September 5, 2008

PREAMBLE:
The following draft recommendations were developed by the National Vaccine Advisory Committee (NVAC) Vaccine Finance Working Group (VFWG) and will be presented to the NVAC in September 2008 for a provisional vote on the policies within each recommendation. All acceptable recommendations will then be analyzed with regard to the fiscal impact of the recommendation and this impact will be presented for a final vote at the February 2009 NVAC meeting. The final recommendations will then be formally made to the Assistant Secretary for Health, who will determine implementation options and next steps.

DRAFT RECOMMENDATIONS

Recommendation #1. NVAC recommends the VFC program be extended to include access to VFC eligible underinsured children and adolescents receiving immunizations in public health clinics and thus not be limited to access only at Federally Qualified Health Centers and Rural Health Clinics.

Pros: provides greater access to vaccines for underinsured children and adolescents; removes vaccine cost as a barrier for underinsured children and adolescents at non-FQHC/RHC sites; could reduce state reliance on limited Section 317 funds; would decrease the pressure to increase Section 317 appropriations each time a new vaccine is recommended; would not change market share as children and adolescents covered are generally those already covered by public sector financing for older vaccines; if pursued through legislation, would solve the problem in all 50 states.

Cons: if accomplished through modification of VFC legislation, it could risk other modifications that could weaken the VFC program; would not cover underinsured children and adolescents in private provider offices; may cause underinsured children and adolescents to leave their medical home to receive vaccines; if not pursued through legislation, would require individual efforts by each state and FQHC that may lead to inequitable solutions across states.

Recommendation #2. NVAC recommends expansion of VFC to cover vaccine administration reimbursement for all VFC-eligible children and adolescents. (Currently the vaccine administration fee is not covered by VFC). This should include children on Medicaid as this would provide for a single system and uniform vaccine administration fee. The vaccine administration reimbursement should be sufficient to cover the costs of vaccine administration (as referenced elsewhere in these recommendations*).*

Pros: would provide a uniform national system of reimbursement for vaccine administration and eliminate the current state-to-state variation in Medicaid administration fees; if the federal government used the Medicare influenza vaccine administration fee or other evidence-based method as a model, this would provide reimbursement that covers provider costs in most circumstances; no need for state expenditures for vaccine administration; saves state Medicaid funds which could go to other services; provides incentive for providers to serve all VFC-eligible children and adolescents regardless of reason for eligibility including the uninsured, and Alaska Natives/ American Indians. This approach also covers vaccine administration for underinsured children who are VFC eligible; eliminates inequities in VFC program; automatically removes major financial barriers (i.e., paying

for vaccine administration) to access to vaccines recommended by the ACIP, based on the vote of the committee.

Cons: requires amending VFC legislation, which could risk other modifications that could weaken the VFC program; increases the federal budget; requires states to develop administration fee reimbursement mechanisms.

Improving reimbursement for vaccine administration for VFC-eligible children and

Recommendation #3. NVAC recommends CDC and CMS annually update, publish, and disseminate actual Medicaid vaccine administration reimbursement rates by state.

Pros: would bring attention to the issue which might cause states to reevaluate the adequacy of their reimbursement rates; would provide information for state-by-state advocacy to increase state-specific Medicaid reimbursement rates; doesn't require federal legislative action.

Cons: publication of information does not directly achieve change; only addresses administration fees in Medicaid, not for other groups of VFC-eligible children and adolescents.

Recommendation #4. NVAC recommends CMS update the maximum allowable Medicaid administration reimbursement amounts for each state and include all appropriate non-vaccine related costs as determined by current studies. These efforts should be coordinated with AMA's review of RVU coding (Rec. #6).

Pros: provides federal support for states currently at the cap to increase reimbursement if desired; caps may be more reflective of current costs than prior caps; attention to issue might cause states to reevaluate their reimbursement levels; doesn't require federal legislative action.

Cons: updating the caps does not assure reimbursement would increase to the cap level; state budgets are limited; only addresses administration fees in Medicaid, not for other groups of VFC-eligible children and adolescents.

Recommendation #5. NVAC recommends increasing the federal match (i.e. a larger federal proportion) for vaccine administration reimbursement in Medicaid to levels for other services of public health importance (e.g. family planning services).

Pros: requires only action and funding at the federal level.

Cons: requires federal legislation; only covers VFC children and adolescents in Medicaid and not other VFC eligible persons; sets precedent to increase Federal Medical Assistance Percentages (FMAP) rates for services other than vaccination.

Supporting delivery of vaccines in the medical home by improving business practices in

Recommendation #6. NVAC recommends the American Medical Association's (AMA) RVS Update Committee (RUC) should review its Relative Value Unit (RVU) coding to ensure that it accurately reflects the non-vaccine costs of vaccination including the potential costs and savings from the use of combination vaccines.

Pros: the Resource-Based Relative Value Scale (RBRVS) is the basis of reimbursement for many public and private insurers; therefore, this will help make insurance reimbursement commensurate with provider costs (these include: vaccine acquisition, storage, inventory management, data entry into immunization information systems, alarm systems, backup power systems, catastrophic loss insurance, and other costs); assures no duplication of reimbursement by clarifying components of E&M and vaccine administration codes; efforts by the AMA to update vaccine administration RVUs are already underway.

Cons: may impact how RVUs for other services are calculated.

Recommendation #7. NVAC recommends vaccine manufacturers and third-party vaccine distributors work on an individual basis with providers to reduce the financial burden for initial and ongoing vaccine inventories, particularly for new vaccines. This may include extending payment periods (e.g. from 60 days to 90 or over 120 days), or until vaccine has been administered and reimbursed. It may also include options not related to payment terms for vaccine inventory.

Pros: reduces up-front costs to providers; allows provider time to obtain income from reimbursements for vaccine administration before paying for product, alleviating cash-flow concerns; several manufacturers have already undertaken such efforts.

Cons: may create cash-flow difficulties for manufacturers and distributors who have organized business systems around collections on a 30- to 60-day cycle.

Recommendation #8. NVAC recommends professional medical organizations provide their members with technical assistance on efficient business practices associated with providing immunizations, such as how to contract and bill appropriately. Medical societies should identify best business practices to assure efficient and appropriate use of ACIP recommended vaccines and appropriate use of CPT codes, including Evaluation and Management (E&M) codes, when submitting claims for vaccines and vaccine administration. These organizations may receive federal assistance from CMS or other relevant agencies.

Pros: helps improve business practices among vaccine providers; helps increase marginal profit per dose for providers who may be paying above market averages for vaccine; multiple medical professional organizations have already undertaken this type of training.

Cons: none noted, although organizations must be sure not to give the appearance of collusion or violate antitrust laws by sharing proprietary information on contract terms or vaccine purchase prices.

Recommendation #9. NVAC recommends medical providers, particularly in smaller practices, should participate in pools of vaccine purchasers to obtain volume ordering discounts. This may be done by individual providers joining or forming purchasing collaboratives, or through a regional vaccine purchasing contract held by professional medical organizations on behalf of providers.

Pros: lower purchase prices make it more likely that insurance reimbursements will cover the costs and could increase the return on provider investments in vaccine purchases; could provide incentives to private practitioners to continue providing vaccines; may allow small providers to purchase newer, more expensive vaccines that would otherwise be unaffordable; would result in lower cash outlays to purchase initial vaccine inventories; AAP already developing a list of group purchasing organizations that accept pediatricians as participants

Cons: may lower revenues for manufacturers and distributors for vaccine sales; organizations must be sure not to give the appearance of collusion or violate antitrust laws by sharing proprietary information on contract terms or vaccine purchase prices.

Recommendation #10. NVAC recommends CDC, professional medical organizations, and other relevant stakeholders develop and support additional employer health education efforts. These efforts should communicate the value of good preventive care including recommended vaccinations.

Pros: gives employers an understanding of the importance of vaccines; communicates cost-effectiveness of vaccines to employers; supports educational efforts already undertaken by employer groups.

Cons: will have impact only to the extent that employers change vaccination benefits purchasing based on this education.

Recommendation #11. NVAC recommends health insurers and all private healthcare purchasers adopt contract benefit language that is flexible enough to permit coverage and reimbursement for new or recently altered ACIP recommendations as well as vaccine price changes that occur in the middle of a contract period.

Pros: likely to decrease the time from ACIP recommendations to insurance coverage for recommended vaccines.

Cons: requires insurer-by-insurer decision-making and may lead to non-uniform implementation.

Recommendation #12. NVAC recommends that all public and private health insurance plans voluntarily provide first-dollar coverage (i.e., no deductibles or co-pays) for all ACIP-recommended vaccines and their administration for children and adolescents.

Pros: could eliminate parent out-of-pocket costs that may serve as a barrier to obtaining vaccines for their children; could assure providers receive full reimbursement since it will not have to come from parent out-of-pocket funds; could eliminate underinsurance.

Cons: no guarantee of first-dollar coverage; (first dollar) coverage may decrease manufacturer incentives to reduce prices to gain a greater market share since parents would not have to directly cover any of the costs; first dollar coverage may increase the cost of insurance premiums, reducing the number of people who would opt to take the coverage, which could in turn increase the number of people on public coverage or increase the number of uninsured, leading to greater public program costs at the federal, state, and local levels.

NB: To the extent that this recommendation has support from any employer or healthcare purchaser group, that support is contingent upon the voluntary nature of the proposed recommendation. Employers and healthcare purchasers represented on the workgroup strongly and uniformly objected to mandates for insurance benefits or coverage levels.

Recommendation #13. NVAC recommends that insurers and healthcare purchasers should develop reimbursement policies for vaccinations that are based on methodologically sound cost studies of efficient practices. These cost studies should factor in all costs associated with vaccine administration (including purchase of the vaccine, handling, storage, labor, patient or parental education, and record keeping).

Pros: adjusts reimbursement to levels needed to cover actual provider costs with a margin of profit.

Cons: no means to assure compliance.

Recommendation #14. NVAC recommends Congress request an annual report on the CDC's professional judgment of the size and scope of the Section 317 program appropriation needed for vaccine purchase, vaccination infrastructure, and vaccine administration. Congress should ensure that Section 317 funding is provided at levels specified in CDC's annual report to Congress.

Pros: enforces an existing Institute of Medicine recommendation from the "Calling the Shots" report recommending "that CDC be required to notify Congress each year of the estimated cost impact of new vaccines that have been added to the immunization schedule so that these figures can be considered in reviewing the vaccine purchase and infrastructure budgets for the Section 317 program"; allows the program to provide realistic estimates of need not filtered through the traditional budget process, which weighs program needs in the context of overall executive branch priorities for limited resources and through which budget requests to Congress may not fully cover program needs.

Cons: none identified.

Recommendation #15. NVAC recommends CDC and CMS continue to collect and publish data on the costs and reimbursements associated with public and private vaccine administration. Costs include costs associated with the delivery of vaccines including activities such as inputting data into immunization registries and maintenance of appropriate storage requirements for vaccines. NVAC recommends that these published data be updated every five years and also include information about reimbursement by provider type, geographic region, and insurance status. States and local health departments

should use this information in determining vaccine administration reimbursement rates in Medicaid.

Pros: improve stakeholders' understanding of costs to vaccinate.

Cons: none noted.

Recommendation #16. NVAC recommends NVPO calculate the marginal increase in insurance premiums if insurance plans were to provide coverage for all routinely ACIP-recommended vaccines.

Pros: provides a context for the cost of insurance coverage for vaccines with respect to total insurance costs.

Cons: calculation methodology may not be generalizable to all types of insurance plans.

Recommendation #17. NVAC recommends that NVAC convene one or more expert panels representing all impacted stakeholders to determine if policy options could be developed that would be acceptable to stakeholders to address the burden of financing for private sector child and adolescent vaccinations on the topic of tax credits as incentives for insurers, employers, and/or employees (consumers) to reduce or eliminate underinsurance, and whether these credits would provide added value to vaccination of children and adolescents.

Pros: explores other options.

Cons: difficult to gain acceptability of all stakeholders.

Recommendation #18: NVAC recommends that the CDC substantially decrease the time from creation to official publication of ACIP recommendations in order to expedite coverage decisions by payers to cover new vaccines and new indications for vaccines currently available.

Pros: faster adoption of coverage benefits supporting new vaccine recommendations by private insurers who wait for MMWR publication to begin coverage.

Cons: none noted.

Recommendation #19: NVAC recommends that Congress expand Section 317 funding to support the additional national, state and local public health infrastructure (e.g., widespread and effective education and promotion for healthcare providers, adolescents, and their parents; coordination of supplementary and alternative venues for adolescent vaccinations; record keeping and registries; vaccine safety surveillance; disease surveillance) needed for adolescent vaccination programs as well as childhood vaccination programs for new recommendations such as universal influenza vaccination.

Pros: decreases need for state discretionary funding to support adolescent vaccination infrastructure; increases number of venues at which adolescents might be vaccinated; tailors vaccine delivery to healthcare usage patterns of adolescents, which are less concentrated around regular visits to a primary care provider.

Cons: Section 317 appropriations are discretionary and determined annually; therefore funding increases would not be permanent.

Recommendation #20: NVAC recommends continuation of federal funding for cost-benefit studies of vaccinations targeted for children and adolescents.

Pros: improve stakeholder understanding of costs and benefits related to new child and adolescent vaccines.

Cons: none noted.

Recommendation #21. NVAC recommends that state, local and federal governments along with professional organizations outreach to medical providers who currently serve VFC-eligible children and adolescents to encourage these providers to participate in VFC if they currently do not. Outreach directed at providers serving adolescents who may not have provided vaccinations in the past (e.g. obstetrician gynecologists) is a particular priority.

Pros: adds providers to VFC who serve children and adolescents eligible for free vaccines under VFC (e.g., obstetrician gynecologists for adolescent females) and therefore fulfills the intent of the VFC entitlement.

Cons: none identified.

Recommendation #22. NVAC recommends states and localities develop mechanisms for billing insured children and adolescents served in the public sector. NVAC recommends CDC provide support to states and localities by disseminating best practices and providing technical assistance to develop these billing mechanisms. This may require additional resources not currently in CDC's immunization program budget. Further, NVAC urges states and localities to reinvest reimbursements from public and private payers back into immunization programs.

Pros: conserves and reinvests funds for immunization; ASTHO is already providing support for such systems

Cons: may require state by state legislation; states and localities may prefer insurance reimbursements to go into state or local general funds to allow flexibility in their use.

Recommendation #23: NVAC recommends ensuring adequate funding to cover all costs (including those incurred by schools) arising from assuring compliance with child and adolescent immunization mandates for school attendance.

Pros: encourages compliance with mandates; protects schools from financial consequences of un-immunized students; provides societal support for societal benefit (herd immunity).

Cons: does not suggest specific sources of funds or provide action steps for specific stakeholders to pursue; limited state and school district budgets may complicate efforts to ensure funding; potential duplication of effort as many students will already have private insurance coverage for mandated vaccines.

Recommendation #24: NVAC recommends promotion of shared public and private sector approaches to help fund school-based and other complementary-venue child and adolescent immunization efforts.

Pros: increases number of venues at which children and adolescents might be vaccinated; provides opportunities to reach children and adolescents who do not regularly encounter the traditional healthcare system; provides societal support for societal benefit (herd immunity).

Cons: does not suggest specific sources of funds or provide action steps for specific stakeholders to pursue; limited state and school-district budgets may complicate efforts to ensure funding.

The following future steps to ensure that all children and adolescents have access to routinely recommended vaccines without financial barriers will be proposed to the National Vaccine Advisory Committee in September 2008:

1. The National Vaccine Advisory Committee should evaluate the impact of its recommendations for financing child and adolescent vaccines by revisiting the recommendations one year following their formal adoption. To inform this evaluation, the Committee should monitor implementation of the recommendations by requesting periodic reports from the various stakeholder groups identified in the recommendations detailing activities undertaken by these stakeholders to implement the recommendations.
2. Given that this current September vote is a provisional vote on the policy recommendations set forth in this document, the National Vaccine Program Office should do a fiscal analysis of each of the provisionally adoped recommendations.. This analysis will be presented to NVAC at the time of the final vote.

The following recommendations have been removed from consideration following feedback of the Vaccine Financing Working Group, the National Vaccine Advisory Committee members, and Stakeholder Meeting attendees:

A. NVAC recommends expansion of appropriations of federal Section 317 funds to cover vaccine administration reimbursement for VFC-eligible non-Medicaid children and adolescents and for states to establish vaccine administration reimbursement systems.

B. NVAC recommends that the Section 317 program appropriation language be amended to call for an increase in the appropriation amount each year by at least equivalent rates of increase to the VFC program.

Justification: In general, solutions relying on 317 funds require annual efforts to increase the amount of the appropriation. These recommendations would increase the scope of 317 at a time when it is not meeting its traditional obligations and so would be very unlikely to have any impact.

C. NVAC recommends expansion of Section 317 federal program funding to support vaccine purchase for all children and adolescents who traditionally have relied on Section 317 for their vaccines. This includes support to eliminate recently implemented 2-tiered systems for new ACIP recommendations and support for vaccine purchase for underinsured children and adolescents in all states. Professional judgment from the CDC on the cost to provide this level of support is detailed in the 2008 "Report to Congress on the 317 Immunization Program."

Justification: Because they require annual appropriations, 317-based solutions are not optimal for long-term programmatic fixes, which are the priority of the VFWG. However, the VFWG recognizes the importance of the 317 program in supporting state and local vaccination delivery systems, and has made two general recommendations to increase 317 funding as needed to continue this support (see #14 and #19, above).

D. NVAC recommends expansion of VFC to include underinsured children and adolescents in any setting.

E. Refine the Vaccines for Children (VFC) program so that all VFC-enrolled providers are allowed to use VFC vaccine to vaccinate adolescents who are underinsured for one or more of the recommended vaccines and who cannot otherwise afford to be vaccinated.

Justification: Expanding VFC to underinsured children in any setting would threaten the private vaccine market and could cause employers and healthcare purchasers to reduce or drop vaccine benefits coverage.

F. NVAC recommends all states reimburse for vaccine administration at the CMS established maximum allowable reimbursement amount. NVAC recommends CMS work with the states to achieve this.

G. NVAC recommends states fund state Medicaid and State Children's Health Insurance Plan (SCHIP) managed care plans at a level that would provide vaccine administration reimbursement at the CMS established maximum allowable Medicaid reimbursement amount. CMS should work with states to achieve this.

H. NVAC recommends state and local governments use state and local funds to cover the provision of recommended vaccines to underinsured and non-VFC eligible children and adolescents served at public health department clinics and private medical setting.

Justification: There is concern that state-by-state solutions are unlikely to significantly contribute to ameliorating a national problem, and may lead to inequity among states. In addition, most state budgets are currently unable to assume additional financial burdens.

I. NVAC recommends that CMS set minimum required reimbursement levels for Medicaid vaccine administration.

Justification: In addition to creating an additional financial burden for many states, setting a minimum reimbursement may result in states with higher reimbursement rates choosing to reimburse at the minimum rate, resulting in a loss to providers.

J. NVAC recommends that the NVAC convene one or more expert panels representing all impacted stakeholders to determine if policy options could be developed that would be acceptable to stakeholders to address the burden of financing for private sector childhood vaccinations for (1) some form of insurance mandates for first-dollar coverage of recommended vaccines and their administration and (2) some form of universal federal vaccine purchase or universal federal reimbursement for vaccines and vaccine administration.

Justification: These ideas were judged to be currently beyond the reach of a consensus agreement.