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RE: HB 5744 AN ACT CONCERNING CHILDHOOD IMMUNIZATION.

Proposed H.B. No. 6158 AN ACT CONCERNING VACCINE DISTRIBUTION.

I am Louis Terranova, Senior Health Policy Analyst at the American Academy of Pediatrics (AAP), in Elk Grove Village, IL. The Connecticut Chapter is one of 66 chapters of the Academy. The AAP is the national professional society for pediatricians dedicated to the health of all children. I staff the AAP private payer advocacy within the Academy's Department of Practice. I am here today to speak on the practice expenses related to vaccines and the need for adequate payment. Immunizations are a strategic priority of the Academy and one of the goals of the American Academy of Pediatrics (AAP), shared by the American Academy of Family Physicians (AAFP) and the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), is to promote maximum immunization coverage for all infants, children, adolescents, and young adults. To achieve this goal, physicians must be paid a fee that includes three components:

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- the entire costs (direct and indirect) of vaccine product-related expenses,
- vaccine administration expenses, including counseling of parents
- and a margin for overall overhead expenses.

Private physician practice is the backbone of the immunization delivery infrastructure. It is a business venture that must run on sound, generally accepted business principles to remain solvent. Vaccine purchase, storage, maintenance, counseling, administration, and overhead expenses related to these activities are among the top expenses for the pediatric practice. Private physician practice for children, as we know it, will fail if the total cost of providing immunizations exceeds payments for that service. Therefore, payments from public and private sector payers must ensure recovery of the total direct and indirect practice expenses, including the time spent counseling families on the indications for and potential adverse effects of each vaccine product.

Federal and state provided vaccines represent benefits and challenges for vaccinating children. The greatest benefit from Federal vaccine programs is that the vaccine product is provided to practices at no cost, thus relieving the provider of the financial burden of purchasing the vaccine product. However, as custodians of the State supplied vaccine, all other expenses, including vaccine storage, maintenance, counseling, administration, vaccine spoilage and loss, and overhead are still incurred by the practice. In circumstances in which the State supplies the vaccine product, all overhead costs related to the vaccine product still must be paid either through enhanced payment of the immunization administration fee, or some other arrangement by the payer. In the private market, physicians are paid for these costs through payment for the vaccine product in addition to the

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administration fee. Therefore, it is important for payers to recognize the costs associated with vaccines and their administration.

Whether the vaccine is publically or privately purchased, maintaining a vaccine inventory incurs costs just as in any other business. These costs are traditionally subsumed in payment for vaccine product. Because vaccine product is not traditionally billed in a federal or state supplied vaccine environment, these costs must be covered with enhanced payment for immunization administration or other arrangement.

- **Personnel costs for ordering and inventory:** Medical office staff (clinical and administrative) time to monitor vaccine stock; place orders; prepare reports as required; ensure safe storage procedures (locks, alarms, temperature controls, etc.)
- **Storage costs:** Vaccines must be stored at very specific temperature ranges and, therefore, require special monitoring and storage equipment. The practice expense component of the total immunization administration code pays for part of the vaccine storage costs; however, there are certain expenses that are **not** included that must be compensated: refrigerators/ freezer(s), refrigerator/freezer lock(s), refrigerator/freezer alarm system(s), and generators for continued electrical supply (all of which are depreciated).
- **Insurance against loss of the vaccine:** Professional liability malpractice insurance does not cover vaccine product, so additional insurance coverage is needed by the practice. This is especially important as states implement recovery programs if a practice can no longer use their vaccine stock due to disasters, equipment failure, etc.
- **Recovery of costs attributable to uncontrollable circumstances:** If practices are held accountable for lost vaccine, this could include situations of drawing up the vaccine and having the patient/family reconsider and refuse or a loss of dose that may occur in attempting to vaccinate an uncooperative/combatative child.
- **Federal or state-specific requirements:** In an environment where vaccine is supplied, there are frequently additional inventory and reporting requirements, which adds staff time that must be compensated appropriately.

In a federal or state supplied vaccine environment, payment for the overhead costs for vaccines must be adequately covered. To account for the indirect (overhead) vaccine expenses, the AAP *Endorsed Principles on Benefit Plan Coverage and Payment* recommends vaccine payments to be at least 125% of the total vaccine cost (direct and indirect costs).

Thank you for allowing me to present this information to you. Are there any questions that you may have.

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The Business Case for Pricing Vaccines

Revised March 2012

One of the goals of the American Academy of Pediatrics (AAP), shared by the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), is to promote maximum immunization coverage for all infants, children, adolescents, and young adults. To achieve this goal, physicians must be paid for the full costs (direct and indirect) of vaccine product-related expenses and vaccine administration expenses as well as the margin for overall overhead expenses. Because the private physician practice is the backbone of the immunization delivery infrastructure, public and private sector payers must recognize that a pediatric practice is really a business entity and must run on sound, generally accepted business principles to remain viable. Vaccines are among the top overhead expenses for the pediatric practice. Therefore, payments must ensure recovery of the total direct and indirect practice expenses and a margin for both the vaccine product and the vaccine administration office costs and the time spent counseling families on the indications for and potential adverse effects of each vaccine product.

The number of vaccines continues to increase and the costs have become increasingly high, necessitating a more business-like approach to payment because of the increased potential for uncompensated costs. For most states, which are non-universal purchase, the direct and indirect expenses in maintaining the vaccine product must be accounted for in a compensation formula that incorporates these factors in the vaccine purchase as well as a margin to incentivize immunizations. For universal purchase states, this means having an acceptable immunization administration fee that also covers compensation for indirect vaccine acquisition and maintenance expenses as there are no direct vaccine purchase costs and no mechanism for paying indirect expenses.

Several studies published in the *Pediatrics* supplement, "Financing of Childhood and Adolescent Vaccines,"¹ underscore the need for appropriate payment to cover the total costs for immunizations. In one major study, a cross-sectional survey of private practices in 5 states (California, Georgia, Michigan, New York, and Texas) concluded that there is a wide variation in payment for vaccines and administration fees by payers, resulting in the "need for providers to seek opportunities to reduce costs and increase reimbursements."²

Vaccine Product-Related Expenses: *This is separately reportable from the immunization administration.*

Some payers mistakenly try to maintain that inadequate vaccine payments can be made up by nominal immunization administration fees. ***However, these are two separate expenses, and both need to be appropriately covered by payers. The payment for vaccines is a legitimate expense that must cover the total direct and indirect expenses as listed below.***

1. ***Purchase price (acquisition cost) of the vaccine:*** This is the amount paid by the physician for the vaccine. Although discounts may exist, these are not available to all pediatric practices and may be time limited. An accurate and verifiable public source on the current manufacturer's price for vaccines can be accessed on the CDC vaccine price list for the private sector at: <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm> The AAP believes that the CDC private payer vaccine price list should be used as a transparent methodologic basis for vaccine acquisition and invoice cost as part of the total cost of the vaccine.

2. ***Personnel costs for ordering and inventory:*** Medical office staff (clinical and administrative) time to monitor vaccine stock; place orders; negotiate costs, delivery, and payment terms; and ensure safe storage procedures (locks, alarms, temperature controls, etc)

3. **Storage costs:** Vaccines must be stored at very specific temperature ranges and, therefore, require special monitoring and storage equipment. The practice expense component of the total immunization administration code pays for part of the vaccine storage costs; however, there are certain expenses that are **not** included that must be compensated: freezer(s), freezer lock(s), freezer alarm system(s), and generators for continued electrical supply (all of which are depreciated).

4. **Insurance against loss of the vaccine:** Professional liability malpractice insurance does not cover vaccine product, so additional insurance coverage is needed by the practice.

5. **Recovery of costs attributable to inventory shrinkage, wastage, and nonpayment:** In the retail market, inventory shrinkage refers to the uncompensated loss of product due to theft, vendor error, and administrative error. Additionally, there is an estimated wastage/nonpayment of at least 5% (this should be accurately accounted for in each office). This includes drawing up the vaccine and having the patient/family reconsider and refuse, resulting in subsequent nonpayment, or a loss of dose that may occur in attempting to vaccinate an uncooperative/combatative patient. This would also include collection costs in response to nonpayment by the patient or third-party payer.

6. **Lost opportunity costs:** This is the cost of maintaining a large vaccine inventory. Between \$10,000 and \$15,000 in inventory is maintained per pediatrician or other provider of vaccines. Every business with this level of money tied up in product inventory must receive an appropriate return on its investment, and so should every pediatric practice.

When the direct and indirect expenses are totaled for the vaccine product, estimates range from 17% to 28% depending on the practice. Therefore, payments for the vaccine should be at the level that covers the total vaccine expenses. So what would be appropriate payment for vaccine product expenses for the total direct and indirect costs? Payments must:

- Be free of any discounts and based on a transparent and verifiable data source, such as the CDC vaccine price list for the private sector, available at: <http://www.cdc.gov/vaccines/programs/vfc/cdc-vac-price-list.htm>.
- Cover the vaccine product purchase price as well as all related office expenses as noted above and a return on the investment for the dollars invested in vaccine inventory.
- Be at least 125% of the current CDC vaccine price list for the private sector

Pediatric practices are the public health infrastructure for the nation's childhood immunization program. It is imperative to incentivize pediatricians to participate in immunization efforts by appropriate payment for vaccines.

References

¹ Financing of Childhood and Adolescent Vaccines. *Pediatrics*. 2009;124(Suppl 5). Available at: http://pediatrics.aappublications.org/content/vol124/Supplement_5/

² Freed GL, Cowan AE, Gregory S, Clark SJ. Variation in provider vaccine purchase prices and payer reimbursement. *Pediatrics*. 2009;124(Suppl 5):S459-S465. Available at: http://pediatrics.aappublications.org/cgi/content/full/124/Supplement_5/S459



The Business Case for Pricing Immunization Administration

One of the goals of the American Academy of Pediatrics (AAP), shared by the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) is to promote maximum immunization coverage for all infants, children, adolescents, and young adults. To achieve this goal, physicians must be paid for the full costs (direct and indirect) of vaccine product-related expenses and vaccine administration expenses as well as the margin for overall overhead expenses. Because the private physician practice is the backbone of the immunization delivery infrastructure, payers must recognize that a pediatric practice is really a business entity and must run on sound, generally accepted business principles to remain viable. Vaccines are among the top overhead expenses for the pediatric practice. Therefore, payments must ensure reimbursement for the total direct and indirect practice expenses and a margin for both the vaccine product and the vaccine administration office costs and the time spent counseling families on the indications for and potential side effects of each vaccine product.

Immunization Administration Expenses: This service is separately reportable from the vaccine product. Some payers mistakenly try to maintain that inadequate vaccine payments can be made up by nominal immunization administration fees. **However, these are two separate expenses and both need to be appropriately covered by payers.**

Several studies published in the *Pediatrics* supplement, "Financing of Childhood and Adolescent Vaccines"¹, underscore the need for appropriate payment to cover the total costs for immunizations. In one study on variable costs for immunizations by pediatric practices in Colorado it was determined that the variable costs of vaccine administration exceeded reimbursement from some insurers and health plans.²

The Centers for Medicare and Medicaid Services (CMS) uses its Medicare Resource-Based Relative Value Scale (RBRVS), which assigns relative value units (RVUs) to services based on the resources utilized. The RVUs of a *Current Procedural Terminology* (CPT) code take into account the physician work, practice expenses, and professional insurance liability expenses associated with that service. For immunization administration, these components are detailed below.

1. Physician Work Component: The total value of physician work contained in the Medicare RBRVS physician fee schedule includes:

- Physician time required to perform the service
- Technical skill and physical effort
- Mental effort and judgment
- Psychological stress associated with the physician's concerns about the iatrogenic risk to the patient

2. Practice Expense Component: Medicare RBRVS uses both direct and indirect practice expenses to determine practice expense RVUs, including the resources used within the facility or physician's office (or patient's home) in providing the service. The practice expense component of the immunization administration fee includes: 1) clinical staff time (RN/LPN/MA blend, including time for vaccine registry input, refrigerator/freezer temperature log monitoring/documentation, and refrigerator/freezer alarm monitoring/documentation); 2) medical supplies (1 pair non-sterile gloves, 7 feet of exam table paper, 1 OSHA-compliant syringe with needle, 1 CDC information sheet, 2 alcohol swabs, 1 band-aid) and; 3) medical equipment (exam table, dedicated full size vaccine refrigerator with alarm/lock [commercial grade], and refrigerator/freezer vaccine temperature monitor/alarm).

3. Professional Liability Insurance Expense Component: The professional liability insurance RVUs assigned to a code are based on CMS historic malpractice claims data.

These three components are combined to create total RVUs (see Table below).

2012 Medicare Relative Value Units for Immunization Administration

CPT code and description	Physician Work RVUs	Practice Expense RVUs (Non-Facility)	Professional Insurance Liability RVUs	Total RVUs (Non-Facility)	Total RVUs x 2012 Medicare conversion factor (\$34.0376) = Medicare Amount (Non-Facility)
90460 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first vaccine/toxoid component *	0.17	0.54	0.01	0.72	\$24.51
90461 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine/toxoid component *	0.15	0.21	0.01	0.37	\$12.59
90471 Immunization administration, one injection **	0.17	0.53	0.01	0.71	\$24.17
90472 Immunization administration, each additional injection**	0.15	0.19	0.01	0.35	\$11.91
90473 Immunization administration by intranasal/oral route, first administration**	0.17	0.47	0.01	0.65	\$22.12
90474 Immunization administration by intranasal/oral route, each additional vaccine **	0.15	0.18	0.01	0.34	\$11.57

* CPT codes 90460 and 90461 are reported for patients under 19 years of age and when counseling is performed on the patient by the physician or other qualified health care professional. It should also be noted that the following codes are reported per vaccine component rather than per injection/administration and make no distinction between routes of administration (i.e., injectable versus oral/intranasal).

**These codes are reported for older patients (i.e., those 19 years and older) or if there is no counseling performed on the patient or the healthcare professional counseling does not meet state requirements for an "other qualified healthcare professional". It should also be noted that the following codes are reported per injection/administration and allow distinction between routes of administration (i.e., injectable versus oral/intranasal).

As a separately reported service, payments for immunization administration need to

- Adequately cover those costs to the practice which are separate from the direct and indirect costs associated with the vaccine product
- Be at least 100% of the current Medicare Resource Based Relative Value Scale (RBRVS) physician fee schedule

Insurers understand business principles including the concept of return on investment and expect it in their business. There is no reason physicians should accept carrier refusal to pay separately and adequately for the vaccine product **and** the administration/counseling. Viable businesses pass on their increased costs to their purchasers to maintain profitability. The pediatric practice has a legitimate business case to make for separate and adequate payment for vaccines and immunization administration and carriers need to provide adequate payments to cover the total direct and indirect expenses for both the vaccine product and the administration.

Pediatric practices are the public health infrastructure for the nation's childhood immunization program. It is imperative to incentivize pediatricians to participate in immunization efforts by appropriate payment for immunization administration.

References

1. Financing of Childhood and Adolescent Vaccines; Pediatrics Supplement 2009 Available at: http://pediatrics.aappublications.org/content/vol124/Supplement_5/
2. Judith E. Glazner, MS, Brenda Beaty, MSPH and Stephen Berman, MD
Cost of Vaccine Administration Among Pediatric Practices Pediatrics 2009; 124:S492-S498 Available at: http://pediatrics.aappublications.org/cgi/content/abstract/124/Supplement_5/S492