinations for all children and adolescents, including those eligible for the Vaccines for Children (VFC) program. This program requires separate vaccine supplies, storage, documentation methodology, and reporting. We are concerned that pharmacies will not have the capacity to adhere to these requirements, and therefore will not provide immunizations under VFC, further exacerbating inequities for low-income patients.

Under normal circumstances, most children and adolescents receive vaccines as part of routine well-child check-ups, during which other important health care is provided, including developmental and mental health screenings, counseling about nutrition and injury-prevention, and chronic disease management. Physicians provide valuable anticipatory guidance and also diagnose diseases and conditions that can respond to early intervention. The administration's action will have the effect of disconnecting children from this essential care.

Conversations about immunizations are a critical part of these visits and can be tailored to respond to parents' unique questions. In fact, dialogue between physicians and parents are an essential component of addressing vaccine hesitancy, one of the primary reasons child vaccination rates are not higher. Physicians develop longitudinal, trusting relationships with families that facilitate discussion about the safety and efficacy of vaccines. These conversations are crucial to addressing parental concerns about vaccines and ensuring that children receive all of their indicated vaccinations.

In order to avoid errors and combat vaccine hesitancy, primary care physicians meticulously document and report each vaccine that is administered. This is paramount when a child is catching up on missed immunizations and there must be deviation from the regular immunization schedule. Documentation and reporting of vaccinations is a time intensive process, which many pharmacies may not have ample staff to complete. A common frustration of primary care physicians is that some pharmacists do not report back to them which vaccines were administered to their patients or the immunization information systems, increasing the probability of errors and negatively impacting quality of care.

While many families were reticent to or prohibited from taking their children to the doctor's office early in the course of the pandemic, rates of pediatric primary care visits are returning to baseline. While primary care medical practices have experienced financial stress as a result of the pandemic, they are still open for business and those that serve children have ample supplies of vaccine ready to administer.

As childhood vaccination rates continue to return to normal, our collective organizations urge you to rescind this amendment to the PREP Act and instead encourage families to take their children to their medical homes to get their needed vaccines. We also encourage the federal government to invest in vitally needed public awareness activities to increase vaccine confidence.

Sincerely,

American Academy of Family Physicians
American Academy of Pediatrics
American Medical Association