

BIO Principles on Vaccine Financing Policy

Significant investment in vaccine development has resulted in a number of new immunizations in the past decades, including vaccines that protect against hepatitis A and B, herpes zoster, human papillomavirus (HPV), meningococcal infection, pertussis, pneumococcal infection, and rotavirus. In addition to new antigens, the biotechnology industry has developed and continues to develop advances in other vaccines technologies, including new adjuvants to increase vaccine efficacy, new delivery technologies, and enhanced manufacturing technologies and capacity.

Continued investment in vaccines is important to further the public health contribution of these life-saving products. High immunization rates are also needed to fully realize the value of vaccines, both for the individual and for society. It is important to recognize that the availability of future vaccines and the continued supply of existing vaccines are dependent on a system in which vaccine development continues to attract investment dollars in competition with other investment opportunities. BIO member companies recognize that there are a number of access and availability challenges that must be overcome to increase immunization rates in a sustainable environment, and believe that none of these barriers can be addressed in a vacuum and that all stakeholders' voices must be considered as solutions are developed.

PRINCIPLE 1: Enhance access to vaccines for vulnerable populations while maintaining a strong private market.

While recognizing the need for the public sector to provide a safety net for individuals who would not otherwise have access to vaccines, maintaining a strong private market for vaccines is critical for the long-term health and sustainability of the industry.

- There are vulnerable populations without private market insurance for whom public programs provide a safety net for access. It is important to recognize that the sustainability of such public programs is dependent on a strong private market, and any policies that serve to enhance access to vulnerable populations must be carefully designed so that they do not erode the private market.
- BIO supports careful expanded access of the Vaccines for Children (VFC) program to include underinsured children in public health clinics. In order to maintain the sustainability of the vaccine enterprise, it is critical that policies that seek to enhance access to VFC vaccines do not erode the private market. Therefore, expanded access of the VFC program should not include coverage for the underinsured in all VFC-provider settings, as this may create incentives for private insurers to drop or reduce immunization benefits.
- Government price caps in the public sector market disrupt the market due to the large role of the Federal government in vaccine purchasing, and would erode incentives for continued investment in vaccines and vaccine technologies.
- It is important and useful to have a clear definition of 'underinsured' in order to effectively develop targeted public policies and to distinguish between those who have co-pays or deductibles and those with no vaccine coverage.

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PRINCIPLE 2: Ensure adequate reimbursement for all costs of vaccination.

Health care providers should be adequately reimbursed for administration of vaccines, and public policies should encourage and incentivize adequate and expedient insurance coverage of all ACIP recommended vaccines.

- The health value of vaccines warrants full and first-dollar coverage of immunizations by insurers and employers. Incentives to encourage implementation of full and first-dollar coverage should be explored for all types of health plans (including fee-for-service, capitated, consumer driven, health savings accounts, and high deductible plans). Possible initiatives include tax incentives for employers and self-employed to offer full and first-dollar coverage. The merits of individual tax credits for the uninsured should also be explored.
- Insurance reimbursement for the administration of vaccines should recognize all costs associated with immunization and provide an adequate return on the provider's investment. Private insurers should be informed of the total costs associated with immunization, including costs of administration, insurance, storage, counseling, waste/loss, record keeping and opportunity costs. Reimbursement should adequately reflect all of these costs.
- Medicaid reimbursement rates for administration fees should be enhanced and disparities among state reimbursement rates reduced. Budgetary impacts should be evaluated and unintended consequences should be avoided.
- When provisional ACIP recommendations for a vaccine are issued, insurers should implement coverage immediately and provide adequate reimbursement without a lag up to official publication. Claims systems should also be brought up to speed as soon as possible to avoid a lag behind coverage decisions.
- BIO recognizes that inventory carrying costs and delays or inadequacies in reimbursements create challenges for providers in offering immunization services. Vaccine manufacturers, on an individual basis, can work with providers and distributor in addressing these issues.
- Programs such as pay-for-performance systems that include measurable adult/adolescent immunization goals should be considered.

PRINCIPLE 3: Importance of addressing the spectrum of immunization challenges, including infrastructure and awareness.

There are several barriers to enhanced immunization rates. Inadequacies in infrastructure and awareness create primary challenges that must be addressed. BIO encourages increased research into barriers to enhanced immunization.

- Additional research is needed to better understand the true barriers to vaccination. The Federal government plays an important role in researching barriers to immunization, and there is a particular need to research barriers to adult and adolescent immunization.
- The Federal government should develop and support comprehensive educational campaigns to inform health care providers, the public, and payers of the value of vaccines.
- A combination of public and private efforts will be needed to increase vaccination rates for yearly seasonal diseases where infrastructure challenges are compounded with a limited timeframe.

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- Immunization stakeholders should mobilize as appropriate to encourage standard immunization registries that are routinely used by providers and better systems for reminding and recalling patients.
- Other programs to maximize immunization rates might include identification of missed opportunities to vaccinate and increasing the use of standing orders authorizing nurses and pharmacists to administer vaccinations according to an institution- or physician-approved protocol without a physician's *ad hoc* order.

PRINCIPLE 4: Ensure adequate financial support at Federal and State levels of existing public programs.

Strong support by both the Federal government and States of existing public programs is essential to ensuring an adequate immunization infrastructure. Infrastructure includes public and professional education and awareness, registry development and maintenance, trained professionals to administer vaccines and maintain records, refrigerators, syringes and other materials necessary to maintain and administer vaccines and incorporation of wellness into health care practices.

- Section 317 funding must keep pace with immunization infrastructure needs in order to enable implementation of ACIP recommendations.
- BIO supports strong annual appropriations for existing Section 317 statutory authorities.
- The professional judgments of the Centers for Disease Control and Prevention (CDC) and State-level immunization programs are important to inform policy discussions on the funding needs of Section 317.
- State governments play an important role and have the responsibility to ensure an adequate immunization infrastructure.