



Assessing the Impact of Changes in Colorado to the Section 317 Immunization Grant Program

The Section 317 Immunization Grant Program provides funding to support the nation's vaccine delivery system and immunization infrastructure. Since its inception in 1962, the goal of the program, according to a 2012 Centers for Disease Control and Prevention (CDC) report, "has always been to achieve and maintain high immunization coverage rates by improving access to safe and effective vaccines."¹ Named after the legislation that authorized the program over 50 years ago, the federal Section 317 Immunization Grant Program (the 317 program) funds the purchase and delivery of vaccines for eligible populations, and supports immunization program operations at the national, state and local levels.

Over its 50-year history, it has achieved this goal by investing resources to strengthen immunization systems and fill gaps in immunization coverage for vulnerable populations not covered through other sources, including the federal Vaccines for Children (VFC) program or through private insurance. Over the years, priorities and policies have shifted to respond to changes in vaccine policies or recommendations, and also changes in the broader health care landscape. With the advent of the Affordable Care Act (ACA)—and the resulting expansion in public and private coverage—the program is again at an important inflection point. "With the changes in insurance coverage it is time to allow 317 to evolve once again to best address the needs of individuals served by our vaccine programs," the CDC stated.²

In 2012, the CDC clarified eligibility rules, to among other things, restrict eligibility for 317 vaccines to individuals without access to vaccine coverage through public or private insurance. Designed to invest public resources wisely, the policy has created challenges and issues for Colorado's public health agencies and other vaccine providers that had previously relied on 317 vaccines as a vaccine safety net. This brief examines the changing environment and its impact on Colorado's 317 providers and their patients.

Overview of the Federal Section 317 Program

Section 317 of the Public Health Service Act is a federal grant program administered by the CDC. The program provides grants to immunization programs in 64 states, cities and territories for vaccine purchase, as well as other functions, such as technical assistance, capacity-building and infrastructure support (Figure 1). The 317 program also supports vaccine purchase for time-sensitive and urgent public health vaccination needs, such as providing unrestricted vaccines during pertussis outbreaks or other emergencies such as the recent floods. Case in point: in 2012, Colorado experienced the highest number of reported cases of pertussis in 64 years, and 317

funding was used to purchase vaccines available to any eligible individual, regardless of insurance status or ability to pay. 317 funds will continue to serve a vital outbreak response role in 2013, as the number of reported cases in Colorado—1,011 as of October 12, 2013—is on pace to be another record year.

Unlike the VFC program which is a federally funded entitlement program, the 317 program is a discretionary grant program, which means that it is subject to the annual appropriation process.³ In fiscal year 2012, Section 317 appropriations totaled \$552 million—nearly half of which supported immunization infrastructure grants to state immunization programs. That same year, the Immunization Section distributed over 1 million doses of vaccine, valued at nearly \$43 million through these programs. Like other 317 grantees, Colorado has experienced significant reductions in 317 funding. Since 2008, Colorado's Section 317 vaccine budget has declined by over 70 percent to approximately \$1.3 million; in 2013, it represents less than three percent of the public vaccine distributed statewide.⁴

Figure 1. Role of Section 317 Funding to Prevent Infectious Disease

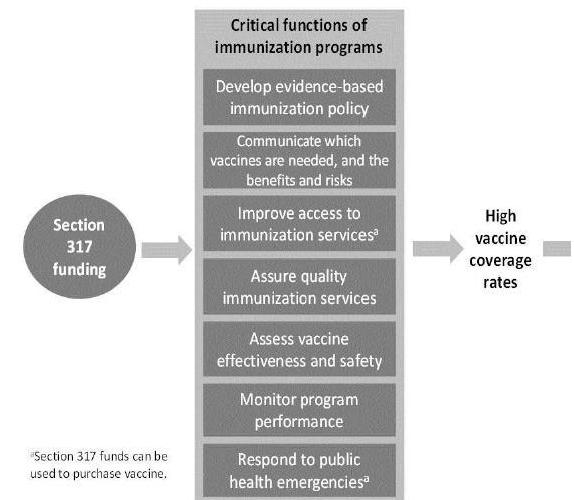


Figure 3: Role of Section 317 Immunization Program funding in preventing infectious disease

Source: National Vaccine Advisory Committee, "Protecting the Public's Health," 2012.

The ACA, 317 in Transition: Program Changes and Implications for Vaccine Providers and Patients

How does the ACA impact immunizations?

As the ACA is implemented, more people will have public or private insurance coverage, and many children will be covered for vaccines through the federal VFC program or private insurance. The ACA also required new health plans to cover recommended preventive services—including vaccines recommended by the Advisory Committee on Immunization Practices—without charging a deductible, copayment or coinsurance. The change did not affect so-called “grandfathered” plans sold before March 23, 2010, however. And while in 2013, 36 percent of those who receive health insurance coverage through their employers were enrolled in a grandfathered health plan⁵, by 2014 the ACA will require that any remaining grandfathered plans be considered as providing “minimum essential benefits,” including preventive services. However, ACA provisions state that “first dollar coverage,” or the absence of deductibles, copayments or coinsurance, for immunizations, require a visit to an “in-network” provider.

The ACA also provides a financial incentive for providing eligible services, including immunizations, to Medicaid patients. This provision, referred to as the “Medicaid bump,” provides an additional vaccine administration fee of \$15.05. This amount is calculated based on the difference between

the previous Medicaid vaccine administration fee of \$6.33 and the current Medicare fee of \$21.68. And while the incentive addresses the historically low Medicaid vaccine administration fee, it is only temporary and just applies to services provided between January 1, 2013 and December 31, 2014. Also local public health agencies (LPHA), federally-qualified health centers (FQHC) and rural health centers (RHC) are not eligible for the incentive.

What's Different about 317?

Prior to October 1, 2012, states had much discretion in how to use 317 funding to best support their state vaccination networks. In Colorado, the funding was used historically as the safety net vaccine source so that all LPHAs were able to vaccinate any child regardless of their source of payment. However, to ensure that federally purchased vaccines were being used for those most in need and least able to pay for vaccines, the CDC implemented a policy change, effective October 1, 2012, that restricted the use of federal 317 funds to certain populations. "Section 317 vaccine is a precious national resource that will continue to be used to fill critical public health needs, such as providing routine vaccination for those with no insurance and responding to outbreaks of vaccine-preventable diseases," the CDC states.⁶

The CDC's 2012 guidance stipulated that 317 vaccines could no longer be used for routinely immunizing fully insured individuals, unless they qualified as an "exception" in the federal policy. According to CDC guidance, states were no longer permitted to use Section 317 vaccine for children, adolescents and adults who have public or private insurance that covers vaccinations. According to the CDC, the new policy "focuses on ensuring that insured individuals receive their vaccination through their insurance provider network, and are not subsidized through federal funding." As a result, as described in Table 1 on the following page, fully insured children and adults, except in limited circumstances (such as during a disease outbreak or disaster relief effort), are not eligible to receive Section 317 vaccines. These individuals should visit their primary health care provider for their immunizations, according to CDC guidance. Underinsured children, as defined below, may receive VFC vaccines in a FQHC, RHC or other approved, "deputized" provider, such as an LPHA that has entered into an agreement with an FQHC.

Key Definitions

Underinsured: A person who has health insurance, but the coverage does not include vaccines or a person whose insurance covers only selected vaccines. Children who are underinsured for selected vaccines are VFC-eligible for non-covered vaccines only. Underinsured children are eligible to receive VFC vaccine only through a FQHC or RHC or under an approved deputation agreement.

Fully insured: Anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or copay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met. In other words, individuals with cost-sharing insurance plans are not considered as "underinsured" and therefore are not eligible to receive publicly-funded vaccines. These individuals must pay out-of-pocket for immunizations.

Source: CDC, 2013.

Table 1. Section 317 Definitions of Eligibility

Individuals Eligible for Section 317 Vaccines (as of October 2012)	<ul style="list-style-type: none"> • Newborns receiving the birth dose of hepatitis B prior to hospital discharge that are covered under bundled delivery or global delivery package (no routine services can be individually billed) that does not include hepatitis B vaccine • Fully Insured infants of hepatitis B infected women and the household or sexual contacts of hepatitis B infected individuals • Uninsured or underinsured adults • Fully insured individuals seeking vaccines during public health response activities including: <ul style="list-style-type: none"> ◦ Outbreak response ◦ Post-exposure prophylaxis ◦ Disaster relief efforts ◦ Mass vaccination campaigns or exercises for public health preparedness • Individuals in correctional facilities and jails
Individuals Not Eligible for Section 317 Vaccines (as of October 2012)	<p>Except for certain exceptions, defined above, the following individuals are not eligible for Section 317 vaccines:</p> <ul style="list-style-type: none"> • Fully insured children and adults seen in public clinics • Fully insured children and adults seen in private provider offices • Adults with Medicare Part B • Adults with Medicaid coverage for vaccines • Fully insured adults seen in STD/HIV clinics or drug treatment centers • Fully insured parents of newborn infants participating in Tdap cocooning projects • Fully insured adults at high risk for acquiring Hepatitis A • Fully insured children and adults with a high co-pay or deductible • Fully insured students receiving vaccines for college entry at Public health clinics or college health facilities • Fully insured children and adults in low medical access areas • Fully insured adults in LTCs/eldercare • Fully insured children in school-based health centers or clinics • Fully insured “high risk” occupational groups (e.g., first responders, EMS) for hepatitis A or B or other diseases • Fully insured adults and children receiving vaccines as part of a community-wide outreach event • Children who are insured by SCHIP stand-alone programs

Source: CDC, “Questions and Answers about Vaccines Purchased with 317 Funds,” 2013.

Policy in Practice: Challenges and Issues for Colorado Vaccine Providers and Patients

In light of impending coverage expansions, and enhanced requirements for vaccine coverage, the CDC determined in a 2013 report to Congress that “at a population level, only a few gaps in vaccine coverage for financially vulnerable individuals remain.” However, a closer inspection of Colorado’s immunization system reveals why these gaps persist, and in some cases, have grown more complicated to address than before changes were implemented. Among those still experiencing

gaps in vaccine coverage: underinsured children not vaccinated at FQHCs or RHCs, uninsured, financially vulnerable adults, and insured individuals who have financial or geographic barriers that impede access to vaccines.

What are some of the impacts of these changes?

These policy changes impact Colorado's 317 vaccine providers—which include FQHCs, RHCs, LPHAs and participating public clinics—and their clients in several ways. For many providers, the shift has been difficult, both for clients and program staff. Before the policy took effect, states had been permitted to use 317 vaccines broadly as a safety net for publicly and privately insured children and, more recently, adults who lacked access to affordable and timely vaccines. Despite having vaccine coverage, individuals sought vaccines through their LPHAs for a variety of reasons:

- In many rural communities, the LPHA is the primary or sole vaccine provider and vaccines may not be readily available in the patient's medical home.
- LPHAs may offer more convenient walk-in scheduling, hours of operation or geographic location for obtaining vaccines.
- Patients with high deductibles or high copayments rely on LPHAs for access to free or low-cost vaccines.
- Some patients may be new to the area or not have a primary care medical home.
- Some patients may see a provider who does not stock some or all recommended children's vaccines.
- Some physicians do not stock vaccines because they are costly to keep on hand or cumbersome to administer.
- Many provider offices lack staff capacity to handle billing and reporting of immunization data, so they rely on public health to administer vaccines.
- Some patients need vaccines quickly and can't wait days or weeks to schedule an appointment—a reality in some physician offices and FQHCs—especially if the child or adult needs an updated immunization record to attend school.
- Younger patients may not be able to receive vaccines at pharmacies or retail clinics due to age restrictions
- LPHAs used to offer non-VFC eligible patients vaccines at a low cost, regardless of their insurance status
- Public and private providers may not see patients with whom they do not have a provider-patient relationship.

Because of these factors, re-directing patients to their primary care health professional may not be a feasible option for all LPHA patients, creating concern that they will forego the opportunity to receive necessary vaccines. "As long as I've been in public health, we've had the ability to serve anyone who walks in the door," says Lynn Trefren, Nurse Manager at Tri-County Health Department. The circumstances that brought children and adults to Tri-County's clinics varied, but the end result, Trefren said, was that people received recommended vaccines. "We were able to serve everyone."

The Colorado Children's Immunization Coalition, an independent 501(c)3 dedicated to mobilizing diverse partners and families to advance children's health through immunization, contacted

program managers and public health staff in a small number of rural and suburban public health agencies to identify some of the challenges and implications for public health vaccine providers. While their circumstances differ, some common themes and challenges emerged.

Financial Barriers for Patients. Previously, the 317 program used to cover costs for all children, adolescents and adults, regardless of insurance status. For individuals who struggled to meet high deductibles or cost-sharing under their insurance policies, access to free or low-cost vaccines was critical. The full series of recommended immunizations can exceed \$1,000 in an infant's first year of life, a prohibitive cost for many families who have to pay out-of-pocket for vaccines.

As a result of 317 changes, individuals with cost-sharing insurance plans with high deductibles or co-pays are no longer eligible to receive publicly-funded vaccines. LPHAs and other 317 providers must turn insured patients away or bill patients up-front for privately purchased vaccines. In Tri-County Health Department, patients receive a "superbill" that they can use to seek reimbursement; however, for many patients, the up-front cost of paying for vaccines is cost-prohibitive. "For many people, they're not planning on coming in and spending this kind of money," says Karen Miller, vaccine coordinator at Tri-County Health Department. "They just don't have it."

Patients in rural and urban communities face the same financial barriers. "Anecdotally, we know that people have walked out of here and not returned for second dose, but we don't know how many," said Kindra Mulch, Director of the Kit Carson County Health and Human Services Department. According to Denver Public Health's Sarah Rodgers, "In public health, we don't want to turn people away." But with 10 percent of patients now paying out-of-pocket for immunizations, Rodgers said the cost is a burden.

Also, as noted, federal guidelines state underinsured children are eligible to get VFC vaccine at an FQHC, RHC or approved "deputized" provider. In Colorado, LPHAs are eligible to be deputized and they must enter into an agreement with an FQHC or RHC in order for that underinsured child to receive VFC vaccine. By June, 2013, all Colorado LPHAs had entered into such an agreement with FQHCs or RHCs. In other words, deputized LPHAs, which include each of Colorado's 54 independent LPHAs, can provide VFC vaccines to underinsured children, preserving 317 resources for individuals who do not qualify for VFC vaccines. While deputization addresses access for the underinsured, access problems persist for individuals with high deductibles or cost-sharing plans.

Geographic Barriers. In some locations in Colorado, especially rural areas, patients must travel many miles to obtain immunizations. In Kit Carson County, for example, the LPHA is the primary provider of vaccines for the entire county. Another clinic provides vaccines in the county, but it is located approximately an hour away from the LPHA and they do not provide all recommended vaccines. "People get frustrated if they drove 30 minutes to get here and then realize that they

Impacts of 317 Changes on Colorado Vaccine Providers

- Financial barriers for patients
- Geographic barriers for patients
- Confusion and frustration for LPHA patients
- Administrative, financial and operational challenges for LPHAs
- Missed opportunities to immunize
- Uncertainties about the future

don't have the resources to pay for their vaccines," Mulch said. "We think some of them mean to come back (for their vaccines), but they don't," she said. Even in suburban and urban locations, patients face transportation and other barriers—such as lack of time off at work—when they are re-directed to another provider.

Confusion and Frustration. Most patients do not understand the complex rules governing vaccine delivery. Patients are frequently confused about why now they are unable to receive vaccines at the LPHA. "At one point, our office was the place to get immunized, [patients] didn't have to be quizzed," said Mulch. "Now we have to ascertain whether they have health insurance, what they're here for, what their payer source is, then [we determine] what it costs and they decide if they're going to pay for it." Mulch says "it confuses clients."

Public health agencies can launch awareness campaigns and attempt to notify patients before they arrive, but they do not have the capacity to reach everyone. "Many people come [to Tri-County] because they always have and we have to turn them away," says Karen Miller, vaccine coordinator at Tri-County Health Department. "They can't pay out of pocket, they can't afford their deductible, and even if they wanted to go to their provider, sometimes they can't get in for two or three months," says Miller. "They feel really stuck."

Administrative, Financing and Operational Challenges for LPHAs. LPHAs have had to take on additional functions, including communicating changes to patients, helping patients discern whether they have immunization benefits, helping patients understand where to receive vaccines, and in some cases, helping them enroll in Medicaid or Colorado's Child Health Plan Plus. Small staff size and limited training budgets strain staff capacity to take on these additional roles.

Purchasing private vaccines is costly for LPHAs, which typically must purchase private vaccines up-front out of their immunization budget. "We determined that based on our size that we should buy and stock vaccines so we don't have to turn people away," says Lynn Trefren, Nurse Manager at Tri-County Health Department. Tri-County established an account with vaccine manufacturers. The county pays for vaccines out of the immunization budget and then seeks reimbursement from the client, Medicaid or Colorado's Child Health Plan Plus. For many smaller counties, the large upfront vaccine costs are prohibitive. Although manufacturers offer volume pricing, many Colorado LPHAs do not order enough vaccine to qualify for those discounts.⁷

LPHAs that provide privately-purchased vaccines also need a billing system or method for obtaining reimbursement from insurers. For many, this is a strain on their available human and operational resources. Unlike private providers that are accustomed to billing insurance for almost all services, smaller LPHAs do not have similar economies of scale and, therefore, struggle to train staff and

New LPHA Roles Arising from 317 Changes

- Communicating changes to patients so they understand new policies
- Helping patients understand insurance benefits
- Helping patients identify vaccine resources and locations
- Helping eligible patients enroll in coverage sources
- Purchasing and managing inventory of private vaccines
- Developing billing systems and reimbursement procedures

develop billing and collections functions for what can amount to a relatively small volume of vaccines. Some LPHAs report that negotiating contracts with insurance companies is difficult because companies may not certify LPHAs as “preferred providers.”

Maintaining an accurate inventory management system is also a challenge. According to Trefren, “Keeping a separate stock adds one more layer of complication.” Because of rules that require separation of private and public vaccines, providers must establish procedures for managing and delivering vaccines from the appropriate vaccine stock. The problem of maintaining separate stocks is especially pronounced when health departments deliver vaccine clinics in schools and other community settings. “We now have to take two (vaccine) ‘pots’ to schools,” said Sarah Rodgers, Clinic Administrator for the Denver Public Health Immunization Program “If you go into local schools during flu season and give 2,000 vaccines during a small time period, you don’t have a mechanism for tracking who is eligible for what vaccine, Rodgers said. Families provide insurance information but it is not always correct. “This has really stretched our internal staff,” Rodgers said.

Missed Opportunities to Immunize. In many rural communities, including Kit Carson County, the LPHA may be the only vaccine provider that provides a full range of recommended vaccines. According to a 2013 report about the role of LPHAs in the state, “approximately 70 percent of Colorado’s 54 LPHAs are a primary provider of childhood and adult immunizations in their communities—regardless of insurance status.”⁸ In those communities, the report states that “LPHAs are the go-to source for vaccinations.” As a result of new rules, public health nurses observe missed opportunities to immunize patients when they are re-directed to another office for vaccines. Although public health nurses do not have a way to track whether these individuals ever received vaccines, some suspect that they give up. “I don’t know where they go,” says Miller. “I am highly suspicious that they’re not following up.”

Uncertainties about the Future. Although ACA coverage expansion provisions are expected to improve access to immunization coverage, it is not clear how soon—or to what extent—the access challenges will resolve. As more Coloradans have access to public and private coverage with immunization benefits, LPHAs can play an important role in assuring access to safe and affordable vaccines. According to Mulch, many of Colorado’s LPHAs are the sole immunization provider in the community, especially in rural areas, and therefore, it is critical that payers recognize and reimburse them for providing vaccines. “We want to be certain that payers and insurance companies recognize that we provide vaccines,” she said. “What we’re afraid of with reform is that there will be opportunities for paying certain providers, but [payers] have historically not considered public health as a provider.”

Addressing Challenges: New Roles and Opportunities for Public Health

Despite the challenges, ACA provisions and the 317 policy change also provide important opportunities for enhancing vaccine coverage and strengthening the vaccine infrastructure. The recent pertussis outbreak and September 2013 floods in Colorado demonstrate the importance of 317 funding to avert public health crises through a rapid and widespread response.

In addition to these events, the 317 program also presents expanded opportunities to vaccinate uninsured and underinsured adults, which creates new opportunities for public health to cast a wider net with this underserved population. According to Rodgers, although the 317 changes have

reduced the availability of 317 vaccines for children, the new rules have expanded Denver Public Health's ability to immunize uninsured and underinsured adults. The statewide billing initiative encouraged Denver Public Health to bill some privately insured individuals and Medicaid. "Now we are billing for vaccines," Rodgers said. In the second quarter of 2013, Denver Public Health administered 769 adult vaccines, as compared to 347 adult vaccines provided in the second quarter of 2012. "The availability of 317 vaccine for adults has increased the number of vaccines we administered by 50 percent," Rodgers said. "This helps our uninsured adult population, but this is still a problem for the children who are privately insured and have nowhere to obtain their vaccines."

Federal and state financial and technical assistance resources are available to assist LPHAs as they struggle to address the challenges listed above. For example, CDC is partnering with 28 of the 64 317 grantees to implement billing systems for immunization services provided in public health clinics. The work is generating best practices and helping to identify solutions to common billing and contractual problems. In Colorado, CDC funds supported the Reimbursement Immunization Opportunity (RIZO) project which awarded \$997,000 in grants to 27 LPHAs. While these efforts are achieving positive results, billing at LPHAs is not yet sustainable.⁹ According to CDPHE, approximately 29 percent of Colorado's LPHAs have indicated that their current billing model is sustainable.¹⁰

Conclusion

Public health professionals will assume new roles in a rapidly changing health care and immunization delivery system. "We're heading in the direction of having a broader role, and not just giving shots but improving infrastructure," says Trefren. "We're all looking at ways to make the system better and we look at the ACA as an opportunity to provide more wrap-around support and less direct service." Moving forward, as the 317 program will continue to evolve, Colorado will need to identify new solutions to ensure all Coloradoans have full access to immunizations, as well as to meet emerging public health needs. LPHAs will continue to play a crucial role in ensuring access to vaccines, especially in communities where they are the main vaccine provider.

¹ Department of Health and Human Services, Centers for Disease Control and Prevention, *Report to Congress on Section 317 Immunization Program* (Atlanta, 2013), 9, <http://www.317coalition.org/documents/CDCRTConSection317ImmunizationProgram.pdf>.

² CDC, "Questions and Answers about Vaccines Purchased with 317 Funds," <http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/317-QandA.htm>; accessed October 2013.

³ National Vaccine Advisory Committee, "Protecting the Public's Health: Critical Functions of the Section 317 Immunization Program," http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2012/protecting_the_public_health.pdf.

⁴ CDPHE, Unpublished and draft report, *Overview of Vaccine Access in Colorado*, October 2013.

⁵ Kaiser Family Foundation and Health Research Education Trust, 2012. Employer Health Benefits 2012 Annual Survey.

⁶ CDC, "Questions and Answers about Vaccines Purchased with 317 Funds," 2, <http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/317-QandA.htm>; accessed October 2013.

⁷ CDPHE, Unpublished and draft report, *Overview of Vaccine Access in Colorado*, October 2013.

⁸ Edie Sohn, Lisa VanRaemdonck, Lou Ann Wilroy, *The Role of Local Public Health Agencies in Achieving Triple Aim*, May 2013, http://civhc.org/getmedia/66c62833-6f27-4167-8ff4-18e1eb858e4d/LPHA-White-Paper-FINAL-5.13_CIVHC_CALPHO.pdf.aspx/

⁹ CDPHE, Unpublished and draft report, *Overview of Vaccine Access in Colorado*, October 2013.

¹⁰ *Ibid.*